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VacCiencia es una publicación dirigida a investigadores y especialistas dedicados a la vacunología y temas afines, con el ojetivo de serle útil.

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La Comisión Europea aprueba Capvaxive, la vacuna antineumocócica conjugada 21-valente de MSD

1 abr. MSD ha anunciado que la Comisión Europea (CE) ha aprobado Capvaxive, su vacuna antineumocócica conjugada 21-valente, para la inmunización activa para la prevención de la enfermedad invasiva y la neumonía causada por los serotipos de Streptococcus pneumoniae (3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F y 35B) en individuos de 18 años o más. Se trata de una vacuna antineumocócica diseñada específicamente para ayudar a proteger a los adultos frente a los serotipos que causan la mayoría de los casos de enfermedad neumocócica invasiva (ENI). La aprobación de la vacuna por parte de la CE se basa en datos de seguridad e inmunogenicidad del programa clínico de fase III STRIDE.

Esta decisión autoriza la comercialización de la vacuna en los 27 estados miembros de la Unión Europea (UE), así como en Islandia, Liechtenstein y Noruega. Su disponibilidad en cada país dependerá de varios factores, incluido el cumplimiento de los procedimientos de reembolso. La vacuna fue aprobada en los EE.UU. en junio de 2024, en Canadá en julio de 2024 y en Australia en enero de 2025.

"La enfermedad neumocócica sigue representando un riesgo significativo para los adultos en Europa, especialmente para aquellos de 65 años o más, así como para los adultos más jóvenes que están inmunocomprometidos o padecen enfermedades crónicas", explica Lina Pérez Breva, del Departamento de Investigación de Vacunas en Fisabio – Salud Pública de Valencia. "Basándonos en los datos del programa clínico de fase III STRIDE, la vacuna ofrece cobertura contra los serotipos responsables de la mayoría de los casos de enfermedad invasiva en adultos, lo que convierte esta aprobación en la UE en un paso importante para ayudar a proteger a los adultos de la enfermedad neumocócica".

"Al centrado en los serotipos que han sido responsables de una mayor parte de casos de enfermedad neumocócica invasiva en adultos, esta vacuna nos ayuda a proteger específicamente a los adultos", explica Paula Annunziato, vicepresidenta sénior de enfermedades infecciosas y vacunas, Desarrollo Clínico Global de los Laboratorios de Investigación de MSD. "Estamos orgullosos de ofrecer esta vacuna a los adultos en Europa para que puedan beneficiarse de su amplia protección y estamos entusiasmados por seguir trabajando con las autoridades reguladoras para expandir la disponibilidad de la vacuna a nivel mundial".

La siguiente tabla muestra la cobertura de serotipos responsables de la enfermedad neumocócica invasiva (ENI) en adultos de diferentes países de la UE para Capvaxive (V116):

Cobertura de serotipos responsables de la ENI en países seleccionados de la UE			
País	**Edad**	**Año reportado**	**V116**
Alemania	≥60	2020	~84%
Francia	>65	2022	~85%
Italia	>65	2023	~77%
España	>65	2020	~82%

Los datos incluidos corresponden a países seleccionados según su pertenencia a la UE, el tamaño de su población y el año más reciente disponible.

Estos valores se basan en datos epidemiológicos a nivel nacional, por lo que pueden existir variaciones regionales; no refleja la eficacia de la vacuna.

La decisión de la CE sigue la recomendación positiva del Comité de Medicamentos para Uso Humano (CHMP) de la Agencia Europea de Medicamentos (EMA), emitida en enero de 2025. y se basó en los resultados del ensayo fundamental de fase III STRIDE-3, que evaluó V116 en comparación con PCV20 en adultos mayores de 18 años que no habían recibido previamente una vacuna antineumocócica, y STRIDE-10, que comparó V116 con PPSV23 (vacuna antineumocócica polivalente 23-valente) en adultos de 50 años o más que no hayan recibido previamente una vacuna antineumocócica. La aprobación también se respalda con los resultados de los ensayos fase III STRIDE-4, STRIDE-5 (NCT05526716), STRIDE-6 y STRIDE-7.

