



EN ESTE NÚMERO

VacCiencia es una publicación dirigida a investigadores y especialistas dedicados a la vacunología y temas afines, con el objetivo de serle útil. Usted puede realizar sugerencias sobre los contenidos y de esta forma crear una retroalimentación que nos permita acercarnos más a sus necesidades de información.

- Resumen de la información publicada por la OMS sobre los candidatos vacunales en desarrollo contra la COVID-19 a nivel mundial.
- Noticias más recientes en la Web sobre vacunas.
- Artículos científicos más recientes de Medline sobre vacunas.
- Patentes más recientes en Patentscope sobre vacunas.
- Patentes más recientes en USPTO sobre vacunas.

Resumen de la información publicada por la OMS sobre los candidatos vacunales contra la COVID-19 en desarrollo a nivel mundial

Última actualización por la OMS: 1 de junio de 2021.

Fuente de información utilizada:



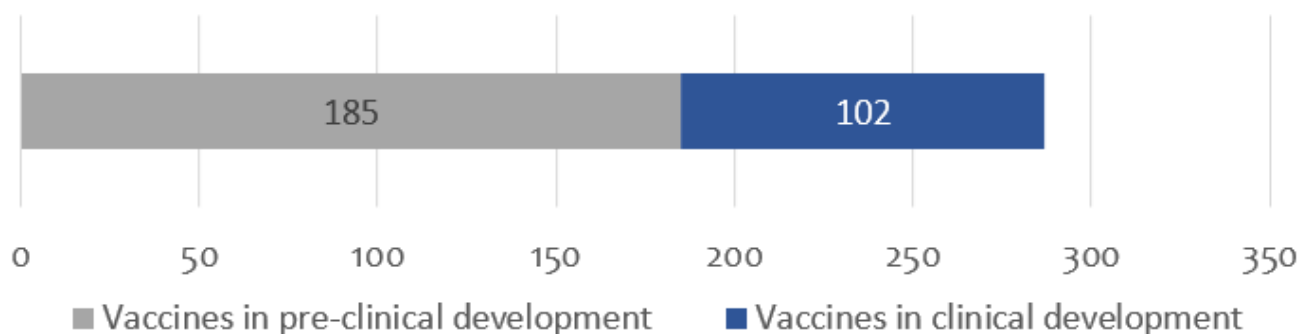
World Health Organization



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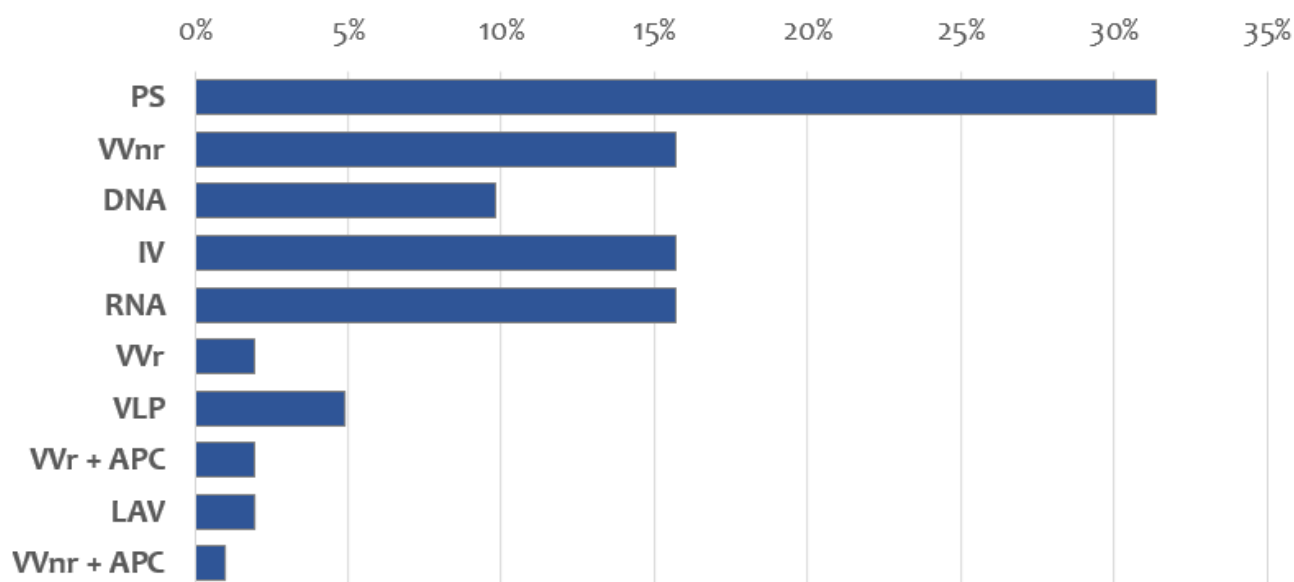
Powering research to prevent epidemics

102 candidatos vacunales en evaluación clínica y 185 en evaluación preclínica.



Candidatos vacunales en evaluación clínica por plataforma

Platform	Candidate vaccines (no. and %)
PS	Protein subunit 32 31%
VVnr	Viral Vector (non-replicating) 16 16%
DNA	DNA 10 10%
IV	Inactivated Virus 16 16%
RNA	RNA 16 16%
VVr	Viral Vector (replicating) 2 2%
VLP	Virus Like Particle 5 5%
VVr + APC	VVr + Antigen Presenting Cell 2 2%
LAV	Live Attenuated Virus 2 2%
VVnr + APC	VVnr + Antigen Presenting Cell 1 1%
	102



Candidatos vacunales más avanzados a nivel global

Desarrollador de la vacuna/fabricante/país	Plataforma de la vacuna	Fase
Sinovac/China	Virus Inactivado	4
Wuhan Institute of Biological Products/Sinopharm/China	Virus Inactivado	3
Beijing Institute of Biological Products/Sinopharm/China	Virus Inactivado	4
University of Oxford/AstraZeneca/Reino Unido	Vector viral no replicativo	4
CanSino Biological Inc./Beijing Institute Biotechnology/China	Vector viral no replicativo	4
Gamaleya Research Institute/Rusia	Vector viral no replicativo	3
Janssen Pharmaceutical Companies/Estados Unidos	Vector viral no replicativo	3
Novavax/Estados Unidos	Subunidad proteica	3
Moderna/NIAID/Estados Unidos	ARN	4
Pfizer/BioNTech Fosun Pharma/Estados Unidos	ARN	4
Anhui Zhifei Longcom Biopharmac./Inst. Microbiology, Chinese Academy Sciences	Subunidad proteica	3
CureVac AG/Alemania	ARN	3
Institute of Medical Biology/Chinese Academy of Medical Sciences	Virus inactivado	3
Research Institute for Biological Safety Problems, Kazakhstan	Virus inactivado	3
Zyklus Cadila Healthcare Ltd./India	ADN	3
Bharat Biotech/India	Virus Inactivado	3
Sanofi Pasteur + GSK/Francia/Gran Bretaña	Subunidad proteica	3
Shenzhen Kangtai Biological Products Co., Ltd./ China	Virus Inactivado	3
Instituto Finlay de Vacunas/Cuba	Subunidad proteica	3
Federal Budgetary Research Institution State Research Center of Virology and Biotechnology "Vector"/Rusia	Subunidad proteica	3
Academy Military Science (AMS) Walvax Biotechnology, Suzhou Abogen Bioscience/China	ARN	3
Center for Genetic Engineering and Biotechnology (CIGB)/Cuba	Subunidad proteica	3
Valneva, National Institute for Health Research, Reino Unido	Virus inactivo	3

Candidatos vacunales mucosales en evaluación clínica

Desarrollador de la vacuna/fabricante/país	Plataforma de la vacuna	Vía de administración	Fase
University of Oxford/Reino Unido	Vector viral no replicativo	Intranasal	1
Vaxart/Estados Unidos	Vector viral no replicativo	Oral	1
Univ. Hong Kong, Xiamen Univ./Beiging Wantai Biol. Pharm./China	Vector viral replicativo	Intranasal	2
Symvivo/Canadá	ADN	Oral	1
ImmunityBio, Inc./Estados Unidos	Vector viral no replicativo	Oral or IM	1/2
Codagenix/Serum Institute of India	Virus vivo atenuado	Intranasal	1
Center for Genetic Engineering and Biotechnology (CIGB)/Cuba	Subunidad proteica	Intranasal	1/2
Altimmune, Inc./Estados Unidos	Vector viral no replicativo	Intranasal	1
Razi Vaccine and Serum Research Institute/India	Subunidad proteica	Intranasal	2
Bharat Biotech International Limited/India	Vector viral no replicativo	Intranasal	1
Meissa Vaccines, Inc./Estados Unidos	Virus vivo atenuado	Intranasal	1
Laboratorio Avi-Mex/México	Virus inactivado	IM o IN	1
VaxForm/Estados Unidos	Subunidad proteica	Oral	1

Noticias en la Web

Los expertos de Salamanca, divididos sobre la segunda dosis a los vacunados con AstraZeneca

May 22. La mayoría cree que lo ideal sería completar la vacunación con el antídoto inoculado la primera vez. La decisión del Gobierno de completar con Pfizer la vacunación de los menores de 60 años que recibieron la primera dosis de AstraZeneca ha dividido a los afectados —unos prefieren que les inyecten de nuevo el antídoto de Oxford, tal y como se ha permitido después, previo consentimiento, mientras que otros se sienten más seguro con la vacuna de Pfizer—, y también a los expertos en virología, epidemiología y farmacología. Mientras algunos especialistas consultados por este periódico muestran su desconcierto por una decisión asociada a un estudio con un número muy pequeño de personas, otros consideran que lo importante es que el proceso de vacunación prosiga.

“Todo aquello que facilite la vacunación y que ofrezca más opciones es mejor que estar parados en el proceso de vacunación”, afirma Ana Fernández Sesma, viróloga del Hospital Monte Sinaí de Nueva York y recuerda: “Hay datos suficientes de millones de vacunaciones en Inglaterra y otros países y la recomendación de la EMA (Agencia Europea del Medicamento) que avalan que la segunda dosis de AstraZeneca se puede administrar y es eficaz”.

En cuanto a la combinación de AstraZeneca y Pfizer, la experta explica que el estudio sugiere que no sería perjudicial el combinar los dos tipos de vacunas, pero señala que “no aporta datos de porcentajes de efectos adversos como trombos al ser un número limitado de personas y ser todavía resultados preliminares”. En cualquier caso insiste: “Las dos opciones funcionan y con cualquiera de las dos la persona vacunada tendrá una mejor protección contra el SARS-Cov-2 que las que tienen una dosis sola”.

Precisamente, esa es una de las cuestiones en las que los especialistas inciden: mejor dos dosis, aunque sean de diferentes vacunas, que una sola dosis.

Acerca del estudio, Estanislao Nistal, virólogo formado en Salamanca y ahora en la Universidad San Pablo CEU, comenta: “Los resultados del estudio Combivacs son interesantes, aunque no resuelven una serie de problemas planteados de base”.

En este sentido, el especialista apunta que no se aclara el tema de los trombos y, por tanto, “la decisión que se tome sigue sin estar fundamentada en evidencias, que por otro lado no pueden ser resueltas con un ensayo clínico dada su bajísima incidencia y el altísimo número de personas que habría que incluir en el estudio para saber si tiene efectos adversos”. Y una cuestión más: “El estudio no compara la inmunidad generada con dos dosis de AstraZeneca frente a una dosis de AstraZeneca y segunda de Pfizer, con lo que no se permite saber si una u otra opción va a tener mejor o peor impacto tanto a corto como a medio plazo”. Ante esta situación, Nistal recomienda a las autoridades sanitarias informar de los pros y contras de seguir con una pauta o combinarla y plantear la posibilidad de tener una libre elección de otra opción en los casos particulares de las vacunaciones de menores de 60 que hayan recibido una dosis de ‘Astra’, así como recordar la importancia de completar las dos dosis vacunales como una medida para potenciar la seguridad y protección frente a la COVID-19.

Del mismo modo, Raquel Carnero, consultora en farmacéuticas, incide en que el estudio del Carlos III sobre la combinación de las dos vacunas, no es un ensayo clínico, y considera que “parece más una maniobra de justificación política, ya que desde el punto de vista regulatorio no se entiende”.

Carnero recuerda que Castilla y León, como otras autonomías, no están satisfechas con la decisión del Ministerio de Sanidad, pero van a tener que asumirla. Además, plantea una cuestión importante: “Van a dejar a los que solo reciban una dosis sin pasaporte COVID”.

Luis Félix Valero, epidemiólogo de la Universidad de Salamanca, responsable de la comisión de

seguimiento de la COVID-19 en la institución académica, se muestra claramente a favor de completar la vacunación con una segunda dosis del mismo tipo de vacuna.

“Informes previos de la Agencia Europea del Medicamento han indicado que la pauta de vacunación completa con AstraZeneca es eficaz y segura, siendo los beneficios muy superiores a los riesgos asociados. Si bien las dos posibilidades de vacunación, serían seguras y eficaces, no se debería generar incertidumbre dejando a la población la decisión de qué tipo de vacuna quiere recibir”, explica el experto.

Esa es la sensación que tienen algunos ciudadanos, que el Gobierno les pasa la pelota sin tener suficientes datos para decidir.

En este sentido, Martín Pérez y Andrés, profesor de Inmunología del Estudio salmantino, aporta una cuestión más: “Los estudios realizados tanto en España como en otros países son limitados, pero parece que la inmunidad que proporciona la vacunación sería al menos tan intensa como el protocolo original de AstraZeneca y las complicaciones no serían más severas. En cualquier caso, no se puede descartar por completo que no aparezca alguna complicación como las observadas con el protocolo original, ya que el número de personas en las que se ha probado es pequeño”.

Y es que todos los especialistas coinciden en el reducido número de personas que han participado en el ensayo del Carlos III.

Sin duda, el más optimista de los expertos consultados es Juan Ayllón, director del Área de Medicina Preventiva y Salud Pública de la Universidad de Burgos, que afirma: “Hay base para ambas decisiones”, y no se posiciona a favor de ninguna de las dos posibilidades.

Fuente: La Gaceta de Salamanca. Disponible en <https://cutt.ly/bnzOfmB>

NGOs expose the mega rich that benefit from monopoly control of vaccine alliance

May 22. Profits from COVID-19 jabs have helped at least nine people become billionaires, a campaign group claimed, calling for an end to pharmaceutical corporations' “monopoly control” on vaccine technology.