Datos clínicos que respaldan la aprobación de la CE

V116 fue aprobado por la CE en base a datos que incluyeron estudios clínicos de Fase III diseñados para evaluar su perfil de seguridad e inmunogenicidad en una variedad de poblaciones adultas. Estos estudios incluyen:

STRIDE-3

Este estudio doble ciego de fase III evaluó V116 en comparación con PCV20 en personas de 18 años o más que no habían recibido previamente una vacuna antineumocócica. Los participantes de 50 años o más fueron asignados a la cohorte 1 (n=2.362) y los participantes de 18 a 49 años a la cohorte 2 (n=300). Los participantes fueron aleatorios para recibir una dosis única de V116 o PCV20. Los resultados del estudio incluyen:

- En personas de 50 años o más (cohorte 1), V116 no fue inferior a PCV20 para los 10 serotipos compartidos por ambas vacunas (3, 6A, 7F, 8, 10A, 11A, 12F, 19A, 22F, 33F), según lo evaluado por los títulos medios geométricos (GMTs, por sus siglas en inglés) de actividad opsonofagocítica (OPA, por sus siglas en inglés) específicos de serotipo al mes de la vacunación.
- V116 fue superior a PCV20 para 10 de los 11 serotipos incluidos en V116 pero no en PCV20 (9N, 15A, 16F, 17F, 20A, 23A, 23B, 24F, 31, 35B), según lo evaluado por los GMTs de OPA específicos de serotipo 1 mes después de la vacunación y las proporciones de pacientes con un aumento mayor o igual a cuatro veces en OPA desde la prevacunación hasta 1 mes después de la vacunación.
- Se observaron respuestas inmunes para el serotipo 15C en los participantes que recibieron V116, pero no cumplieron los criterios de superioridad estadística.
- En personas de 18 a 49 años de edad (cohorte 2), V116 provocó respuestas inmunes no inferiores (inmunopuente) en comparación con personas de 50 a 64 años de edad, según lo evaluado por los GMTs de OPA serotipo-específicos 1 mes después de la vacunación.
- En ambas cohortes, el V116 tenía un perfil de seguridad comparable al PCV20.

STRIDE-10

Este estudio aleatorio, doble ciego, de fase III evaluó V116 en comparación con PPSV23 en personas de 50 años de edad o más que no habían recibido previamente una vacuna conjugada antineumocócica (n=1.484). Los resultados del estudio incluyen:

- V116 no fue inferior a PPSV23 para los 12 serotipos comunes y fue superior a PPSV23 para los nueve serotipos únicos de V116, según lo evaluado por los GMTs de OPA específicos de serotipo 30 días después de la vacunación.
- La proporción de pacientes con un aumento de ≥4 veces en las proporciones de GMT de OPA desde el

día 1 hasta el día 30 para la OPA específica de serotipo para V116 fue superior a PPSV23 para ocho de los nueve serotipos únicos de V116 en comparación con PPSV23.

- V116 mostró un perfil de seguridad comparable al de PPSV23.

STRIDE-4

Este estudio aleatorio, doble ciego, de fase III de consistencia entre lotes evaluó V116 en personas de 18 a 49 años que no habían recibido previamente una vacuna conjugada antineumocócica (n=2.162). Los participantes fueron aleatorizados para recibir una dosis única de uno de los tres lotes de V116 o PPSV23 (vacuna antineumocócica polisacárida 23-valente). Los resultados del estudio incluyen:

- En los tres lotes, V116 generó una respuesta inmune equivalente, según lo evaluado por los GMTs de OPA y las concentraciones medias geométricas (GMCs, por sus siglas en inglés) de Inmunoglobulina G (IgG) 30 días después de la vacunación.
- Los GMT de OPA fueron generalmente comparables entre los lotes combinados de V116 y los grupos de PPSV23 para los serotipos comunes, y fueron más altos en el grupo de V116 para los serotipos únicos de V116.
- V116 mostró un perfil de seguridad equivalente al de PPSV23.

STRIDE-5

Este estudio aleatorio, doble ciego, de fase III, evaluó V116 cuando se administró de forma concomitante o secuencial (30 días después) con la vacuna de gripe cuadrivalente (QIV, por sus siglas en inglés) en adultos de 50 años o más (n=1.080). Los resultados del estudio incluyen:

- Para los criterios de valoración primarios de inmunogenicidad, V116 administrada concomitantemente con QIV no fue inferior a V116 administrada secuencialmente con QIV para 20 de los 21 serotipos de V116 según la evaluación de los GMTs de OPA, así como para tres de las cuatro cepas de gripe de QIV, según lo evaluado por los GMTs de inhibición de la hemaglutinación (HAI, por sus siglas en inglés) al mes de la vacunación).
- Las tasas y la gravedad de las reacciones adversas sistémicas solicitadas y de las reacciones adversas locales solicitadas en el lugar de inyección de V116 fueron similares cuando V116 se administró con o sin QIV inactivada.

STRIDE-6

Este estudio descriptivo aleatorio de fase III evaluó V116 en personas de 50 años o más que habían recibido previamente una vacuna antineumocócica al menos un año antes del reclutamiento. Los participantes se inscribieron en una de las tres cohortes en función de su historial previo de vacunación antineumocócica (cohorte 1: PPSV23 [vacuna antineumocócica polisacárida 23-valente], cohorte 2: PCV13 [vacuna neumocócica conjugada 13-valente], o cohorte 3: PPSV23 seguida o precedida de PCV13, PPSV23 precedida de PCV15 [vacuna antineumocócica conjugada 15-valente], o PCV15 sola). Los participantes de la cohorte 1 fueron aleatorizados para recibir V116 (n=231) o PCV15 (n=119), los participantes de la cohorte 2 fueron aleatorizados para recibir V116 (n=176) o PPSV23 (n=85), y los participantes de la cohorte 3 fueron aleatorizados para recibir V116 (n=106). En cada una de las 3 cohortes, se evaluaron los GMTs de OPA específicos del serotipo y la proporción de personas con un aumento ≥4 veces en las respuestas de OPA desde el inicio hasta 1 mes después de la vacunación. Los resultados del estudio incluyen:

- En la cohorte 1, V116 produjo respuestas de OPA comparables a PCV15 para los 6 serotipos comunes, y más altas para los 15 serotipos únicos y el serotipo 15B.

- En la cohorte 2, V116 produjo respuestas de OPA comparables a PPSV23 para los 12 serotipos comunes y el serotipo 15B, y más altos para los 9 serotipos únicos.
- Las respuestas de OPA a V116 fueron similares en las 3 cohortes de participantes que habían recibido previamente una o más vacunas antineumocócicas.
- V116 tenía un perfil de seguridad comparable al de PCV15 y PPSV23.

STRIDE-7

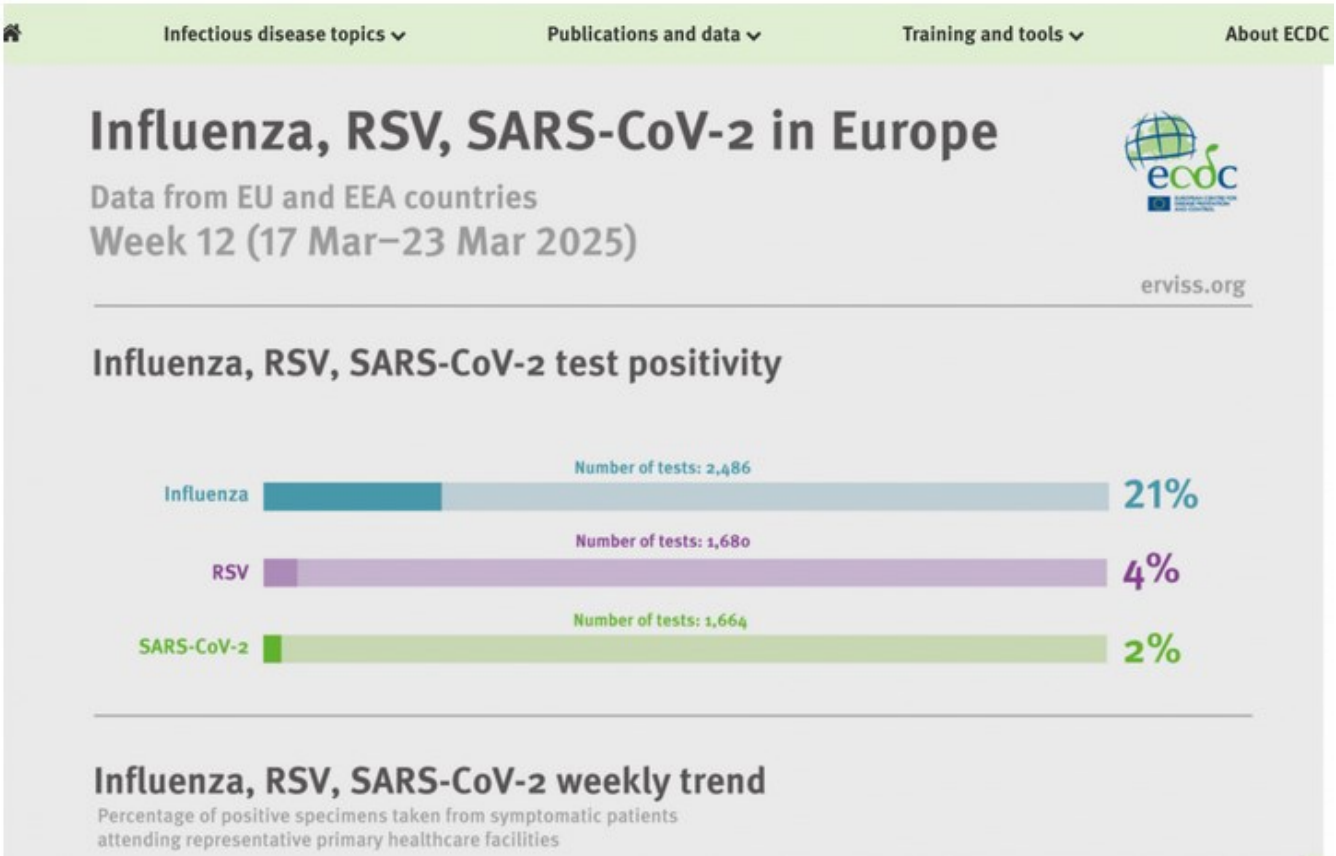
Este estudio doble ciego de fase III evaluó V116 en personas de 18 años o más con el virus de la inmunodeficiencia humana (VIH) (n=304) que no habían recibido vacuna antineumocócica o que tenían experiencia previa con la vacuna antes del estudio. Los participantes fueron aleatorios para recibir V116 o PCV15 + PPSV23. Los resultados del estudio incluyen:

- V116 fue inmunogénica para todos los serotipos cubiertos por la vacuna, según lo evaluado por los GMTs de OPA y las GMCs de IgG 30 días después de la vacunación.
- V116 generó respuestas inmunes comparables a las de PCV15+PPSV23 para los 13 serotipos compartidos y respuestas inmunes más altas para los ocho serotipos cubiertos únicamente por V116, según lo evaluado por los GMTs de OPA específicos de serotipo y las GMCs de IgG a los 30 días.
- Menos participantes experimentaron eventos adversos (EA) con V116 (71,6%) en comparación con PCV15+PPSV23 (91%), principalmente debido a menos EA en el sitio de inyección.

Fuente: El Global Farma. Disponible en https://n9.cl/1s6mj

Europe Approves RSV Vaccine for Most Adults

Apr 2. As the respiratory syncytial virus (RSV) season diminishes in 2025, most European adults are gaining access to an innovative vaccine.



Pfizer Inc. today announced that the European Commission (EC) has issued a decision amending the marketing authorization for ABRYSVO®, the company's bivalent RSV prefusion F vaccine, to extend the indication to include prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 18 through 59 years of age.

This action by the EC expands the previous authorization for individuals aged 60 and older, and ABRYSVO now offers the broadest RSV vaccine indication in the EU.

"We are thrilled that ABRYSVO is now approved in the EU to help prevent RSV in adults aged 18 and older, which causes approximately 158,000 adult hospital admissions annually from RSV disease, a common respiratory virus with symptoms that can be severe or even life-threatening," said Alexandre de Germay, Chief International Commercial Officer, Executive Vice President, Pfizer, in a press release on April 1, 2025.

In Europe, RSV is a common respiratory virus that causes mild, cold-like symptoms. However, in infants under six months of age, people over 65, and people with a compromised immune system, RSV can cause severe illness and death.

According to the ECDC on April 2, 2025, RSV activity peaked in the EU/EEA in week 52, 2024, and has since decreased, but has remained elevated, with considerable variation between countries.

Before visiting Europe, travel clinics and pharmacies in the United States offer RSV vaccination services.

Fuente: VAX BEFORE TRAVEL. Disponible en https://n9.cl/ik8ox

11 needle-free vaccines that could transform global immunisation

Apr 2. Postable, relatively painless, easier to administer than traditional vaccines, microarray patches (MAPs) could transform immunisation in low-income and pandemic settings.

A vaccine patch being applied. Credit: Vaxxas

"Because of these qualities, Gavi and its partners have prioritised MAPs as the number one priority delivery innovation for vaccines, with the potential to increase vaccine coverage and equity in low- and middle-income countries," says Dr Tiziana Scarna, senior manager in innovation and special products at Gavi, the Vaccine Alliance.

However, a major barrier to developing them is a lack of guidance about which vaccine patches would have the greatest health impact in these settings – and would therefore be most attractive to the governments and organisations who purchase them.

To help address this, the Vaccine Innovation Prioritisation Strategy (VIPS) Alliance – a collaborative effort by Gavi, the World Health Organization (WHO), the Gates Foundation, UNICEF and PATH to evaluate, prioritise and drive forward vaccine product innovations – launched a process to identify which vaccine patches hold the greatest potential to boost immunisation coverage in low- and middle-income countries.

"Development of vaccine MAPs will need a substantial investment from vaccine manufacturers – but manufacturers want to be able to apply this technology to multiple vaccines in their portfolio to reduce the cost of this innovation," says Dr Birgitte Giersing, team lead for vaccine prioritisation and platforms at WHO, who

was involved in the research. “This is why this prioritisation exercise is needed; it signals which vaccine MAPs are considered important and helps de-risk investment decisions.”

Their final assessment, published in Vaccine, identifies 11 candidates that would be most relevant to and valuable for immunisation programmes in low- and middle-income countries.

Here’s what we know about these vaccine candidates and the difference that they could make.

Needle-free immunisation

MAPs are small, sticking plaster-like devices studded with hundreds of microscopic projections that deliver vaccine to the top layers of the skin.