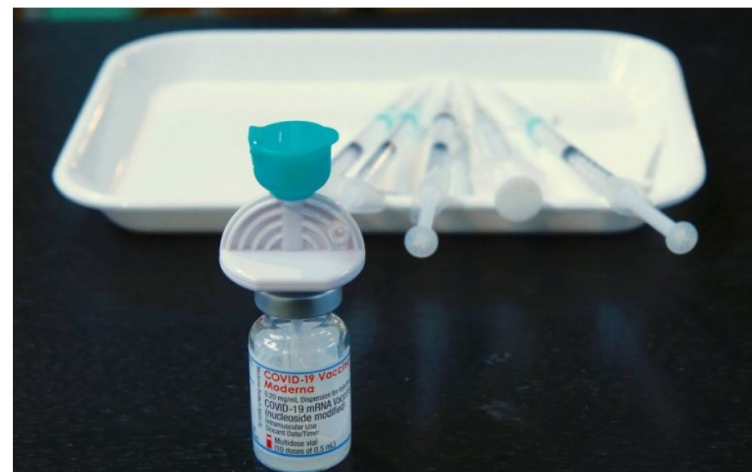
“Between them, the nine new billionaires have a combined net wealth of US\$19.3 billion, enough to fully vaccinate all people in low-income countries 1.3 times,” The People's Vaccine Alliance said in a statement.

The alliance, a network of organizations and activists campaigning for an end to property rights and patents for inoculations, said its figures were based on the Forbes Rich List data.

“These billionaires are the human face of the huge profits many pharmaceutical corporations are making from the monopoly they hold on these vaccines,” said Anna Marriott from charity Oxfam, which is part of the alliance.

In addition to the new mega-rich, eight existing billionaires have seen their combined wealth increase by US\$32.2 billion thanks to the vaccine roll-out, the alliance said.

Topping the list of new vaccine billionaires were the CEO of Moderna Stéphane Bancel, and his BioNTech counterpart Ugur Sahin. Three other neo-billionaires are co-founders of the Chinese vaccine company CanSino Biologics.



The People's Vaccine alliance, a network of NGOs campaigning for an end to patents for inoculations said its figures were based on the Forbes Rich List data.

While several G20 countries have rejected growing calls for intellectual property protections on COVID-19 vaccines. Proponents say doing so would boost production in developing countries and address the dramatic inequity in access.

President Joe Biden administration in the US as well as influential figures like Pope Francis, back the idea of a global waiver on patent protections.

Fuente: Merco Press. Disponible en <https://cutt.ly/PnzPNSV>

Should Your Child Get the COVID Vaccine?

May 22. A pediatric infectious disease expert answers questions about whether the vaccine is safe and why children need it.

The following essay is reprinted with permission from The Conversation, an online publication covering the latest research.

The FDA expanded emergency use authorization of the Pfizer-BioNTech COVID-19 vaccine to include adolescents 12 to 15 years of age on May 10, 2021. The Centers for Disease Control and Prevention followed with recommendations endorsing use in this age group after their advisory group meeting on May 12. The American Academy of Pediatrics also supports this decision.

Dr. Debbie-Ann Shirley is an associate professor of pediatrics at the University of Virginia specializing in pediatric infectious diseases. Here she addresses some of the concerns parents may have about their teen or preteen getting the COVID-19 vaccine.

1. Does the vaccine work in adolescents?

Yes, recently released data from Pfizer-BioNTech shows that the COVID-19 vaccine seems to work really well in this age group. The COVID-19 vaccine was found to be 100% efficacious in preventing symptomatic COVID-19 in an ongoing clinical trial of children in the U.S. aged 12 to 15. Adolescents made high levels of antibody in response to the vaccine, and their immune response was just as strong as what has been seen in older teens and young adults 16-25 years of age.

2. How do I know whether the vaccine is safe for my child?

So far, the COVID-19 vaccine appears to be safe and well tolerated in adolescents. All of the COVID-19 vaccines authorized for use in the U.S. have undergone rigorous study, but we don't want to assume that children are little adults. This is why it is so important to study these vaccines just as carefully in children before health authorities could recommend use. Ongoing studies will continue to follow vaccinated children closely and robust safety monitoring will help rapidly identify rare or unexpected concerns if they emerge.

3. I thought children were low-risk – do they still need to get the vaccine?

Currently, children represent nearly one-quarter of all new reported weekly COVID-19 cases in the U.S. While serious illness from COVID-19 is rare in children, it does occur – thousands of children have been hospitalized and at least 351 children have died from COVID-19 in the U.S. Some children who get seriously ill from COVID-19 may have underlying health conditions, but not all do. Vaccination will help protect children from developing serious illness.

Additionally, since adolescents can transmit COVID-19 to others, vaccinating children may prove to be an important part of safely getting back to normal activities of life, including attending school in person, participating in team sports and spending time with friends. A large survey of school-aged children showed

that children in full or partial virtual school reported lower levels of physical activity, less in-person time socializing with friends and worse mental or emotional health compared with those receiving full in-person schooling. Children are experiencing unprecedented increases in indirect adverse health and educational consequences related to the pandemic, and we need to find ways to help them get quickly and safely back to normal life. Vaccination is one of them.



4. What side effects might I expect for my child?

Nonsevere side effects may be experienced following vaccination. The most commonly reported side effects have been pain and swelling at the injection site. Other common side effects include tiredness and headache. Similar to young adults, some adolescents have experienced fever, chills, muscle aches and joint pain, which may be more common after the second dose. These effects are short-lived, however, and most resolve within one to two days.

Some adolescents may faint when receiving an injection. If this is a concern for your child, let your vaccine administration site know ahead of time – your child can be given the vaccine while they're seated or lying down to avoid injuries from falling.

5. Have there been any severe reactions among children?

No serious adverse events related to vaccination were reported in the Pfizer-BioNTech clinical trial. Serious allergic reactions have rarely been reported in older people. Anyone with a known severe or immediate allergy to the vaccine or any component of the vaccine should not get the vaccine. If your child has a history of any severe allergic reactions or any type of immediate allergic reaction to a vaccine or injectable therapy, let the vaccine site administrator know so that your child can be monitored for at least 30 minutes after getting the vaccine.

Parents should talk to a trusted health care provider or allergist if they have specific questions about the possibility of an allergic reaction in their child.

6. When will a COVID-19 vaccine be authorized for children younger than 12 years?

COVID-19 vaccine makers have begun or are planning to begin testing COVID-19 vaccines in younger children. As more information becomes available, the authorized age recommendations may change. Children ages 2-11 years old could potentially be eligible as early as the end of this year.

7. If I've been vaccinated but my child hasn't, could I still give the virus to them?

The COVID-19 vaccines do not contain live COVID-19 virus, so they cannot cause COVID-19. Rather, getting vaccinated will help protect both you and your children from COVID-19. Studies have shown that vaccinated pregnant and lactating mothers can pass protective immunity on to their young infants across the placenta and in breast milk—one more benefit of vaccination.

Though researchers are still learning how well the vaccine can help prevent spread, vaccination is still an important way to limit infecting people who are not yet eligible for the vaccine, like younger children.

Fuente: SCIENTIFIC AMERICAN. Disponible en <https://cutt.ly/xnzSZBw>

Moderna pedirá a la UE que autorice su vacuna para el grupo de 12 a 17 años

23 may. El laboratorio estadounidense Moderna va a presentar a comienzos de junio una demanda de autorización a la Agencia Europea del Medicamento (AEM) para que su vacuna pueda ser utilizada para los adolescentes de 12 a 17 años.

Su consejero delegado, el francés Stéphane Bancel, lo anuncia en una entrevista publicada este domingo por Le Journal du Dimanche, en la que justifica la rápida apertura de la vacunación para ese grupo de edad para protegerse con la inmunidad colectiva ante el riesgo de una eventual nueva ola epidémica.

A su juicio, "lo ideal" sería proteger a esos adolescentes "antes de finales de agosto. Si no se vacuna masivamente, no se puede descartar el riesgo de una cuarta ola".

Bancel afirma que habrá que dar una tercera dosis de refuerzo a las personas que ya fueron vacunadas, empezando "desde el final del verano" con los grupos de riesgo a los que se les inoculó a comienzos de año, y en particular con las personas que viven en residencias.

Advierte de que "dos o tres meses de retraso supondría numerosas hospitalizaciones y muertes".

Al final -añade- "todos los adultos, incluso los jóvenes" tendrán que recibir una dosis de refuerzo "para proteger a las personas frágiles no vacunadas" en nombre del principio de precaución.

Aunque cree que la vacuna de Moderna ofrece inmunidad durante un periodo de uno a tres años, "la llegada de variantes aumenta el nivel de la amenaza".

Bancel afirma que su empresa podría producir 3.000 millones de dosis anuales, lo que unido a los 4.000 millones que tiene previsto fabricar Pfizer-BioNTech, daría dosis suficientes para vacunar a todos los habitantes de la Tierra con una dosis.

Es una de las razones que da para oponerse a la suspensión de las patentes de las vacunas. También insiste en que sin las patentes su laboratorio no habría conseguido en los mercados los 1.800 millones de dólares con los que desarrolló la tecnología del ARN mensajero.

Además, recuerda que ahora solo Pfizer y Moderna tienen capacidad en el mundo para producir vacunas con ARN mensajero. Si se suspendieran las patentes, los otros fabricantes tendrían que comprar máquinas y contratar personal especializado, y con el tiempo necesario para hacerlo no habría avances en la inmunización este año.

Por ahora, 90 millones de personas en todo el mundo han recibido las dos dosis de Moderna.

El consejero delegado reitera sus críticas a la Unión Europea por su "falta de anticipación" en los primeros meses de la pandemia para trabajar con los laboratorios en las vacunas.

Dice que puso presión a la Comisión Europea -sin éxito- para que les hiciera un avance y poder lanzar así la producción en el Viejo Continente rápidamente, como ocurrió en Estados Unidos, cuya Administración se movilizó desde la primavera de 2020, pero con Bruselas no se consiguió hasta la firma del contrato en noviembre.

Fuente: SWI swissinfo.ch. Disponible en <https://cutt.ly/4nzGiZT>



Vacunas contra la covid-19: "Seremos capaces de salir juntos de esta pandemia. Solo así nos aseguraremos de que la luz al final del túnel no sea solo para los ricos, sino para todos"

23 may. El microbiólogo John McConnell tiene un privilegio único: leer de primera mano los estudios que evalúan la seguridad y eficacia de las vacunas contra la COVID-19.

El científico es editor en jefe de *The Lancet Infectious Diseases*, una revista científica que ha publicado las investigaciones más importantes sobre la pandemia y las vacunas en los últimos meses.

Es el responsable de recibir los estudios originales enviados por laboratorios y especialistas de diversas partes del mundo, y remitirlos al equipo de editores independientes, quienes revisan y analizan el contenido antes de su divulgación.

Con un título en Microbiología Clínica y Parasitología de la Universidad de East London, en Inglaterra, McConnell ha trabajado en *The Lancet* desde 1990. En 2001, fue uno de los fundadores y pronto se convirtió en editor en jefe de *The Lancet Infectious Diseases*, una revista centrada 100% en enfermedades infecciosas.

En una entrevista reciente con BBC Brasil realizada por correo electrónico, McConnell evaluó el ritmo actual de vacunación en el mundo y destacó que el fin de la pandemia está necesariamente ligado a acciones globales.

"Creo que seremos capaces de salir juntos de esta pandemia, siempre y cuando no perdamos el enfoque. Solo así nos aseguraremos de que la luz al final del túnel no esté destinada solo a los ricos y afortunados, sino para todos", dijo. A continuación se muestran los principales extractos de la entrevista.

En una hazaña sin precedentes, la humanidad pudo desarrollar, probar y aprobar varias vacunas contra la misma enfermedad en poco menos de un año. ¿Cómo evalúa este progreso?

Creo que es la culminación de muchos años de trabajo en el desarrollo de tecnologías, lo que nos ha permitido generar varios tipos diferentes de vacunas que ahora se están aplicando a miles de millones de personas. Una de esas tecnologías, que utiliza virus inactivos, existe desde hace un siglo o más. La tecnología que utiliza las llamadas subunidades de proteínas se ha aplicado a las vacunas contra la hepatitis B, por ejemplo, durante muchos años. E incluso las vacunas de vectores virales, como las de Johnson&Johnson y AstraZeneca/Oxford, utilizan una tecnología que se ha utilizado en ensayos clínicos durante unos 20 años, principalmente en tres inmunizadores autorizados contra el ébola.

Y aunque se cree que las vacunas de ARNm, como las de Pfizer/BioNTech y Moderna, son nuevas y esta es la primera vez que se utiliza dicha tecnología, la verdad es que se está trabajando en el desarrollo de productos similares desde hace casi 30 años. Antes de la COVID-19 había vacunas en ensayos clínicos que usaban tecnología de ARNm contra enfermedades como el sida, el zika y la rabia, por ejemplo.

Por lo tanto, aunque las vacunas Pfizer/BioNTech y Moderna son las primeras en utilizar esta tecnología a gran escala en humanos, se basan en conocimientos existentes y bien probados.

Entonces, en cierto modo, tuvimos suerte de que la pandemia llegara en un momento en el que tenemos algunas formas muy bien establecidas de producir vacunas, así como un conjunto de nuevas tecnologías para las que había un poco de experiencia clínica.

Como mencionó, tenemos varias plataformas tecnológicas exitosas en este momento. ¿Qué importancia tiene esta variedad?

Nunca se garantizó que una tecnología en particular funcionaría, por lo que creo que fue muy importante tener una variedad de intentos diferentes, incluso si, cuando se aplican en la vida real, son comparables en términos de efectividad.

Es importante tener vacunas que se puedan distribuir de diferentes formas. Por ejemplo, las vacunas Pfizer/BioNtech y Moderna necesitan una cadena de frío para su distribución que requiere congelación, mientras que las vacunas AstraZeneca/Oxford y Johnson & Johnson solo requieren refrigeradores regulares. La vacuna de Bharat Biotech se puede mantener a temperatura ambiente.

Necesitamos una gama de tecnologías que se puedan llevar a diferentes contextos en todo el mundo.

También es importante contar con vacunas que puedan modificarse a medida que surjan nuevas variantes del coronavirus. Algunas de las tecnologías se adaptan más fácilmente que otras.

También debo agregar que, al utilizar diferentes formas de producción de vacunas, estamos aprovechando al máximo las instalaciones de fabricación disponibles en todo el mundo. Si tuviéramos que depender únicamente de la tecnología ARNm, no habría forma de producir dosis suficientes para 2022 o 2023, incluso en países de altos ingresos.