Unlike liquid vaccines, which require constant refrigeration to remain effective, and trained professionals to inject and dispose of the syringes, patches are designed to be more stable at room temperature for a few days, easier to transport, and applied to the skin with minimal training.

Removing the need for needles could also remove one key motivation behind vaccine hesitancy.

“For millions of children in remote, hard-to-reach and conflict-affected communities, MAPs could be a game-changer,” says UNICEF vaccine specialist, Dr Jean-Pierre Amorij, who took part in the research. “These vaccine patches could be a more effective way to reach children who would otherwise miss out on life-saving immunization.”

Indeed, “in some cases, such as for measles, MAPs are considered essential to be able to reach global and regional elimination targets – and are likely to be needed more than ever in the current environment of vaccine hesitancy,” said Giersing.

Because of these attributes, microarray patches have been prioritised by the VIPS Alliance as an innovation that could help address immunisation barriers and increase coverage and equitable access to vaccines. Yet, although the technology underpinning them has been in development for several decades, so far only a handful of vaccine patches have entered clinical trials – including candidates against measles, rubella, COVID -19, seasonal influenza and hepatitis B.

One issue is that microarray patches are considered a novel vaccine product with a complex development pathway. They require significant upfront investment, so manufacturers need to know if there will be a market for these products before committing further resources to developing and testing them.

Prioritisation process

In 2021, the VIPS Alliance published a five-year action plan to help accelerate the development of vaccine microarray patches – including a requirement to identify which patches should be considered the highest priority for lower-income settings.

“There isn’t necessarily a case for replacing needle syringes with patches everywhere. But there are specific cases where we think a patch would be advantageous,” says Scarna, who led the research.

“These are generally vaccines that either need very high population coverage to have the greatest public health impact, those that are not only administered through routine [childhood] immunisation schedules but target other segments of the population for which the immunisation platform is not as well-established, or those that need to be delivered outside of health facilities.”

“It is also important that these products are financially sustainable, so we sought to identify vaccines that could potentially have a market in low- and middle-income, or even high-income countries.”

From an initial reference list of 91 vaccine targets, the VIPS Alliance applied various filters to identify those with the greatest applicability to low- and middle-income countries.

They then consulted an external advisory group to assess the potential regulatory pathways, programmatic impact and financial sustainability of these candidates, before arriving at a final shortlist of 11 vaccine patches.

Priority vaccines

The 11 candidates fell into two categories: priority group one included vaccine targets with high potential programmatic impact, financial sustainability or interest from funders. This included vaccines against hepatitis B virus; measles, mumps and rubella viruses; human papillomavirus (HPV); rabies virus, yellow fever; COVID -19; and both seasonal and pandemic influenza viruses.

Priority group two included vaccines against Group B streptococcus (a leading cause of meningitis and bloodstream infections in newborns); Five strains of Meningococcus bacteria (major causes of neurological disease and disability in sub-Saharan Africa); Salmonella Typhi (which causes typhoid fever); and Pneumococcus (the leading cause of severe pneumonia and bacterial meningitis worldwide).

Of these candidates, measles-rubella vaccine patches are at the most advanced stage of development. A Phase 1/2 study conducted in adults and children in The Gambia found that the vaccine patch was safe and well tolerated, while the immune responses it triggered were similar to those of an injected measles-rubella vaccine.

Micron Biomedical, which developed the measles-rubella vaccine patch, is currently scaling up its manufacturing capacity, ahead of further trials.

“We are hoping that this measles-rubella vaccine will be a trailblazer, and once we will have manufacturing proof of concept for this one, the level of interest and investment in other vaccine microarray patches in the pipeline will increase, accelerating their development,” says Scarna.

Other recent clinical trials that have shown promising results include vaccines against influenza, COVID-19 and hepatitis B.

“An influenza vaccine MAP that eliminates the need for constant refrigeration, improves ease of use and increases a person’s immune response to the vaccine could facilitate administering millions of seasonal influenza vaccines globally every year,” says Collrane Frivold, a Technical Officer in the Medical Devices and Health Technologies Program at PATH, who co-authored the VIPS assessment.

“A hepatitis B vaccine MAP that is easy to use and is more stable at room temperature could improve access to birth-dose vaccination for the millions of newborns who are born outside of health facilities each year, while MAPs for influenza or COVID-19 vaccines could simplify delivery to hard-to-reach populations during future outbreaks.”

Fuente: GAVI. Disponible en https://n9.cl/h8ayk

La «enfermedad X» y las vacunas para combatir futuras pandemias, en la Real Academia de Farmacia de Galicia

3 abr. La Real Academia de Farmacia de Galicia ha acogido la ceremonia de ingreso como académica de número de María Eugenia Puentes Colorado, directora hasta hace unos meses de I+D de CZ Vaccine, de la filial Biofabri del Grupo Zendal.

El discurso de ingreso de la especialista en vacunas, “El desarrollo de vacunas ante futuras pandemias: La enfermedad X”, contestado por el académico de número Manuel Puga, tuvo como eje la explicación de la llamada “enfermedad X” como patología nueva causada por un virus, “que representa todo lo que desconocemos, puede (o no) ser mortal o muy contagiosa y puede llegar a ser (o no) una amenaza para

nuestra forma de vida" en palabras de Puentes Colorado. La COVID-19, prosigue la académica, es un perfecto ejemplo de enfermedad X.

Por ello, y dada la experiencia previa en COVID 19 y sus fatales consecuencias, causadas en parte por la falta inicial de vacunas efectivas, la Organización Mundial de la Salud llama a la prioridad estratégica de la comunidad internacional investigadora, clínica, institucional y económica, de "hacer presión en la necesidad de desarrollar herramientas frente a familias enteras de virus, en vez de centrarse en virus específicos".

Entre estas "herramientas" se refirió a las vacunas como algunos de los más potentes y eficientes instrumentos en la lucha para superar las epidemias; y a la conveniencia de "acelerar el camino del desarrollo tradicional de una nueva vacuna, ya que es un proceso largo, costoso, que requiere como media 15 años y no permite responder con rapidez a una emergencia sanitaria".

La lección que aprendimos con la COVID-19

Durante la pandemia los plazos de desarrollo se redujeron de manera extraordinaria en todas las fases, lo que representó un cambio de paradigma en la creación de vacunas, que fue posible gracias al conocimiento previo sobre los coronavirus, la integración de recursos humanos y técnicos, y la concentración de financiación, entre otros factores.

Plan estratégico para el desarrollo de vacunas contra futuras pandemias

La Coalición para Innovaciones en Preparación para Epidemias ha diseñado un plan estratégico, llamado Misión 100 días "*A Moonshot*", cuyo objetivo es revolucionar la respuesta ante pandemias. Este ambicioso plan busca que, en un plazo de 100 días desde la identificación de un brote de un patógeno potencialmente pandémico, se disponga de vacunas seguras y eficaces, con autorización inicial, listas para producirse a gran escala y ser accesibles en todo el mundo, para poder actuar sobre la población más vulnerable y controlar el avance de la epidemia.

Para lograrlo, es fundamental invertir con antelación en la fase pre-pandemia, para desarrollar vacunas prototipo frente a posibles amenazas. Para que esta misión tenga éxito, según explica la académica, es crucial contar con un enfoque y compromiso global, asentado en cinco requisitos científicos y tecnológicos:

1. Desarrollar prototipos vacunales para patógenos representativos de múltiples familias virales en una plataforma tecnológica de rápida respuesta, que pueda ser utilizada bien directamente (si existe suficiente protección cruzada) o ser rápidamente adaptada si un virus emerge.
2. Disponer de capacidades de fabricación de vacunas a nivel mundial.
3. Preparar a nivel mundial infraestructuras listas para la realización de ensayos clínicos y así poder probar simultáneamente múltiples candidatos vacunales y obtener con rapidez resultados de seguridad y eficacia.
4. Identificar biomarcadores tempranos de eficacia que permitan medir la respuesta inmune y la protección inducida por la vacuna con mayor rapidez.
5. Contar con una red global de vigilancia y alerta epidemiológica robusta, integrada bajo el concepto de «Una sola Salud» (*One Health*), que abarque la salud humana, animal y ambiental, permitiendo la detección temprana y la caracterización del brote y del patógeno.

María Eugenia Puentes advirtió, además, que es necesario modificar los procedimientos regulatorios, a menudo marcados por una burocracia lenta y compleja, para facilitar la rápida implementación de esta estrategia global.

Fuente: EL GLOBAL FARMA. Disponible en https://n9.cl/83s6u

GSK, Pfizer resolve RSV patent feud amid vaccine market uncertainty

Apr 4. As the respiratory syncytial virus (RSV) vaccine field grapples with a significantly reduced market size thanks to regulatory uncertainties, GSK and Pfizer have decided to lay to rest their patent feud.

Stock photo/Getty Images

GSK and Pfizer have moved to scrap a patent lawsuit around their respective RSV vaccines, according to a filing in the U.S. District Court in Delaware.

The settlement comes after a U.K. high court in November sided with Pfizer, ruling that two GSK RSV vaccine patents were invalid.

GSK brought the lawsuit to Pfizer in 2023, shortly after the FDA's back-to-back approvals for GSK's RSV shot Arexvy and Pfizer's rival product Abrysvo. The British pharma claimed that the Pfizer vaccine infringed on four of its patents related to the antigen technology used in its shot.