¿Y cómo fue seguir tantas noticias y conocer, de primera mano, los resultados de seguridad y eficacia de las vacunas que el mundo entero esperaba con tanto interés?

Es un gran honor ser el canal a través del cual fluye esta increíblemente importante investigación durante la mayor emergencia de salud pública en el mundo en los últimos 100 años. Es un verdadero privilegio ver este material y organizar su revisión antes de su publicación. Realmente me siento honrada y espero que lo que estamos haciendo como editores tenga algún impacto en el control de la pandemia lo antes posible.

En algunos países, como Israel, los Emiratos Árabes Unidos y el Reino Unido, la campaña de inmunización contra la COVID-19 está muy avanzada. ¿Qué nos dice esta experiencia de la vida real sobre la efectividad de las vacunas disponibles?

Las vacunas parecen ser incluso más efectivas cuando se aplican a grandes poblaciones que en los ensayos clínicos. Los datos de Israel y el Reino Unido muestran alrededor del 90% de efectividad en la prevención de todas las formas de COVID-19 para la vacuna Pfizer/BioNTech y alrededor del 88% para la vacuna AstraZeneca/Oxford.

Es muy alentador que las vacunas que se utilizan en todo el mundo parezcan ser en gran medida eficaces contra variantes del virus, especialmente en términos de prevenir enfermedades graves y la muerte, aunque no necesariamente previenen la infección en sí.

Chile es un buen ejemplo de cómo funcionan realmente las vacunas. Allí está claro que los casos se han estabilizado o están disminuyendo en los individuos que han sido vacunados, mientras que sigue aumentando en los que no han sido inmunizados.

La razón del aumento de casos, por lo tanto, no es que la vacuna finalmente no esté funcionando, sino que aún no se ha administrado a un número suficiente de personas.

Si, por un lado, la campaña despega en algunos lugares, otros países están lidiando con la escasez o la falta absoluta de vacunas. ¿Cómo valora esta desigualdad global?

Existe un mecanismo global llamado Covax, que fue diseñado para comprar vacunas y distribuir las a países que no pueden financiar sus propios programas de vacunación.

En la actualidad, este programa fue diseñado para ayudar a vacunar solo al 20% de las personas en estas naciones de ingresos bajos y medios.

En la progresión actual, será necesario hasta finales de 2023 para que las vacunas estén disponibles para todos en el mundo.

Es imperativo que otros países, cuando hayan vacunado completamente a sus poblaciones, pongan las dosis restantes a disposición de los gobiernos que no pueden pagarlas.

Algunos de estos países más ricos incluso han adquirido suficientes vacunas para cubrir tres o cuatro veces su población total.

¿Cree que es posible solucionar este problema de desigualdad global?

Es muy importante que los gobiernos tengan en cuenta el interés global en minimizar la cantidad de virus en circulación en todo el mundo.

Cuando se completen los programas de vacunación en estos lugares y se planifiquen los refuerzos necesarios en un futuro próximo, los países con existencias restantes deberán considerar seriamente la posibilidad de donar dosis sobrantes.

Mientras el virus permanezca en circulación, siempre existe la posibilidad de una mutación para la cual algunas vacunas actuales pueden no ser efectivos.

Dejo aquí una sugerencia, sobre la que no tengo opinión formada ni datos suficientes. Pero, ¿deberíamos dar prioridad a la vacunación de los niños, que no son particularmente susceptibles a esta enfermedad y es muy poco probable que presenten síntomas graves o mueran? ¿O deberíamos dar prioridad a las personas mayores y vulnerables en los países de ingresos bajos y medianos?

Para acortar este plazo de 2023, cuando todo el mundo estará vacunado de acuerdo con las proyecciones actuales, debemos hacernos preguntas sobre nuestras prioridades, y no solo mirar la realidad interna de nuestros propios países.

Incluso con la aprobación de las primeras vacunas contra la COVID-19, tenemos otras candidatas que aún están en estudio. ¿Por qué es importante tener más opciones de inmunizaciones contra la COVID-19?

Bueno, las vacunas que aún están en desarrollo tendrán la oportunidad de modificar sus formulaciones, para que estén dirigidas contra las nuevas variedades de coronavirus.

El mayor problema es que simplemente no hay suficientes vacunas para todos. Actualmente, hay muchas fábricas en el mundo que producen los inmunizadores. Si diferentes países tienen sus propias instalaciones de producción de vacunas y pueden satisfacer sus demandas, es extremadamente importante controlar la pandemia lo antes posible.

Además, también existe un problema de precio. Algunos fabricantes, por el tipo de tecnología que están

utilizando, han producido vacunas mucho más baratas y mucho más fáciles de distribuir que las que fueron desarrolladas por Pfizer/BioNTech, por ejemplo. No puedo imaginar cómo se vacunaría a todos en el mundo si solo confiáramos en la vacuna Pfizer/BioNTech.

Así como tenemos un arsenal de antibióticos muy amplio, por ejemplo, creo que necesitamos un arsenal de vacunas variado.

¿Cómo ayudará la vacunación a sacar al mundo de esta pandemia? ¿Ve la luz al final del túnel?

Sí, ciertamente hay una luz al final del túnel. Para los países que han implementado su programa de vacunación rápidamente, esta luz es muy fuerte.

Israel ya ha reabierto completamente y el Reino Unido está en camino. Francia tuvo que introducir una nueva cuarentena, pero la combinación de medidas de vacunación y restricción está llevando a ese país a una posición en la que pronto podrá comenzar a flexibilizar las políticas.

Incluso Estados Unidos está cambiando este juego, aunque no es la misma realidad para todos los estados. Sin embargo, los lugares donde existe una aceptación generalizada de la vacuna y donde las medidas de distancia física han sido más estrictas, definitivamente están evolucionando bien.

Algunos datos publicados por la autoridad de salud pública en Inglaterra (*Public Health England*), indican que casi el 70% de todos los donantes de sangre tienen anticuerpos contra el coronavirus.

Este 70% es el número establecido como la seroprevalencia necesaria para que exista la inmunidad colectiva. Todavía no podemos trazar una línea estricta al respecto, pero se cree que es una tasa importante.

También sabemos que menos del 20% de esta seroprevalencia es causada por una infección natural. Entonces, la mayor parte provino de la vacunación.

Todavía necesitamos organizar y disponer de una variedad de vacunas, pero hay una esperanza real.

Esa luz todavía es oscura para los países del sur de Asia, como Pakistán, Bangladesh y Nepal, que no pueden pagar las vacunas. En la misma línea, menos del 2% de toda la población del continente africano ya ha recibido sus dosis. Por lo tanto, algunas partes del mundo tienen mucho retraso.

Creo que podremos salir juntos de esta pandemia, siempre que no perdamos el enfoque. Solo así nos aseguraremos de que la luz al final del túnel no esté destinada solo a los ricos y afortunados, sino a todos.

Fuente: BBC NEWS. Disponible en <https://cutt.ly/JnzKTpl>

Biocen, la estratégica etapa final en la fabricación de vacunas y otros productos de la biotecnología cubana

24 may. Nuestro recorrido por el Centro Nacional de Biopreparados (Biocen), empresa de alta tecnología del grupo BioCubaFarma en Bejucal, Mayabeque, cerca de la periferia habanera, comienza en la Planta de Envase. En esta jornada están etiquetando y envasando la Soberana 02.

De la máquina de etiquetado, que controlan dos operarios, salen los bulbos de la vacuna anti-COVID-19 en cajuelas hacia una mesa cercana,



donde otra operaria los revisa y coloca en un carrito en el que seguirán camino hacia el área de envase. Allí, en dos salas, unas dos decenas de trabajadoras los colocan en estuches –cada uno de 25 bulbos, con la identidad de la vacuna y otros datos– en los que harán su viaje final hacia los vacunatorios.

El itinerario partió del Centro de Inmunología Molecular, donde, en un fermentador, se cultiva en células de mamífero (CHO, derivadas de ovario de hámster chino) la proteína RBD del virus SARS-CoV-2. De ahí, pasa al Instituto Finlay de Vacunas (donde se concibió el inmunógeno) y se conjuga el RBD con –en el caso de la Soberana 02– el toxoide tetánico. Ese ingrediente farmacéutico activo (IFA) conjugado se envía a Biocen, donde se realiza la formulación, el escalado productivo, y transcurre el proceso final hasta el envasado.

Mientras miramos los viales salir de la máquina de etiquetado, preguntamos cuántos salen en cada cajuela. Nos responden que 208. Hoy etiquetan y envasan Soberana 02 en presentación multidosis (10 dosis). Inevitablemente, hacemos la matemática: 2 080 dosis en cada cajuela. Y el flujo es constante. La máquina es rápida. Los operarios no se detienen.

En cada estuche de 25 unidades donde son colocados en la mesa de envase van, entonces, 250 dosis. Ahí también, mientras envasan, las operarias revisan los bulbos en busca de la más mínima imperfección en el etiquetado. Es uno de los detalles en la industria biotecnológica y en Biocen: la revisión, el control de la calidad constante, desde el primer paso de fabricación hasta la liberación final de cada lote por la autoridad regulatoria para la distribución.



Lo apreciamos minutos después, en la Planta de Parenterales 2. Allí comenzamos el recorrido por la sala automatizada de control, donde se siguen en pantallas todas las áreas de producción y se monitorean los parámetros de la planta.

De IFA conjugado a vacuna

Se escucha o lee “formulación”, “llenado” o “escalado productivo” y todo puede parecer simple, pero llevar el IFA a producto final –algo que, como característica de la industria biofarmacéutica a nivel mundial, se hace en locaciones o plantas distintas, incluso de países distintos– requiere plataformas tecnológicas (tanto maquinaria como procesos de producción) muy avanzadas, *know how* y detallados y estrictos procesos de validación y auditoría permanentes.

Según datos de la industria, el antígeno de la vacuna Pfizer/BioNTech se fabrica en Misuri y el ARNm en Massachussets, mientras que la formulación y el envasado tienen sede en Michigan y Puurs (Bélgica). Este año, BioNTech abrió otra planta productiva en Marburgo (Alemania), pero igual el envasado se hace en Puurs.

Moderna usa plantas para producir antígenos en Nuevo Hampshire, Pensilvania y Suiza, y dos especializadas en acabado en España e Indiana. Un análisis reciente refería que la vacuna de AstraZeneca/Oxford se produce en 25 plantas distribuidas en todo el mundo.

Hay que sumar a eso que estas cadenas dependen de plantas o laboratorios que suministran lípidos, enzimas, material genético y otros componentes, tanto sustancias como implementos especializados empleados en la producción.

En abril, leímos sobre países latinoamericanos que producirían el IFA y asumirían el llenado de una de las vacunas disponibles en el mercado, por acuerdo con la compañía desarrolladora.

El dueño de uno de los laboratorios implicados, al explicar demoras en el llenado, publicó en Twitter que “envasar cada tipo de vacuna requiere una serie de equipos e insumos específicos que, por la alta demanda global, hoy resultan imposibles de conseguir rápidamente”. Hablaba también de la “capacitación del personal científico y técnico para esta fabricación en particular”, que implica “reentrenar personal y realizar nuevas inversiones”. Además, puntualizaba que su compañía no puede disponer del principio activo como si le perteneciera, “porque no es la propietaria”, menos aún de la vacuna.

Es decir... Plataformas tecnológicas, equipos altamente especializados, *know how*, plantas con tecnología de punta; especialistas, técnicos y operarios bien capacitados. Todo acorde con regulaciones estrictas, validado y auditado nacional e internacionalmente y certificado por los reguladores sanitarios. Igualmente, insumos y materiales específicos de alta demanda en un mercado tensionado por la crisis sanitaria y bajo presión de la competencia (por vacunas y componentes); desarrollo y producción en cadena (en lo que es una ventaja, en el caso de Cuba, el enfoque de cooperación, el conocimiento y los procesos compartidos entre centros de la isla) y, entre muchos otros, un detalle importante: la propiedad sobre el IFA y las vacunas. En Cuba, ambos son cubanos.



En el caso de las tres vacunas Soberana, el ciclo comienza en el Centro de Inmunología Molecular (CIM), continúa en el Instituto Finlay de Vacunas (IFV) y concluye en Biocen. Es una de las rutas tecnológicas de las vacunas cubanas; la otra, de Abdala y Mambisa, involucra al CIGB y los Laboratorios Aica.

En la sala de control, el jefe de las plantas de parenterales de Biocen (Parenterales 2 y Parenterales 3), el ingeniero y máster en Ciencias Humberto Pérez de la Concepción, comienza hablándonos de los estrictos protocolos que aseguran la calidad y seguridad de los procesos.

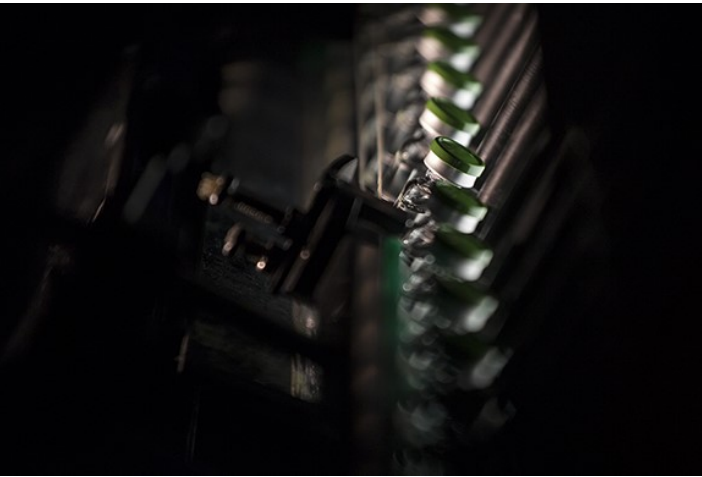
“El cuidado es extremo. El aire es filtrado, no puede haber partículas porque pueden contener microorganismos. Hay requisitos de vestuario y parámetros establecidos de humedad, temperatura, presión y niveles de partículas en el aire, que se mantienen en índices aceptables según las diferentes clasificaciones de áreas”, explica.

Estamos en el inicio, en lo que llaman área “sucia” –que en realidad es un sitio en condiciones ambientales normales–, aunque el aire es acondicionado, filtrado, para temperatura y confort, “pero no es controlado”.

A esa área llegan los trabajadores y en la zona de taquillas se cambian la ropa por un uniforme de circulación interna. “Ahí comienza el paso a las áreas que llamamos limpias o clasificadas, donde se realizan los diferentes procesos.