At that time, the emerging RSV vaccine market was billed as a major blockbuster opportunity. And GSK's first-to-market Arexvy lived up to that expectation with $1.5 billion sales in its first year of commercialization.

Things took a drastic turn in mid-2024, when a Centers for Disease Control and Prevention (CDC) advisory committee narrowed its age recommendation for RSV vaccinations. Both GSK and Pfizer felt the pain immediately, with sales of GSK's Arexvy declining 70% year over year in the last three months of 2024 and Pfizer's Abrysvo revenues dropping 62% during the same period.

Moderna's newer entry, mRESVIA, also suffered a muted launch since its May 2024 approval, with merely $15 million in fourth-quarter sales. The disastrous RSV rollout was a significant reason behind Moderna's launch of a $1.5 billion cost-cutting initiative.

While the companies didn't expect the CDC to change its position on RSV vaccines this year, they were at least hopeful that with forthcoming longer-term data, a more favorable policy might emerge. Then vaccine skeptic Robert F. Kennedy Jr. became the new secretary of the Department of Health and Human Services (HHS).

Just a few weeks into his tenure, RFK Jr. has pushed his anti-vaccine agenda on many fronts. A regular meeting of the CDC vaccination committee was postponed days after RFK Jr. took office. Then, an FDA vaccine advisory committee meeting was canceled.

If those weren't clear enough signals that the RFK Jr.-led health department had turned against vaccines, Peter Marks, M.D., Ph.D., the longtime director of the FDA's Center for Biologics Evaluation and Research, was pushed out last week because of a disagreement with the HHS boss on vaccine policy.

Then, word came out that the FDA's principal deputy commissioner, Sara Brenner, M.D., intervened in the review process of Novavax's COVID-19 vaccine candidate and demanded to see more data. The unusual move by a political appointee at the agency led to the FDA missing its deadline to decide on approval for the Novavax shot.

"If you're going to be a biotech company right now, don't be a vaccine company," Leerink Partners analyst Mani Foroohar, M.D., told Fierce Pharma in an interview.

For drugmakers to keep pressing patent litigation, there needs to be a big enough potential financial gain to make the effort worthwhile. In GSK's suit against Pfizer, the British pharma was seeking monetary damages or royalties and potentially a permanent injunction on the commercialization of Pfizer's RSV vaccine in the U.S.

Meanwhile, the two companies still appear to be locked in a patent battle around mRNA COVID vaccine technologies.

Fuente: FIERCE PHARMA. Disponible en https://n9.cl/l9b3sj

Nigeria recibe un millón de vacunas para hacer frente al brote de meningitis en el país

4 abr. Nigeria recibió esta semana más de un millón de vacunas contra la meningitis de la Alianza para las Vacunas GAVI, que le permitirán hacer frente al brote de la enfermedad que ha registrado 807 casos y 74 muertes hasta el momento, informó este viernes la organización.

«La llegada de las vacunas Men5CV es un hito crucial en la respuesta de Nigeria al actual brote de meningitis», dijo en un comunicado Muhammad Ali Pate, ministro nigeriano de Sanidad, al agradecer «el apoyo de GAVI, la Organización Mundial de la Salud (OMS) y Unicef (Fondo de las Naciones Unidas para la Infancia) para hacer posible este rápido despliegue».

La campaña de vacunación se iniciará inicialmente en los estados noroccidentales de Sokoto y Kebbi, dos de las más afectados por el brote, y cubrirá a la población de entre uno y 29 años, el grupo más afectado, detalló GAVI.

«Todos los niños merecen protección contra enfermedades potencialmente mortales como la meningitis y la llegada de la vacuna (…) marca un paso crítico para detener el brote actual y proteger a las poblaciones más vulnerables de Nigeria, particularmente a los niños y los adultos jóvenes», afirmó la representante de Unicef en Nigeria, Cristian Munduate.

La reserva mundial de vacunas financiada por GAVI fue creada en 2021 y es administrada por el Grupo de Coordinación Internacional (ICG, por sus siglas en inglés), que ha autorizado la entrega de más de 1,5 millones de dosis para la respuesta al actual brote de Nigeria, tras la petición hecha en marzo por el país.

El pasado año, Nigeria se convirtió en el primer país del mundo en administrar la nueva y «revolucionaria» vacuna Men5CV contra la meningitis, según informó la OMS en abril de 2024.

La vacuna protege a las personas contra cinco cepas principales de la bacteria meningocócica (A, C, W, Y y X), que causan la enfermedad.

Nigeria se encuentra entre los 26 países hiperendémicos de meningitis de África, un área conocida como el 'Cinturón Africano de Meningitis', de acuerdo con la OMS.

La meningitis está causada por la inflamación de las membranas que rodean el cerebro y la médula espinal y se transmite a través de un estornudo, la saliva o la flema de la nariz y la garganta de las personas infectadas.