“Estas van desde un área limpia de menor clase hasta aquellas en que se realizan los procesos críticos de fabricación de parenterales, donde el medicamento, o el vial que contiene el medicamento, están expuestos al ambiente. La clase A, la más crítica y de más alta clasificación, es donde están las máquinas de llenado. Ahí todo se realiza bajo flujo laminar y se controla al extremo el índice de partículas.

“En clase A, el operario ingresa y trabaja con toda la anatomía cubierta, incluidos careta, doble traje de aislamiento y doble guante. No puede haber ninguna superficie del cuerpo expuesta, porque en cualquiera



de estas áreas de producción el hombre es el mayor contaminante.

“Luego está la clase B, un poco menos rigurosa. En las operaciones que se realizan el vial no está expuesto, pero es el área que rodea a la clase A; por lo tanto, debe estar controlada, al igual que los requisitos de vestimenta”.

Otra condición del ambiente interior en las plantas de parenterales es la presión. “La presión es positiva desde el lugar más limpio al más sucio o en condiciones ambientales más cercanas a lo normal; hay una cascada de presiones,

cambios de presión de un ambiente a otro, para que el aire salga del lugar más controlado a los menos controlados, hasta el área en condiciones ambientales más cercanas a lo normal.

“Quienes trabajan ahí tienen sobrepresión, están sujetos a condiciones de trabajo irregulares. Tienen este sistema de ropa, que es incómodo, doble uniforme y doble guante los que están en grado A y grado B; careta y otros implementos. Son condiciones difíciles de trabajo.

“Debido a esto, lo máximo que pueden estar en un turno son cinco horas, es el más largo que tenemos. Esto en las clases A y B, las de producción”.

El sistema de presión también se controla en el puesto de control, donde hay un plano de toda la planta, con el sistema de cascada de presiones entre un ambiente y otro. Va pasando desde 10 o 15 pascales de diferencia hasta llegar al ambiente final. O sea, tenemos cuatro clases, puede que haya 60 pascales de diferencia entre el ambiente primario, el más controlado, y el ambiente exterior.

Los trabajadores pasan por chequeos médicos periódicos. No todo el mundo puede trabajar en área aséptica, no solo por la presión, sino también por las condiciones: parados, sometidos a estrés, con un vestuario especial; no pueden salir en turnos de 4 o 5 horas, porque una salida puede implicar una parada del proceso.

En las otras clases, C y D, el área de preparación, se alistan los materiales que pasan al área de producción (formulación y llenado) a través de dispositivos y procesos de esterilización.

“Todo lo que entra al núcleo, el área donde se encuentran las máquinas llenadoras, donde puede estar expuesto el medicamento, tiene que estar estéril”, señala el jefe de las plantas de parenterales de Biocen mientras nos muestra en las pantallas de control las diferentes áreas, donde se ve a los operarios en sus funciones.

Por un lado, tapones y sellos pasan por autoclaves de doble puerta conectadas al área más limpia o crítica. “La autoclave descarga en el área limpia, bajo flujo laminar se recibe lo que ya está estéril, se guarda en esas condiciones y se traslada a las áreas de producción”.

Cuando accedemos –debidamente vestidos– al área de recepción de bulbos ya llenados, vemos en acción, del otro lado del cristal, la máquina llenadora, con los depósitos de tapones y sellos de aluminio, y los viales ingresando por una plataforma móvil desde el horno.

“Los viales transitan por un proceso de lavado para remover cualquier partícula en el interior o exterior, y

después por uno de despirogenización (esterilización por calor seco) en un horno que alcanza los 300 grados. Desde ahí ingresan al área aséptica para alimentar la máquina llenadora, que dispensa el producto en cada vial, según las especificaciones, a partir de un contenedor”, nos dice Pérez.

Ese contenedor llega desde otra parte del área crítica o de producción: la de formulación. En esta funciona un sistema de tanques rígidos y otro de bolsas tipo tanque, desechables, de 50 litros. “El medicamento ya formulado pasa de los reactores o del recipiente donde se realice la formulación a esa bolsa, que luego se conecta a la llenadora –que también recibe viales, tapones y sellos–, y de la máquina salen ya llenos y listos los viales a la inspección visual, el etiquetado y envasado”.

En la Planta de Parenterales 2 funcionan dos máquinas llenadoras con capacidad para 7 000 viales por hora cada una (14 000/hora en total). En Parenterales 3 hay también dos máquinas, una de 12 000 y otra de 4 000 (16 000/hora en total).

Pérez precisa que la Planta de Parenterales 3 está dedicada “a liofilizados y otros productos biológicos o biotecnológicos, principalmente de los centros a lo que damos servicio: el Centro de Ingeniería Genética y Biotecnología (CIGB), el CIM, el IFV y también otros como el Censa, en el caso del Surfacén. La línea de 4 000 se usa para liofilizados, que tienen menor volumen en cuanto a tamaño de lote. La de 12 000, para otros productos con mayor volumen de producción, como, por ejemplo, la eritropoyetina recombinante del CIM”.

En Parenterales 2, las dos líneas de 7 000 son destinadas principalmente a vacunas, “entre ellas las vacunas contra la hepatitis, contra el tétanos y ahora contra la COVID-19”.

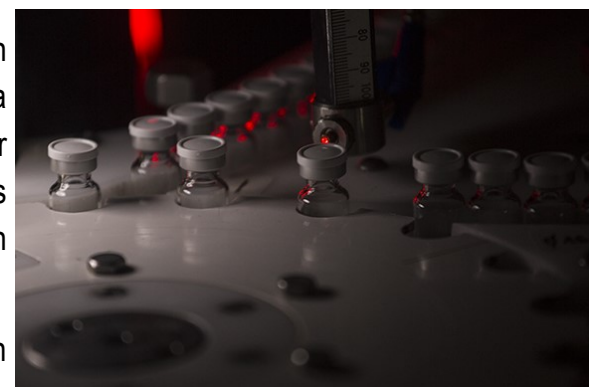
Parenterales 3 está diseñada para procesar dos productos a la vez, pues las dos líneas son paralelas, cada una con su preparación de materiales, su formulación y su sistema de llenado. En Parenterales 2, un solo producto a la vez, pues las dos máquinas llenadoras son servidas por las mismas áreas de preparación de materiales y de formulación.

El día de nuestra visita, en las dos plantas de parenterales de Biocen se llenaba Biomodulina T (de Biocen, un inmunomodulador que está entre los medicamentos empleados en el tratamiento de enfermos de COVID-19), eritropoyetina recombinante (ior ® EPOCIM, del CIM, para el tratamiento de anemia en pacientes con insuficiencia renal crónica, sida, bajo quimioterapia, entre otros), y el medio de transporte para hisopos (BTV, también de Biocen, actualmente destinado a la recolección y el traslado de muestras clínicas a los laboratorios de biología molecular para el diagnóstico confirmatorio por rt-PCR de COVID-19).

De la formulación y el llenado, en el área de producción, los viales pasan a la inspección visual en tres modalidades: manual, semiautomática y automática.

“El ciento por ciento de las unidades tiene que pasar por la inspección visual, en la cual se detecta si el vial tiene el contenido correcto, la apariencia requerida (no puede tener un objeto extraño o un color diferente al que establece la especificación del producto) y otros aspectos más cosméticos, como que el retape del vial esté bien colocado. El vial no puede tener la más mínima ralladura”.

En términos de tiempo, Pérez precisa que la formulación se realiza un día antes o en la madrugada anterior al llenado. Depende del producto, de la cantidad de componentes y las condiciones en que se añade cada uno de esos componentes.



La cadena de procesos previos al llenado de un producto farmacéutico es compleja. “Primero hay que preparar los reactores, los materiales, las soluciones, los componentes activos de la formulación, pero hay excipientes que también hay que preparar, esterilizar y adicionar. Se incluyen el buffer (tampón, solución amortiguadora o reguladora, que mantiene estable el pH); si lo lleva, también preservos, que se prepara y se adiciona al final para asegurar la esterilidad del producto en el vial. Por ejemplo, el tiomersal que se usa en nuestras vacunas cuando son multidosis”.

El de Soberana 02 “es un proceso rápido, pues tiene pocos componentes”. Desde que se preparan los materiales y equipos, toma alrededor de 48 horas.

“Aquí recibimos el ingrediente farmacéutico activo y realizamos el proceso de formulación, que consiste en mezclar ese IFA con los otros componentes o excipientes que contiene la vacuna, en una concentración determinada. Ahí están las sales, un buffer, fosfato, que mantiene el pH en un rango determinado, y, si es presentación multidosis, el preservos, en este caso el tiomersal”.

Cada uno de los reactores pasa por un proceso automático previo de lavado y esterilización. “Cuando están estériles, comenzamos a preparar los componentes de la vacuna, que se mezclan en un orden determinado de adición y a una velocidad específica. Eso da lugar a la vacuna formulada, que le llamamos ‘a granel’ y que se traslada en las bolsas desechables hacia el área de llenado. Estas se conectan a la máquina, que dispensa el producto en los viales, según el volumen programado”.

“Hay que tomar en cuenta que el proceso de llenado tiene una preparación previa: el montaje de todos los componentes de la línea de llenado que tienen que ingresar estériles al área, la conexión del producto a granel a la máquina de llenado, que también tiene su proceso y su procedimiento establecido; el monitoreo del área, el control previo al llenado, el ajuste previo del volumen a dispensar...”

Todas estas son operaciones de rutina antes de cada llenado, e incluyen, después de que todo está listo, la revisión de especialistas y técnicos en el área, y un supervisor de buenas prácticas que garantiza que todas estas operaciones se realicen cumpliendo con lo regulado”.

“Todo –nos comenta el jefe de las plantas– transcurre en ambientes bajo monitoreo las 24 horas, tanto de partículas como de microorganismos. Los datos del monitoreo son registrados y guardados, porque esa información hay que enseñarla a la autoridad regulatoria o a cualquier auditor que, en cualquier momento, necesite comprobar en qué condiciones se hizo, por ejemplo, un lote específico de un producto específico”.

Durante el llenado se toman muestras de todo para comprobar la calidad, tanto microbiológica como físico-química; parámetros como pH, concentración, identidad, todo según la especificación de cada producto, y se envían al laboratorio de control de calidad de Biocen.



Además de una decena de inspecciones o auditorías anuales por parte de la autoridad regulatoria nacional, el Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos (Cecmed), y clientes tanto internos para los que formulan y llenan (CIGB, CIM, IFV, entre otros) como extranjeros (aquellos que compran los productos de esos mismos centros, que son procesados en Biocen), el Centro Nacional de Biopreparados debe pasar por procesos de validación periódicos.

“Cada seis meses, por regulación, debemos realizar una simulación y

validación del proceso. Para garantizar que lo que está ahí está estéril, tenemos que demostrarlo. Lo hacemos con el proceso productivo más crítico, el material de envase más crítico (que demore más tiempo y que tenga más posibilidades de contaminarse; no es lo mismo que entre un microorganismo en un vial unidosis que en uno multidosis, con una abertura mayor, en uno que tarda más en transitar por la línea de llenado que en uno que lo hace más rápido).

“Todo esto se tiene en cuenta. Tomamos un medio de cultivo (una solución enriquecida donde pueden crecer los microorganismos fácilmente), que es el más crítico, el más fácil de contaminarse, y se hace una corrida de llenado.... En esas condiciones se hace la validación, con los mismos operarios, simulando todas las intervenciones y fallos posibles, las paradas. Si en esas condiciones críticas la corrida de llenado sale estéril, tenemos la certeza de que con el producto, que es menos sensible a contaminación, todo va a estar bien”.

Una inversión y mayor capacidad en la planta de IFA

Biocen no se dedica solo a formulación y llenado para otros centros científicos cubanos. Además de la investigación y desarrollo de productos, allí se produce ingrediente farmacéutico activo (IFA) para esos preparados propios y los de otras instituciones del país.

El ingeniero Yoel Perea Martínez, jefe de la Planta de Ingredientes Activos, nos comenta que fabrican el IFA de varios productos, entre ellos la estreptoquinasa recombinante, del CIGB; el LeukoCIM, del CIM; la Biomodulina T y las tres vacunas alergénicas Valergen, de Biocen, y una lista larga de fármacos desarrollados en este y otros centros de la biotecnología cubana, incluidos algunos en fase de ensayos clínicos.

“Hace más de una década, toda la vacuna de alergia de Cuba se produce aquí en Biocen. Suministramos a todas las provincias del país, son de tres ácaros: Valergen DP, del *Dermatophagoides pteronyssinus*; Valergen DS, del *Dermatophagoides siboney*, y Valergen BT, del *Blomia tropicalis*. Son vacunas terapéuticas en función del tipo de alergia que tenga el paciente. El especialista en alergia e inmunología determina el tratamiento y la dosis a aplicar”.

Recientemente, Biocen adquirió una moderna batería de fermentadores, en fase de puesta en marcha durante el mes de mayo. Perea Martínez destaca que su capacidad de fermentación es de 600 litros, con lo que duplica la capacidad de los fermentadores anteriores que sustituye.

Como en el CIGB –explica–, “tenemos montado un sistema de fermentación en bacterias y levadura. Para esta nueva batería de fermentación, Biocen y BioCubaFarma realizaron un proceso de inversión grande y se hizo en medio de las restricciones de la pandemia, no solo económicas, sino de logística, comunicación y transferencia tecnológica. A veces había cierre en el país del fabricante, y estaba el cierre en Cuba. Incluso, hubo que posponerlo en varias ocasiones, pero finalmente se concretó”.

El ingeniero químico Salvador Losada, con una maestría en procesos biotecnológicos y especializado en el área de fermentación en levaduras y bacterias desde su graduación en 1993, nos dice que la moderna batería está compuesta por dos fermentadores, “uno de semilla, que es el pequeño, y otro mayor, de producción”.

Cuenta con tanques auxiliares para el control automático de pH –“uno lo carga y automáticamente el sistema puede inyectar base o ácido en dependencia de la necesidad para mantener el pH estable dentro

del fermentador”–, y hay un tercer tanque auxiliar para el control de espuma.

“La fermentación a veces genera espuma, pues son fermentaciones aerobias, necesitan aire porque consumen oxígeno; por tanto, el movimiento de agitación, más el aire suministrado, puede generar espuma, y mucha espuma puede comprometer el proceso de fermentación... Hay sensores de espuma y, si se llega a cierto nivel, se añade una solución antiespumante y se controla”.

Un sistema computarizado permite el seguimiento y control del proceso desde una pantalla. “Todos los procesos son rastreables, verificables, algo que exigen las entidades regulatorias en la producción de medicamentos de alto estándar”.

El mando computarizado –añade– “nos posibilita controlar el proceso en su totalidad, durante todas las fases de la fermentación, esterilización, temperatura y otros parámetros. Nos da seguridad en cuanto a la capacidad de fermentación. Todo queda registrado: las lecturas de sensores y las acciones del operario.

“Podemos guiarnos, dar seguimiento en línea al proceso de fermentación, la situación tanto del pH y la concentración de oxígeno como del crecimiento celular y el nivel o volumen dentro del fermentador gracias a sensores. Anteriormente teníamos que extraer muestras para apreciar el crecimiento celular; ahora lo vemos online, lo cual nos ayuda en la optimización del producto, porque sabemos cómo está el microorganismo”.

Fue un trabajo conjunto de diseño con el fabricante “y se adaptó a nuestras condiciones, para que sea lo más versátil posible y permita varios tipos de fermentación. Hay fabricantes que lo hacen estándar, pero nosotros lo hicimos de acuerdo con nuestros requerimientos, necesidades y la experiencia de muchos años en fermentación.

“En el diálogo con el fabricante, este fue asimilando y nos dio la oportunidad de tener un equipo hecho según nuestras especificaciones. Sabíamos adónde íbamos, lo que necesitábamos y cómo lo necesitábamos”.

Fuente: Cubadebate. Disponible en <https://cutt.ly/hnz6T7I>

México hará estudios fase 3 de vacuna de Sanofi contra Covid-19

24 may. Hasta ahora, la nación latinoamericana cuenta a su disposición con vacunas de la británica AstraZeneca, la estadounidense Pfizer, la rusa Sputnik V y las chinas CanSino Biologics y Sinovac Biotech.

México llevará a cabo la última etapa de los ensayos clínicos de la vacuna de la farmacéutica francesa Sanofi contra el Covid-19, que sumaría al arsenal de biológicos que está tratando de reunir para luchar contra la pandemia en el país, informó el lunes el canciller, Marcelo Ebrard.



Hasta ahora, la nación latinoamericana cuenta a su disposición con vacunas de la británica AstraZeneca, la estadounidense Pfizer, la rusa Sputnik V y las chinas CanSino Biologics y Sinovac Biotech.

"En México se tienen o ya se han llevado a cabo o se están realizando fase 3 de muy diversas vacunas y

nos notificaron vía (el regulador sanitario) Cofepris (sobre la aprobación de) Sanofi, con una proteína recombinante", dijo Ebrard en un evento virtual de la cancillería.

México ocupa el quinto lugar global en decesos vinculados con el Covid-19, con un total de 221,695, aunque la cifra de muertes y casos han venido disminuyendo sostenidamente en los últimos meses, mientras las autoridades de salud aceleran su plan de vacunación con la meta de completarla en octubre.

El diplomático destacó que el país ha recibido hasta el momento alrededor de 34 millones de dosis de vacunas y espera casi duplicar la cifra para finales del próximo mes. "Vamos a entrar en junio con 40 millones (de dosis) y vamos a salir (...) con 65 millones", aseveró.

A principios de mayo, Ebrard dijo que las autoridades locales también se encaminaban a iniciar pronto estudios en fase 3 de la vacuna de la firma china Walvax.

Si bien el gobierno mexicano fue el primero en la región en iniciar la inmunización de sus casi 126 millones de habitantes a fines del año pasado, hasta la fecha solo un 14.2% de la población ha recibido al menos una dosis de las vacunas, según un recuento de Reuters.

Fuente: EL ECONOMISTA. Disponible en <https://cutt.ly/BnxqLsR>

Pfizer begins testing use of pneumococcal vaccine along with COVID-19 booster shot

May 24. Pfizer Inc (PFE.N) said on Monday it began testing fully vaccinated adults over 65 in a new study that uses the company's 20-valent pneumococcal conjugate vaccine (20vPnC) candidate with a third dose of the Pfizer-BioNTech COVID-19 shot.



The aim of the study is to understand if the combination of the vaccines is safe, and the immune response after adding the pneumonia vaccine to the existing COVID-19 vaccine, Pfizer said.

The vaccine candidate, 20vPnC, is being developed to help protect adults against 20 serotypes responsible for the majority of invasive pneumococcal disease and pneumonia.

The new study will include 600 adults who will be recruited from the two companies' late-stage COVID-19 vaccine study, after having received their second dose of the vaccine at least six months before entering the co-administration study.

COVID-19 vaccines were previously recommended to be administered alone. But based on experience with non-COVID vaccines, the U.S. Centers for Disease Control and Prevention has said COVID-19 shots and other vaccines can be given simultaneously or on the same day.

In December, the U.S. Food and Drug Administration (FDA) accepted for a priority review Pfizer's biologics license application for the investigational 20vPnC in adults over 18 and set an action date for a decision in June. The European Medicines Agency (EMA) accepted the company's marketing authorization application for 20vPnC two months later.

Fuente: REUTERS. Disponible en <https://cutt.ly/knxeOZp>

OMS advierte que vendrá un virus más contagioso y mortal

May 24. La pandemia de COVID-19 no será la única en el mundo, ya que surgirá un nuevo virus que será más contagioso y mortal, alertó el director general de la OMS, Tedros Adhanom Ghebreyesus, durante la 74 Asamblea Anual.

“No se equivoquen: esta no será la última vez que el mundo se enfrente a la amenaza de una pandemia. Según estimaciones evolutivas, surgirá un nuevo virus que podría ser aún más contagioso y más mortal que el virus actual”, subrayó Tedros.



Por ello, el director general de la OMS llamó a la cooperación para enfrentar el futuro virus que podría desencadenar otra pandemia como la actual por COVID-19.

“Este es el momento para las ideas, el compromiso y el liderazgo audaces, para hacer cosas que nunca se han hecho antes. Tenemos que elegir una opción: entre la cooperación, la competencia o la confrontación”, afirmó el director de la OMS.

“Si los más atrasados son los primeros en recibir ayuda, si los más débiles son los primeros en ser fortalecidos y si los más vulnerables son los primeros en ser protegidos, entonces todos ganamos”, destacó. La OMS abrió la posibilidad de crear un tratado internacional con la intención de que el mundo esté preparado para futuras pandemias por virus.

Esta iniciativa de la OMS permitiría crear un sistema de financiación obligatorio para prevenir riesgos, lo que permitiría al órgano ser menos dependiente de los países más ricos que contribuyen de manera voluntaria. Los presidentes de Francia, Alemania y España, entre otros, apoyaron en sus intervenciones ante la Asamblea esta idea de la OMS sobre un nuevo tratado internacional para evitar futuras pandemias.

“También tenemos que dar la posibilidad a la OMS a través de misiones de respuesta rápida de estar en el terreno a la primera señal de una pandemia. Me gustaría atribuirle la competencia de investigar un patógeno que pueda constituir una pandemia y esto le daría acceso rápido a cualquier país del mundo”, sostuvo el mandatario francés, Emmanuel Macron.

El titular de la OMS ejemplifica las oportunidades para la cooperación al señalar el acaparamiento de las vacunas por parte de los países desarrollados.

“La crisis de las vacunas es una desigualdad escandalosa que está perpetuando esta pandemia”, explicó el director de la OMS, recordando que el 75% de las vacunas se han administrado en solo 10 países.

“No hay una forma diplomática de decir esto: un pequeño grupo de países que fabrican y compran la mayoría de las vacunas, están controlando el destino del resto del mundo”, advirtió el doctor de la OMS, Tedros Adhanom.

Por ello, el titular de la OMS, exhortó a la comunidad internacional a donar vacunas al mecanismo COVAX para que en septiembre al menos el 10 % de las poblaciones de todos los países estén vacunadas y se alcance el 30 % a finales de año.

Fuente: tv azteca. Disponible en <https://cutt.ly/MnxDyO>

Moderna dice que su vacuna contra la COVID-19 es segura y parece eficaz en adolescentes

25 may. En un ensayo de fase 2/3 de 3.732 menores de 12 a 17 años en Estados Unidos, los análisis de sangre mostraron que la vacuna de Moderna contra el COVID-19 produjo una respuesta inmune que era equivalente a hallazgos anteriores en adultos.

La compañía no proporcionó un porcentaje de eficacia, ya que el ensayo no fue diseñado para examinar específicamente ese parámetro.

Sin embargo, las observaciones iniciales encontraron que ninguno de los menores que recibieron la vacuna se enfermó con COVID-19 a partir de 14 días después de su segunda dosis.

Cuatro de los menores que recibieron el placebo dieron positivo para COVID-19, lo que Moderna dice que es «consistente con una eficacia de la vacuna del 100%». La compañía señala que la cifra podría cambiar a medida que se recopilan más datos.

Segunda dosis

Moderna también revisó qué tan bien funcionaba la vacuna después de una sola dosis. Los resultados sugieren que después de una dosis, la vacuna fue 93% eficaz para prevenir casos leves de COVID-19, con un solo síntoma en lugar de dos o más síntomas.

Moderna dice que después de una dosis, la vacuna fue 93% eficaz para prevenir casos leves de COVID-19. Moderna anunció los resultados el martes en un comunicado de prensa, y los resultados aún no han sido revisados o publicados por pares.

La compañía dijo que la vacuna era «generalmente bien tolerada» y no se han identificado problemas significativos de seguridad.

Efectos secundarios, que incluyen dolor de cabeza, fatiga, dolor muscular y escalofríos, se detectaron después de la administración de la segunda dosis. También se observó dolor en el lugar de la inyección.

Moderna dice que planea presentar los resultados a la Administración de Alimentos y Medicamentos de Estados Unidos a principios de junio junto con una solicitud de autorización para usar la vacuna en adolescentes. También planea enviar los datos a una publicación revisada por pares.

La vacuna Moderna ya está autorizada para su uso en personas mayores de 18 años. Otra vacuna COVID-19, fabricada por Pfizer / BioNTech, está autorizada para su uso en personas mayores de 12 años.

Fuente: News Channel 3. Disponible en <https://cutt.ly/XnxtEif>

La variante india del SARS-CoV-2 está presente en 44 países, incluida la Argentina

25 may. Se trata de la cepa B.1.617, responsable del aumento masivo de casos varias naciones, que se ha detectado en más de 4500 muestras cargadas en una base de datos de acceso abierto de 44 países en las seis regiones de la OMS.

La variante de la enfermedad COVID-19 responsable de la segunda ola mortal de la India se ha encontrado en 44 países, según la Organización Mundial de la Salud (OMS), que el 11 de mayo la clasificó como “de gran preocupación mundial”.

La agencia de salud de la ONU afirmó que la variante B.1.617, responsable del aumento masivo de casos en India, se ha detectado en más de 4500 muestras cargadas en una base de datos de acceso abierto “de 44 países en las seis regiones de la OMS”, incluido Estados Unidos, Gran Bretaña, Argentina, China, Singapur, Canadá, Australia y Francia.

“La OMS ha recibido informes de detecciones de cinco países adicionales”, indicó la organización en su actualización epidemiológica semanal sobre la pandemia. Esta nueva variante se encontró por primera vez en octubre en India y se cree que se transmite más rápidamente que el virus original y se considera más peligrosa. También fue reclasificado como una “variante de preocupación” por la OMS y agregado a la lista que contiene otras tres variantes de COVID-19, las que se detectaron por primera vez en Gran Bretaña, Brasil y Sudáfrica.

“Una evaluación de riesgo reciente de la situación en la India realizada por la OMS encontró que el resurgimiento y la aceleración de la transmisión de COVID-19 en la India tenían varios factores contribuyentes potenciales, incluido un aumento en la proporción de casos de variantes del SARS-CoV-2 con transmisibilidad potencialmente aumentada”, decía. También señaló que la propagación de la India podría haber sido el resultado de “varios eventos religiosos y políticos de reuniones masivas que aumentaron la mezcla social; y la infrutilización y la reducción de la adherencia a las medidas sociales y de salud pública”.

Según la OMS, aparte de la India, el país que había notificado el mayor número de casos de COVID-19 con esta variante es Gran Bretaña. También señaló la “evidencia preliminar” de que la variante era más resistente al tratamiento con el anticuerpo monoclonal Bamlanivimab, y destacó los primeros estudios de laboratorio que indicaban una “reducción limitada en la neutralización por anticuerpos”. En el informe, hizo hincapié en que los “impactos del mundo real” sobre la eficacia de las vacunas contra la variante, por ejemplo, “pueden ser limitados” y agregó que la propagación de B.1.617, junto con otras variantes más transmisibles, parecía ser uno de los varios factores que alimentaron el dramático aumento en India de nuevos casos y muertes.

Con 1300 millones de personas, informó 200.000 nuevas infecciones en las últimas 24 horas y contabilizó 3500 muertos. Ya son casi 27 millones de personas contagiadas con COVID-19 desde que comenzó la pandemia.

Detectada en Argentina este mes, técnicamente, se la conoce como B.1.617 y presenta más de una docena de mutaciones. Se la ha llamado “doble mutante” por dos mutaciones prominentes: E484Q y L452R (que comparte con la variante de California), y podría ayudar al virus a evadir algunos tipos de anticuerpos que genera el mismo sistema inmune.

Esa variante apareció por primera vez en octubre y ahora es la más común en la India. Se ha encontrado en Gran Bretaña, Estados Unidos, Israel, entre otros 28 países. En diálogo con Infobae, Humberto Debat, investigador en virología del Instituto Nacional de Tecnología Agropecuaria (INTA) y miembro de Proyecto País, que realiza vigilancia genómica del coronavirus y depende del Ministerio de Ciencia, Tecnología e Innovación, comentó: “La variante que fue detectada en India comprende tres sublinajes. Tiene mutaciones que están asociadas a la posibilidad de un mayor escape inmune. Puede ser más transmisible aún que la variante del Reino Unido. No tendría impacto en la eficacia de las vacunas contra el COVID-19”.

De las cinco variantes de preocupación mundial, cuatro se han detectado en la Argentina: Manaos, Inglaterra, India y Sudáfrica. Los tres viajeros que se testearon en Ezeiza y que tenían el coronavirus con variantes de preocupación pasaron a estar en aislamiento, según informó el lunes la directora de epidemiología del Ministerio de Salud de la Nación, Analía Rearte.

Por qué aparecen variantes

En el coronavirus que causa la enfermedad COVID-19, hay una cadena de 30.000 letras que representan propiedades químicas y que conforman su genoma. Para replicarse, el coronavirus se une al exterior de una célula humana y luego entra en ella: secuestra la maquinaria celular y la dirige para que haga copias del virus.

Cuando una célula infectada produce nuevos coronavirus, ocasionalmente comete pequeños errores de copia que se llaman “mutaciones”. “Se produce una mutación o dos por mes”, dijo a Infobae Julia Lo Médico, bióloga especializada en filogenética, quien fue expositora recientemente en un encuentro de capacitación de la Asociación Argentina de Medicina Respiratoria.

Cuando los científicos observan que hay mutaciones distintivas que aumentan su frecuencia se habla de “variante”. “Es el aviso de que algo puede estar pasando”, comentó Lo Médico. “Cada variante tiene una mutación o más”, señaló. “Cuando una variante aumenta su frecuencia en más del 30% regional o 20% mundial se convierte en linaje. A medida que pasa el tiempo y con más contagios, se está favoreciendo a que haya más mutaciones”.

Una variante tiene una o más mutaciones que la diferencian de las otras variantes en circulación. Como se preveía en el inicio de la pandemia, se han reportado múltiples variantes del coronavirus en el mundo.

Algunas de ellas han generado temor por la posibilidad de que alarguen la pandemia o por el riesgo de que hagan que las vacunas sean menos eficaces.

La Organización Mundial de la Salud (OMS) y los Centros para la Prevención y el Control de Enfermedades (CDC) de Estados Unidos) establecieron en marzo los nuevos criterios para clasificar las variantes del coronavirus con la idea de mejorar la calidad del tratamiento que se ofrece a los pacientes afectados. Sirven para evaluar los niveles de transmisión y el riesgo que representan para la población.

Fuente: infobae. Disponible en <https://cutt.ly/PnxuzjZ>

Soberana 02 concluye fase tres de ensayo clínico

27 may. Soberana 02, una de las cinco candidatas de vacunas cubanas contra la COVID-19 concluyó su tercera y última fase de ensayos clínicos, destaca un reportaje del diario Milenio en su versión digital.

Según el medio, el ensayo terminó este miércoles cuando todos los voluntarios que participaron en las pruebas completaron el esquema de inmunización.

Este biológico y Abdala, que ya finalizó su fase 3 a inicios de mayo, son las dos fórmulas más avanzadas de las cinco que desarrolla Cuba contra la COVID-19, y si estos estudios demuestran su efectividad se convertirían en las primeras vacunas desarrolladas en Latinoamérica, añade.

La confirmación de eficacia, expresa el reportaje, permitiría asimismo a las autoridades sanitarias de la isla obtener autorización para uso de emergencia o registro farmacológico, algo que esperan lograr dentro de unos días, en junio.

Esas autorizaciones posibilitarían iniciar la vacunación masiva en el país caribeño, que atraviesa un duro momento de la pandemia, con una tercera oleada de contagios desde hace semanas que no baja del millar de casos diarios pese a las medidas de restricción vigentes.

El gobierno cubano insiste en que tendrá inmunizada a toda su población antes de que acabe el año.

En esta tercera etapa de ensayos realizada en La Habana a doble ciego y con un grupo placebo, administraron la vacuna a 44 mil 10 voluntarios de 19 a 80 años con dos esquemas: uno con dos dosis y otro con esas dos más una de refuerzo de Soberana Plus, otra fórmula en investigación.

Soberana 02 es una vacuna conjugada de subunidad -muy seguras- que combina el antígeno del virus y el toxoide tetánico, y emplea también hidróxido de aluminio para estimular la respuesta del sistema inmune. Su desarrollo está a cargo del Instituto Finlay de Vacunas (IFV).

La directora de Investigaciones Clínicas del IFV, Meiby Rodríguez, explicó que una vez administradas todas las dosis comienza el seguimiento de los voluntarios para detectar posibles contagios como parte de la evaluación de la variable eficacia, fundamental para el registro del antígeno.

Una comparación del número de contagios que ocurran entre quienes recibieron el candidato vacunal y el placebo, es el dato que revelará el porcentaje de efectividad de la fórmula.



Rodríguez dijo está constatado que quienes recibieron placebo en las dos primeras fases de los ensayos clínicos tuvieron dos veces mayor probabilidad de enfermar respecto a los vacunados.

De acuerdo con los datos preliminares de esas etapas, el 76 por ciento de los voluntarios elevó la concentración de anticuerpos específicos contra el virus SARS-CoV-2 tras recibir dos dosis de Soberana 02, un porcentaje que se eleva 'alrededor del 90 por ciento' en el caso de los que recibieron la porción adicional de Soberana Plus, aseguró la científica.

Fuente: 5 DE SEPTIEMBRE. Disponible en <https://cutt.ly/5nxiYiq>

Disponible en Beijing vacuna recombinante de tres inyecciones contra COVID-19

28 may. Las autoridades sanitarias pusieron a disposición de Beijing una vacuna desarrollada por China a partir de proteínas recombinantes contra la COVID-19, cuya administración se divide en tres inyecciones.

La vacuna (células CHO) fue desarrollada conjuntamente por el Instituto de Microbiología de la Academia de Ciencias de China y la compañía Anhui Zhifei Longcom Biopharmaceutical. A partir del jueves, los investigadores del instituto recibieron las primeras inyecciones en el distrito de Haidian de la capital.

China emitió la autorización de uso de emergencia de la vacuna el 10 de marzo y personas de diversas provincias, incluyendo Anhui y Hubei, han sido inoculadas desde entonces. El 3 de mayo, el primer lote de la vacuna salió de la línea de producción en Beijing, según el instituto.

Los resultados de los ensayos de la segunda fase, con personas de entre 18 y 59 años, muestran que el 83 por ciento de los participantes produjeron anticuerpos neutralizantes después de dos dosis, y el 97 por ciento después de la tercera dosis.

Los ensayos de la fase inicial, realizados entre personas de 60 años o más, muestran que la tasa de seroconversión de anticuerpos neutralizantes alcanzó el 95 por ciento después de tres dosis, sin reacciones adversas graves relacionadas con la vacunación.

El nivel de anticuerpos neutralizantes obtenidos es comparable al de otras vacunas de proteína recombinante y ARNm contra la COVID-19 a nivel mundial, destacó el instituto en un comunicado.

La vacuna de proteína recombinante no necesita un laboratorio de bioseguridad de alto grado para su fabricación y puede alcanzar rápidamente una producción a gran escala. Resultan más rentables y fáciles de almacenar y transportar, añadió el fabricante.

Fuente: Spanish.CHINA.ORG.CN. Disponible en <https://cutt.ly/PnxiBdW>

Cuba, Argentina termed fruitful exchange on anti-Covid-19

May 29. The BioCubaFarma Business Group described the meeting held Friday with Argentina's Health Minister Carla Vizzoti, visiting Cuba to learn about progress of anti-Covid-19 vaccine candidates, as fruitful.

On Twitter, BioCubaFarma -dedicated to the development of these formulations, announced that Carla Vizzoti found out about the results of Soberana 02 and Abdala, the two candidates that are currently under phase III of clinical trials.

Accompanied by Presidential Advisor Cecilia Nicolini and Ambassador to Cuba Luis Alberto Larregui, Vizzoti learned about 20-year collaboration between the Cuban biopharmaceutical sector and Argentine institutions.

'We are in Havana to learn from the Cuban health authorities and scientists about progress of Abdala and Soberana 02 vaccine candidates,' Vizzotti tweeted.

Vizzotti highlighted that her delegation came from Mexico, where regional ties and strategies were strengthened and with great pride and joy Presidents Alberto Fernández and Andrés Manuel López Obrador announced the beginning of AstraZeneca vaccine distribution.



Fuente: Prensa Latina. Disponible en <https://cutt.ly/wnQC1xU>

China-Cuba biotechnology innovation center inaugurated

May 29. Representatives from China and Cuba inaugurated an innovation center in the city of Yongzhou, Hunan province, to carry out joint research in biotechnology, a sector with solid ties, diplomatic sources reported today.

The island's ambassador here, Carlos Miguel Pereira, indicated that he led the opening ceremony together with the mayor of that municipality, Zhou Hongwu, and highlighted the importance of the project for bilateral cooperation.

In his intervention, the diplomat thanked those who contributed to materialize it, despite the inconveniences arising from the COVID-19 pandemic and stressed that the facility is called to become a national and international reference.

'(The work) It will allow not only the realization of novel scientific projects in the field of human and animal biomedicine, but also cooperation in the essential education and academic training of scientists from both countries,' Pereira remarked.

He ratified the support and accompaniment from the embassy, the authorities of Havana, the BioCubaFarma group and in particular, the Center for Genetic Engineering and Biotechnology of Cuba, the main manager, developer and strategic partner of the initiative.



He also highlighted the recent approval by the Ministry of Science and Technology of China of two of the six initial projects, including the one linked to the joint development of the PanCorona vaccine against various strains of the SARS-CoV-2 coronavirus and to prevent COVID-19.

On his part, Zhou also expressed gratitude for the work of those who contributed to the construction of the site in the past two years.

According to Pereira, the opening ceremony also included the inauguration of a cooperation center

for post-doctoral programs; the signing of an agreement for university and industrial research and the donation of equipment to BioCubaFarma.

Last year, the assembly of the Yongzhou center was completed, with equipment and laboratories designed by specialists from the island.

Plans and technologies obtained by the scientific personnel of the Caribbean nation will be developed there.

This site is the result of bilateral cooperation and is part of the policy approved by the Chinese government to stimulate innovation capacities through local administrations.

Fuente: Prensa Latina. Disponible en <https://cutt.ly/PnQMbwW>

Francia abre vacunación contra Covid-19 para todas las personas de 18 años en adelante

31 may. Hasta ahora, poco más de 25 millones de franceses han recibido al menos una dosis de vacuna contra la COVID-19, lo que corresponde al 48% de la población adulta. Y poco menos de 11 millones han recibido dos dosis.

Francia abrió este lunes la vacunación contra la COVID-19 para todas las personas de 18 años en adelante, una "etapa clave" para evitar un repunte de la epidemia antes de las vacaciones de verano.

"Estoy convencido de que vamos a ver a mucha gente yendo a vacunarse", estimó el jefe de la campaña de vacunación de Francia, Alain Fischer.

Esta es una "etapa clave" para proteger a la población y "volver a una vida un poco más normal", dijo Fischer a la cadena de noticias LCI.

Pero para poder vacunarse, los franceses deben armarse de paciencia. Las citas disponibles para recibir la vacuna en uno de los centros oficiales se llenan rápidamente, según se puede observar en las plataformas habilitadas para reservar una fecha.

Hasta ahora, poco más de 25 millones de franceses han recibido al menos una dosis de vacuna contra la COVID-19, lo que corresponde al 48% de la población adulta. Y poco menos de 11 millones han recibido dos dosis.

Para el 15 de junio, "es muy probable que hayamos superado" el objetivo del gobierno de 30 millones de vacunados con al menos la primera dosis, apuntó Alain Fischer.

Francia es uno de los países europeos más duramente golpeados por la pandemia. Hasta la fecha se registran 109,000 muertos.

Pero los nuevos casos, muertes y hospitalizaciones han ido disminuyendo en las últimas semanas.

Tras más de seis meses de duras medidas para contener la expansión de la COVID-19 en el país, los franceses recobraron parte de su libertad el pasado 19 de mayo, con la reapertura de las terrazas de cafés y restaurantes, cines y museos.

Tendrán que esperar al 9 de junio para poder comer o tomar un café dentro de un restaurante o bar.

A partir del 30 de junio se podrán celebrar eventos con más de 1,000 personas, pero para poder acceder a éstos se deberá presentar un test negativo o un certificado de inmunidad.

Fuente: EL ECONOMISTA. Disponible en <https://cutt.ly/snQ3f8Z>

What Is Bacterial Meningitis?

Jun 1. A serious illness that affects the membranes around the brain and spinal cord.

Meningitis refers to inflammation of the meninges, the thin membranes that surround the brain and spinal cord. When the meninges become swollen, they can press on the brain and spinal cord, causing serious complications. Bacterial meningitis, also known as pyogenic meningitis, is a type of meningitis caused by a bacterial infection.

Early symptoms of bacterial meningitis may resemble those of a cold, such as a headache and fever, but they may change quickly. Bacterial meningitis can be life-threatening and requires treatment with antibiotics right away. It can cause permanent disabilities, and is considered a medical emergency.

Those with a weakened immune system are at higher risk of developing bacterial meningitis.² Vaccines are the most effective way to protect yourself against bacterial meningitis.

Symptoms

The symptoms of bacterial meningitis often start out mild, and may resemble the symptoms of a cold or upper respiratory infection. They usually appear about three to seven days after exposure to bacteria.

Symptoms can quickly progress to a high fever and severe headache with a very stiff neck. If you are unable to look down to touch your chin to your chest, see your doctor right away.

Many people also experience nausea and vomiting. Other common symptoms include photophobia and confusion. Later symptoms of meningitis are life-threatening, and include seizures and coma.

Bacterial Meningitis in Babies and Children

In newborns, look at the fontanel on their head. This soft spot may appear to be bulging. If you notice a bulging fontanel or abnormal reflexes in your newborn, seek emergency treatment. Infants may appear to react slower than usual and seem irritable. They may not be interested in feeding and could vomit after nursing or drinking milk or formula from a bottle.

Causes

Bacterial meningitis is caused by a bacterial infection. The bacteria can be spread to people through food or close contact. The most common types of bacteria that can lead to bacterial meningitis in the United States include:

- *Streptococcus pneumoniae*
- Group B *Streptococcus*
- *Neisseria meningitidis*
- *Haemophilus influenzae* (Hib)
- *Listeria monocytogenes*

Although these infections can cause meningitis, they usually don't. So just being infected with one of these organisms doesn't mean you are at high risk of meningitis.

Hib and *S. pneumoniae* are spread when a sick person coughs or sneezes in close contact with others.

N. meningitidis is spread through respiratory or throat secretions like saliva. It is usually shared through kissing, coughing, or living in close contact.

Group B *Streptococcus* can be passed from mother to infant during childbirth. All pregnant women should be tested for this bacteria prior to giving birth. If they are positive, antibiotics are given to prevent the newborn from becoming infected.

E. coli can be spread through contaminated food when the person preparing it does not wash their hands after using the bathroom. It can also be spread from mother to infant during childbirth.

L. monocytogenes is also spread through contaminated food, and is dangerous to the fetus if a pregnant mother is exposed.

Types

Pneumococcal Meningitis

Pneumococcal meningitis is the most common and serious form of bacterial meningitis. This type of meningitis can lead to neurological damage. Each year there are about 6,000 new cases in the United States.

Pneumococcal meningitis is caused by the bacteria *Streptococcus pneumoniae*. This type of bacteria is also responsible for bacterial pneumonia and ear and sinus infections. When it spreads to the bloodstream, it can lead to septicemia.

Groups Most At Risk	Type of Bacterial Infection
Newborns	Group B <i>Streptococcus</i> , <i>S. pneumoniae</i> , <i>L. monocytogenes</i> , <i>E. coli</i>
Babies and young children	<i>S. pneumoniae</i> , <i>N. meningitidis</i> , <i>H. influenzae</i> type b (Hib), group B <i>Streptococcus</i>
Teens and young adults	<i>N. meningitidis</i> , <i>S. pneumoniae</i>
Older adults	<i>S. pneumoniae</i> , <i>N. meningitidis</i> , Hib, group B <i>Streptococcus</i> , <i>L. monocytogenes</i>

Groups most at risk of contracting pneumococcal meningitis are those with a compromised immune system or under two years of age. Fortunately, there is a vaccine available for some types of pneumococcal bacteria.

Meningococcal Meningitis

Meningococcal meningitis is caused by *Neisseria meningitidis* and accounts for 2,600 cases in the United

States each year. It is highly contagious, especially for young infants and those living in dormitory settings such as college students.

This type of meningitis has a 10% to 15% death rate, and 10% to 15% of people who have this condition have permanent brain damage. Meningococcal meningitis is contagious, and it's recommended that those living in close contact with someone who has it start prophylactic antibiotic therapy to be safe.

Haemophilus Meningitis

A third type of bacterial meningitis caused by *Haemophilus influenzae* is now preventable with the *Haemophilus influenzae* b vaccine and is rare in the United States. Those most at risk are usually young children without access to the vaccine.

Risk Factors

The risk factors for many types of bacterial meningitis are related to your risk of being exposed to the bacteria. Those living in close quarters with others or who work in a laboratory setting are at higher risk.

Risk factors for bacterial meningitis include:

Age: It's possible to be diagnosed with bacterial meningitis at any age, but infants, teens, and young adults are at higher risk.

Living in community: Living in close quarters with others can put you at higher risk of being exposed to a bacterial infection and bacterial meningitis. Examples include adults living in institutional settings and young adults living on college campuses.

Medical professionals: Those who work with sick individuals or in a lab setting may be more likely to be exposed to dangerous bacterial infections.

Immunocompromised individuals: Certain medical conditions like cancer can weaken one's immune system and make you more susceptible to bacterial infections. If you have had your spleen removed or are currently taking corticosteroids, your risk is higher as well.

Pregnant women are at increased risk of contracting listeriosis, a bacterial infection caused by the bacteria *Listeria monocytogenes*. This condition is usually mild in pregnant women, but can cause serious health problems in the fetus. *L. monocytogenes* are spread through contaminated food. Pregnant women can reduce their risk by avoiding certain foods during their pregnancy.

Fuente: verywell health. Disponible en <https://cutt.ly/InWr9I2>

Moderna busca la aprobación total de la FDA para su vacuna contra la COVID-19

1 jun. Moderna anunció este martes que solicitó la aprobación total para su vacuna contra la COVID-19 para personas de 18 años en adelante.

La empresa dice que seguirá enviando datos de prueba «de forma continua durante las próximas semanas con una solicitud de revisión prioritaria». Una revisión prioritaria solicita a la Administración de Alimentos y Medicamentos de Estados Unidos (FDA) que tome medidas dentro de los 6 meses, en comparación con los 10 meses designados en la revisión estándar.

“Nos complace anunciar este importante paso en el proceso regulatorio de EE.UU. para una Solicitud de

Licencia Biológica (BLA) de nuestra vacuna contra la COVID-19”, dijo el director ejecutivo de Moderna, Stéphane Bancel, en un comunicado. «Esperamos trabajar con la FDA y continuaremos enviando datos de nuestro estudio de Fase 3 y completaremos la presentación continua».

Desde diciembre, la vacuna de dos dosis de Moderna se ha distribuido bajo una autorización de uso de emergencia para personas de 18 años en adelante. El 13 de abril, la compañía anunció que su vacuna mantenía una eficacia superior al 90% seis meses después, la cantidad de tiempo de seguimiento necesaria para solicitar la aprobación de la FDA.

Moderna es la segunda empresa que busca dicha aprobación en Estados Unidos. El 7 de mayo Pfizer anunció que estaba iniciando su propia aplicación para personas mayores de 16 años, luego de un anuncio del 1 de abril de que sus ensayos clínicos mostraban una eficacia superior al 91% después de seis meses. Los expertos dicen que esperan que esta protección dure mucho más tiempo, lo que se confirmará a medida que ingresen más datos.

Recibir la aprobación de la FDA puede motivar a algunas personas que dudan a ponerse esta vacuna, según una investigación publicada el viernes por la Kaiser Fundación.

Tanto Pfizer como Moderna también están estudiando sus vacunas en niños de hasta 6 meses. El mes pasado, la FDA otorgó a la vacuna de Pfizer una autorización de uso de emergencia para niños de 12 a 15 años.

Fuente: CNN en español. Disponible en <https://cutt.ly/MnWofix>



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Estrategia de búsqueda: *Vaccine in the title or abstract AND 20210522:20210601 as the publication date 28 records.*

1.3589901VACCINEBÆRER MED ET PASSIVT KØLESYSTEM

DK - 25.05.2021

Clasificación Internacional [A01N 1/02](#) N° de solicitud 18704997 Solicitante B Medical Systems S.à.r.l.

Inventor/a DE CLERCQ, Julien

The present invention relates to a mobile vaccine carrier (1) comprising a housing (2) having a lid (3) preferably hinged to a base member (4), a vaccine storage member (5) disposed within the housing (2) and defining a storage space for a plurality of vaccine containers (V); and a cooling element (6) disposed within the housing (2). The vaccine storage member (5) further comprises an inner container (7) defining the storage space and having an inlet opening (8) for placing and removing vaccine containers (V); are movable vaccine container holder (9) and a cover member (10) disposed on the lid. The vaccine container holder (9) has an abutment portion (11) abutting against an outer portion (12) of the inner container (7) so that the inlet opening (8) is covered by the vaccine container holder (9) and at least a part of the cover member (10) protrudes into the storage space when the lid (3) is in a closed position. Further, the invention relates to a method for operating a vaccine carrier (1).

2.WO/2021/101187NOVEL VACCINE IMMUNE ADJUVANT COMPOSITION CONTAINING BAVACHIN
WO - 27.05.2021

Clasificación Internacional [A61K 39/39](#) N° de solicitud PCT/KR2020/016066 Solicitante KOREA INSTITUTE OF ORIENTAL MEDICINE Inventor/a JIN, Young Hee

The present invention relates to: a vaccine immune adjuvant composition containing bavachin as an active ingredient, the composition enabling antibody titer to be improved when administered with an antigen and cellular immunity and humoral immunity to be enhanced; a vaccine formulation containing bavachin and an antigen; a method for promoting immune responses, comprising a step of administering an individual with both the vaccine immune adjuvant composition and a vaccine composition or before or after administration of the vaccine composition; and a vaccine adjuvant composition for promoting immune responses, containing bavachin. A vaccine immune adjuvant composition of the present invention contains bavachin isolated from a Psoraleae semen extract of which the safety is ensured, and thus is safe, and can enhance the titer of an antibody produced according to an antigen and both humoral immunity and cellular immunity, thereby being widely usable in the development of an effective vaccine formulation.

3.WO/2021/102307VACCINIA VIRUSES AND METHODS FOR USING VACCINIA VIRUSES
WO - 27.05.2021

Clasificación Internacional [A61K 39/285](#) N° de solicitud PCT/US2020/061578 Solicitante UNIVERSITY OF PITTSBURGH - OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION Inventor/a BARTLETT, David

The disclosure relates to methods and materials for treating cancer. For example, recombinant vaccinia viruses having the ability to direct the expression of membrane-bound IL-12 polypeptides on the surface of infected cells and methods for using such recombinant vaccinia viruses to treat cancer are provided. Specifically, the disclosure provides a recombinant vaccinia virus comprising a vaccinia virus genome comprising a nucleic acid encoding an IL-12p35 polypeptide sequence and an IL-12p40 polypeptide sequence, wherein one of the polypeptide sequences comprises a membrane anchoring polypeptide sequence.

4.WO/2021/099444A NOVEL VACCINE AGAINST HAEMOPHILUS PARASUIS
WO - 27.05.2021

Clasificación Internacional [A61K 39/102](#) N° de solicitud PCT/EP2020/082634 Solicitante INTERVET INTERNATIONAL B.V. Inventor/a JACOBS, Antonius, Arnoldus, Christiaan

The invention pertains to a protein having at least 69% sequence identity with the protein according to SEQ ID No: 1 or an immunogenic fragment of this protein, for use in a prophylactic method to protect a pig against an infection with Haemophilus parasuis by administering a vaccine to the pig, the vaccine comprising the protein or the immunogenic fragment thereof as an antigen. The invention also pertains to a vaccine, a method to manufacture such a vaccine and a method to protect a pig against H. parasuis.

5.WO/2021/098521METHOD FOR RAPID PREPARATION OF EPIDEMIC AND INFECTIOUS BRONCHITIS VACCINE
WO - 27.05.2021

Clasificación Internacional [C12N 7/01](#) N° de solicitud PCT/CN2020/126654 Solicitante SOUTH CHINA AGRICULTURAL UNIVERSITY Inventor/a XIE, Qingmei

The present invention provides a method for rapid preparation of an epidemic and infectious bronchitis vaccine. The method takes infectious clone of an infectious bronchitis virus (IBV) H120 vaccine strain as a skeleton carrier, then replaces an antigen gene in the skeleton carrier with a targeted antigen gene of an infectious bronchitis epidemic virus strain, so as to obtain a method for recombining bronchitis virus, wherein the targeted antigen gene is an S1 gene or an S gene, the S gene being one of S gene

fragments of the infectious bronchitis epidemic virus strain or a fusion gene composed of multiple of the S gene fragments; replacement can also be the simultaneous replacement of the targeted antigen gene and an N gene, and a signal peptide region of an original S1 gene in the skeleton carrier needs to be preserved during the replacement. The method for the rapid preparation of the epidemic and infectious bronchitis vaccine of the present invention has the beneficial effects that an operation method is simple and easy to implement, the repeatability is high, the generation stability is good, the frequent variation of IBV epidemic can be quickly and efficiently tackled, and the method provides a new idea for the construction of a carrier vaccine.

6.WO/2021/099446A NOVEL VACCINE AGAINST HEAMOPHILUS PARASUIS
WO - 27.05.2021

Clasificación Internacional [A61K 39/102](#) N° de solicitud PCT/EP2020/082640 Solicitante INTERVET INTERNATIONAL B.V. Inventor/a JACOBS, Antonius, Arnoldus, Christiaan

The invention pertains to a serine protease antigen which induces antibodies against a protein having at least 69% sequence identity with the Haemophilus parasuis protein according to SEQ ID No: 1, for use in a prophylactic method to protect a pig against an infection with Haemophilus parasuis by administering a vaccine to the pig, wherein the vaccine comprises the serine protease antigen. The invention also pertains to a vaccine, a method to manufacture such a vaccine and a method to protect a pig against H. parasuis.

7.WO/2021/099458A NOVEL VACCINE AGAINST HEAMOPHILUS PARASUIS
WO - 27.05.2021

Clasificación Internacional [A61K 39/102](#) N° de solicitud PCT/EP2020/082677 Solicitante INTERVET INTERNATIONAL B.V. Inventor/a JACOBS, Antonius, Arnoldus, Christiaan

The invention pertains to a protein having at least 69% sequence identity with the protein according to SEQ ID No: 1 or an immunogenic fragment of this protein, for use in a prophylactic method to protect a pig against an infection with Haemophilus parasuis serotype 4 and an infection with Haemophilus parasuis serotype 5, by administering a vaccine to the pig, the vaccine comprising the protein or the immunogenic fragment thereof as an antigen. The invention also pertains to a vaccine, a method to manufacture such a vaccine and a method to protect a pig against H. parasuis.

8.3823666IMPFFSTOFFFORMULIERUNGEN MIT KONSERVIERUNGSSYSTEM
EP - 26.05.2021

Clasificación Internacional [A61K 39/00](#) N° de solicitud 19841047 Solicitante BIOLOGICAL E LTD Inventor/a SANGAREDDY VEERAPANDU

The present invention relates to vaccine formulations comprising preservative systems. More particularly, the present invention relates to preservative systems for vaccine formulations which is free of thiomersal, and comprising 2-phenoxyethanol and at least one other preservative selected from m-cresol, benzyl alcohol, phenol and benzoic acid.

9.20210154291IMMUNOSTIMULATORY COMPOSITIONS, PARTICLES, AND USES RELATED THERETO
US - 27.05.2021

Clasificación Internacional [A61K 39/385](#) N° de solicitud 17132320 Solicitante Emory University Inventor/a Periasamy Selvaraj

In some embodiments, described herein is a method of tumor treatment or tumor vaccination. The method generally comprises applying to a human being in need thereof a tumor therapeutic composition or tumor vaccine defined herein. The tumor therapeutic composition or tumor vaccine can be produced by protein transfer of glycosyl-phosphatidylinositol (GPI)-anchored immunostimulatory or costimulatory molecules

10.20210154281CELL-BASED CANCER VACCINES AND CANCER THERAPIES

US - 27.05.2021

Clasificación Internacional [A61K 39/00](#) N° de solicitud 17033050 Solicitante Massachusetts Institute of Technology Inventor/a Darrell Irvine

Described are cell-based cancer vaccines and anti-cancer immunotherapies. The vaccines include isolated tumor cells activated with one or more genotoxic drugs, and, optionally, treated with one or more MK2 inhibitors. The activated cells are highly immunogenic non-proliferative cells, and may be tested for immunogenicity ex vivo for priming T cells by co-incubating the isolated activated cells with dendritic cells and T cells. The vaccines are typically administered into patient's tumor to provide an intratumoral immune activation. Immune checkpoint inhibitor(s) (ICI) may be administered before, during, or after vaccine administration. ICI may be a component of the vaccine. The vaccines confer heightened cytotoxic immune response against the cancer cells, induce tumor regression, and enhance survival from cancer. The vaccines prevent tumor recurrence and induce a long-lasting anti-tumor immunological memory.

11.WO/2021/099572MEDICAL USES OF 4-1BBL ADJUVANTED RECOMBINANT MODIFIED VACCINIA VIRUS ANKARA (MVA)

WO - 27.05.2021

Clasificación Internacional [A61K 39/00](#) N° de solicitud PCT/EP2020/082888 Solicitante BAVARIAN NORDIC A/S Inventor/a HINTERBERGER, Maria

The invention relates to a recombinant Modified Vaccinia Virus Ankara (MVA) expressing a TAA and the costimulatory molecule 4-1BBL for use in (i) the prevention of recurrence of a solid tumor, wherein the recombinant MVA is intratumorally administered to the solid tumor, or (ii) the treatment, prevention and/or prevention of recurrence of a tumor, wherein the recombinant MVA is intratumorally administered to another solid tumor.

12.20210154296VACCINE OR IMMUNOTHERAPEUTIC AGENT COMPOSITION CONTAINING PHOTOTHERMALLY TREATED CELL LYSATES AS ACTIVE INGREDIENTS

US - 27.05.2021

Clasificación Internacional [A61K 41/00](#) N° de solicitud 16633168 Solicitante INJE UNIVERSITY INDUSTRY-ACADEMIC COOPERATION FOUNDATION Inventor/a Yeon Jeong KIM

Disclosed are a vaccine composition including photothermal (PT)-treated cell lysate as an active ingredient and an immunotherapeutic composition including PT-treated cell lysate as an active ingredient, wherein the PT-treated cells exposed to ex vivo PT treatment maximize the expression of HSPs which enhance immunogenicity, thereby generating cancer-specific immune responses in vivo.

13.WO/2021/099982DOSAGE AND ADMINISTRATION OF A BACTERIAL SACCHARIDE GLYCOCONJUGATE VACCINE

WO - 27.05.2021

Clasificación Internacional [A61K 39/09](#) N° de solicitud PCT/IB2020/060901 Solicitante GLAXOSMITHKLINE BIOLOGICALS SA Inventor/a ADAMO, Roberto

The present invention provides a glycoconjugate for administration to a subject in a method comprising the steps of: (i) administering a first dose of glycoconjugate; (ii) subsequently administering a second dose of glycoconjugate; wherein the amount of glycoconjugate in the first dose or first and second doses are atypically low, and also related aspects.

14.3082855SAMMENSÆTNING

DK - 25.05.2021

Clasificación Internacional [A61K 39/08](#) N° de solicitud 14828499 Solicitante University of Exeter Inventor/a TITBALL, Richard William

The invention provides a composition comprising a reduced toxicity NetB epitope polypeptide and a reduced toxicity Clostridium perfringens alpha-toxin epitope polypeptide. The composition is useful as a vaccine providing complete protection against infection by C. perfringens.

15.20210154284 NOVEL PEPTIDES AND COMBINATION OF PEPTIDES FOR USE IN IMMUNOTHERAPY AGAINST NHL AND OTHER CANCERS

US - 27.05.2021

Clasificación Internacional [A61K 39/00](#) N° de solicitud 17165457 Solicitante Immatics Biotechnologies GmbH Inventor/a Oliver SCHOOR

The present invention relates to peptides, proteins, nucleic acids and cells for use in immunotherapeutic methods. In particular, the present invention relates to the immunotherapy of cancer. The present invention furthermore relates to tumor-associated T-cell peptide epitopes, alone or in combination with other tumor-associated peptides that can for example serve as active pharmaceutical ingredients of vaccine compositions that stimulate anti-tumor immune responses, or to stimulate T cells ex vivo and transfer into patients. Peptides bound to molecules of the major histocompatibility complex (MHC), or peptides as such, can also be targets of antibodies, soluble T-cell receptors, and other binding molecules.

16.2021202909 METHOD FOR THE PROPHYLAXIS OR TREATMENT OF CORONAVIRUS INFECTION USING AN IMMUNOMODULATOR AND VACCINE COMPOSITIONS COMPRISING THE SAME

AU - 27.05.2021

Clasificación Internacional N° de solicitud 2021202909 Solicitante ADVAGENE BIOPHARMA CO., LTD. Inventor/a

17.20210153484 Humanized Mouse Model

US - 27.05.2021

Clasificación Internacional [A01K 67/027](#) N° de solicitud 17045562 Solicitante The Wistar Institute Inventor/a Rajasekharan Somasundaram

The present invention relates to a humanized mouse, methods for generating a humanized mouse, and methods of using the humanized mouse for testing a vaccine, drug or treatment. Also provided are other uses for the humanized mouse.

18.WO/2021/099829 MEDICINE VIAL SYSTEM

WO - 27.05.2021

Clasificación Internacional [A61J 1/14](#) N° de solicitud PCT/IB2020/000921 Solicitante DECOENE, Tine Inventor/a DECOENE, Tine

Working method and system to manage whether or not a needle can be pricked into a medicine vial, preferably a vaccine vial.

19.20210154277 IMMUNOTHERAPEUTIC COMBINATION FOR TREATING CANCER

US - 27.05.2021

Clasificación Internacional [A61K 39/00](#) N° de solicitud 16762397 Solicitante Nektar Therapeutics Inventor/a Jonathan ZALEVSKY Provided herein are methods and compositions for treating a subject having cancer by administering to the subject a neoantigen-based vaccine composition and a long acting, IL-2R β -selective agonist composition comprised of compounds of Formula (I), and optionally, an anti-PD-1 antibody.

20.20210155714 Hybridoma Cell Strain and Monoclonal Antibody Produced Therefrom Against Serine Protease of Trichinella Spiralis in Intestinal Stage and Application Thereof

US - 27.05.2021

Clasificación Internacional [C07K 16/40](#) N° de solicitud 17111608 Solicitante Jilin University Inventor/a Mingyuan LIU

A hybridoma cell strain and a monoclonal antibody secreted therefrom and application thereof belong to the technical field of prevention and treatment of *Trichinella spiralis* (*T. spiralis*). Aiming at the technical problem of how to specifically diagnose trichinellosis, the disclosure provides a hybridoma cell strain deposited under an accession number of CGMCC No. 18317. Tests show that the monoclonal antibody Ts-ZH68-2A4-Ab secreted by the hybridoma cell strain can compete with the positive serum of pigs infected with *T. spiralis* for binding to Ts-ZH68 antigen, and the recognition peptide is ²²²GVDRSATCQGDSGGP²³⁶. The monoclonal antibody of the disclosure and the Ts-ZH68 protein B cell epitope polypeptide recognized by the monoclonal antibody can be used to prepare a reagent or a vaccine for diagnosing or preventing infection of *T. spiralis*, laying the foundation for establishment of a serological diagnosis method of *T. spiralis*.

21.2589096 The pinball herpes antibody system
GB - 26.05.2021

Clasificación Internacional [A61K 39/00](#) N° de solicitud 201916805 Solicitante RAYMOND JOEL RAIRIE
Inventor/a RAYMOND JOEL RAIRIE

An intentional, artificial infection process that generates Herpes Simplex Virus 01 antibodies in a controlled, safe and regulated manner to prevent a human being from generating a viral infection and from getting the associated painful sores. The approach is designed to prevent herpes infection around the genitals, mouth, anus, hands, face and eyes. A doctor artificially infects a patient to allow it to work like a vaccine. The approach may also be applied to protect against neonatal herpes and Alzheimer's disease.

22.2589230 Replication-defective recombinant H9N2 avian influenza virus expressing HA of H5 subtype
GB - 26.05.2021

Clasificación Internacional [C12N 7/01](#) N° de solicitud 202019165 Solicitante UNIV QINGDAO
AGRICULTURAL Inventor/a JUNWEI LI

A method for preparing a replication-defective recombinant H9N2 avian influenza virus expressing HA of H5N1 subtype, comprising constructing a replication-defective recombinant avian influenza virus steadily expressing surface glycoprotein hemagglutinin (HA) of both H9N2 and H5N1 subtypes and subjecting to replication and packaging in a MDCK cell capable of steadily expressing neuraminidase (NA) of both H9N2 subtype to form a recombinant virus particle. The virus particle can be used to prepare an attenuated vaccine.

23.20210154289 Live-Attenuated Yellow Fever Virus Strain Adapted to Grow on Vero Cells and Vaccine Composition Comprising the Same
US - 27.05.2021

Clasificación Internacional [A61K 39/12](#) N° de solicitud 17045322 Solicitante Sanofi Pasteur Inventor/a
Manuel Vangelisti

The invention relates to a live-attenuated yellow fever virus strain adapted to grow on Vero cells from a parent yellow fever virus 17D substrain that is not adapted to grow on Vero cells, wherein said live-attenuated yellow fever virus strain is less neurovirulent than said parent yellow fever virus 17D substrain.

24.WO/2021/102363 METHODS AND COMPOSITIONS FOR RECOMBINANT DENGUE VIRUSES FOR VACCINE AND DIAGNOSTIC DEVELOPMENT
WO - 27.05.2021

Clasificación Internacional [C07K 14/005](#) N° de solicitud PCT/US2020/061661 Solicitante THE
UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL Inventor/a BARIC, Ralph

The present invention provides compositions and methods of use comprising a chimeric dengue virus E glycoprotein comprising a dengue virus E glycoprotein backbone, which comprises amino acid

substitutions that may introduce an epitope that is recognized by an antibody from a dengue virus serotype that is different from the dengue virus serotype of the dengue virus E glycoprotein backbone.

25.2021202950Development of dengue virus vaccine components

AU - 27.05.2021

Clasificación Internacional N° de solicitud 2021202950 Solicitante The Government of the United States of America, as represented by the Secretary, Department of Health and Human Services Inventor/a

26.20210154279TARGET PEPTIDES FOR COLORECTAL CANCER THERAPY AND DIAGNOSTICS

US - 27.05.2021

Clasificación Internacional [A61K 39/00](#) N° de solicitud 16901277 Solicitante University of Virginia Patent Foundation Inventor/a Donald F. Hunt

A set of target peptides are presented by HLA A*0201, B*0301, B*0702 and B*2705 on the surface of disease cells. They are envisioned to, among other things, stimulate an immune response to the proliferative disease, e.g., colorectal cancer, to function as immunotherapeutics in adoptive T cell therapy or as a vaccine, facilitate antibody recognition of tumor boundaries in surgical pathology samples, act as biomarkers for early detection and/or diagnosis of the disease, and/or act as targets in the generation antibody-like molecules which recognize the target-peptide/MHC complex.

27.WO/2021/101813HYBRID VIRUS-LIKE PARTICLES AND USES THEREOF AS A THERAPEUTIC HEPATITIS B VACCINE

WO - 27.05.2021

Clasificación Internacional [A61K 39/29](#) N° de solicitud PCT/US2020/060542 Solicitante VLP BIOTECH, INC. Inventor/a MILICH, David R.

The present disclosure relates to hybrid hepadnavirus core antigens including one or more epitopes of a human hepatitis B virus (HBV) antigen. More specifically, the present disclosure relates to hybrid hepadnavirus core antigens in the form of fusion proteins containing a fragment of the PreS1 region of the HBV surface antigen inserted in a woodchuck hepadnavirus core antigen. The present disclosure further relates to hybrid hepadnavirus core antigens in the form of fusion proteins containing a truncated HBV core antigen and woodchuck hepadnavirus core antigen. Also provided are nucleic acids encoding the hybrid core antigens, and the use of the hybrid core antigens and nucleic acids for treating HBV-infected individuals.

28.3824097HAUPTHISTOKOMPATIBILITÄTSKOMPLEX KLASSE II EXPRIMIERENDER KREBSZELLENIMPFSTOFF UND VERFAHREN ZU SEINER VERWENDUNG ZUR ERZEUGUNG INTEGRIERTER IMMUNANTWORTEN

EP - 26.05.2021

Clasificación Internacional [C12Q 1/68](#) N° de solicitud 19841026 Solicitante HEALTH RESEARCH INC Inventor/a ODUNSI KUNLE

Provided are modified cancer cells that are modified to co-express class II trans-activator (CIITA), and an immuno-stimulatory molecule. The immuno-stimulatory molecule is OX-40-ligand or 4-1BB-Ligand. Methods of making the cells are provided by introducing polynucleotides encoding the CIITA and the immune-stimulatory molecule into cancer cells. Methods of stimulating humoral and cell-mediated immune responses by administering the modified cancer cells, or polynucleotides encoding the CIITA and immune-stimulatory molecules are also provided. These approaches can be used to stimulate an immune response against any of a wide variety of cancer antigens.

Patentes registradas en la United States Patent and Trademark Office (USPTO)

Results Search in US Patent Collection db for: (ABST/vaccine AND ISD/20210522->20210601), 21 records.

PAT. NO.	Title
1 11,021,534	Mycobacterial antigen composition
2 11,020,477	RNA vaccines
3 11,020,475	Cold-adapted live attenuated severe acute respiratory syndrome coronavirus and vaccine containing the same
4 11,020,474	Producing recombinant SARS-CoV-2 spike protein in a pre-fusion state
5 11,020,472	Multivalent recombinant SPV
6 11,020,464	Immunogenic composition targeting S100A9
7 11,020,434	Peptides and combination of peptides of non-canonical origin for use in immunotherapy against different types of cancers
8 11,020,433	Peptides and combination of peptides of non-canonical origin for use in immunotherapy against different types of cancers
9 11,020,432	Peptides and combination thereof for use in the immunotherapy against cancers
10 11,015,221	Markers of immune response
11 11,014,972	B*44 restricted peptides for use in immunotherapy against cancers and related methods
12 11,013,798	Orf virus-based platform for vaccine delivery
13 11,013,797	Porcine epidemic diarrhea preventative or therapeutic method, vaccine, and vaccine kit
14 11,013,795	Antigenically matched influenza vaccines
15 11,013,794	Method for preparing foot-and-mouth disease vaccines
16 11,013,792	Compositions and methods of enhancing immune responses to enteric pathogens
17 11,013,791	NYVAC-based plasmodium malaria vaccine
18 11,013,790	Vaccination with immuno-isolated cells producing an immunomodulator
19 11,013,769	Peptides and combination of peptides of non-canonical origin for use in immunotherapy against different types of cancers
20 11,013,768	Peptides and combination of peptides of non-canonical origin for use in immunotherapy against different types of cancers
21 11,013,766	Peptides and combination of peptides of non-canonical origin for use in immunotherapy against different types of cancers

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