Fuente: SWI swissinfo.ch. Disponible en https://n9.cl/09psz

Switzerland binned unused COVID-19 vaccines worth CHF1.3 billion

Apr 6. The Swiss government threw away unused COVID-19 vaccines worth CHF1.3 billion ($1.5 billion), new figures show.

The Federal Finance Administration confirmed the amount to the Keystone-SDA news agency, following an earlier report on the vaccines in the Sonntagszeitung and Le Matin Dimanche newspapers on Sunday.

Only a quarter of the doses purchased by Switzerland have been used, the news reports stated.

Between 2020 and 2023, Switzerland purchased Covid medical supplies worth around CHF2.3 billion. Material worth CHF570 million was used in Switzerland. It also sent vaccines worth CHF270 million abroad as humanitarian aid.

Only a quarter of the doses purchased by Switzerland have been used, according to news reports. Keystone-SDA

This leaves material worth CHF1.45 billion. According to the government accounts, this was "value-adjusted".

The Federal Finance Administration said 90% of the value adjustments relate to vaccines that had to be disposed of after their expiry date. This corresponds to over CHF1.3 billion.

Fuente: SWI swissinfo.ch. Disponible en https://n9.cl/c0gov

Moderna presents research at infectious disease congress

Apr 7. Moderna Inc (BMV:MRNA). (NASDAQ:MRNA) is set to present a series of scientific studies at the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) Global Congress in Vienna, Austria, from April 11-15, 2025. The biotechnology company will highlight its research in various infectious diseases, including COVID-19, influenza, respiratory syncytial virus (RSV), and more.

At the congress, Moderna will deliver three oral presentations and showcase eight posters and one e-poster, focusing on the immunogenicity and safety of their mRNA vaccine candidates. Notable among these is a study on the immunogenicity of mRNA vaccines encoding for JN.1 and KP.2 against SARS-CoV-2 sublineages and another on the clinical evaluation of a SARS-CoV-2 spike receptor-binding and N-terminal domain COVID-19 vaccine.

The company's RSV vaccine candidate, mRNA-1345, will also be discussed, with presentations on its six-month immunogenicity in older adults and the safety and immunogenicity of revaccination at 24 months. Additionally, interim analysis results from a Phase 1/2 trial for an mRNA mpox vaccine candidate will be shared.

Moderna's research extends to other infectious diseases, with presentations on the long-term safety and immunogenicity of a cytomegalovirus (CMV) vaccine, the persistence and safety of mRNA-based influenza vaccines, and the incidence of norovirus in the United States.

The company, known for its role in developing one of the earliest COVID-19 vaccines, utilizes mRNA technology to create therapies and vaccines for a range of diseases, including infectious diseases, immuno-oncology, rare diseases, and autoimmune disorders.

The information presented at the ESCMID congress is based on a press release statement from Moderna and reflects ongoing research efforts to combat infectious diseases through innovative mRNA technology. However, it should be noted that these forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties.

Fuente: Investing.com. Disponible en https://n9.cl/45ov8

Vacunas para todos: fortaleciendo la producción local y las alianzas estratégicas en América Latina

7 abr. En el Día Mundial de la Salud se recuerda también que las inmunizaciones han prevenido 154 millones de muertes. Es trascendental garantizar que el acceso a la salud y a las vacunas se un derecho para todos.

Personal de Salud administra vacunas. Guatemala ha vacunado al 15% de la población meta. (Foto Prensa Libre: EFE)

Este 7 de abril conmemoramos el Día Mundial de la Salud, una fecha que nos recuerda un principio fundamental: la salud es –o debería ser– un derecho universal. Sin embargo, uno de los retos más persistentes en nuestra región sigue siendo garantizar el acceso equitativo a tratamientos y vacunas que salvan vidas.

Durante los últimos 50 años, la inmunización ha prevenido 154 millones de muertes, lo que equivale a seis vidas salvadas por minuto. Este dato, tan contundente como esperanzador, nos lleva a una pregunta urgente: ¿cómo avanzamos hacia un acceso más justo a las vacunas en América Latina?

La respuesta comienza a construirse en los hechos concretos: por primera vez, Pfizer ha anunciado dos acuerdos de localización de producción de vacunas en América Latina en un mismo año. Este avance sin precedentes responde a un conjunto de factores que hoy hacen posible lo que antes parecía lejano: una necesidad médica apremiante, la existencia de fabricantes locales capaces, un ecosistema favorable a la industria, y un enfoque colaborativo entre sectores públicos y privados con una visión de largo plazo.

Este conjunto de condiciones ha sido clave para que recientemente se concretarán dos hitos de localización que marcan un antes y un después en la historia del acceso a vacunas en la región.

El primero se dio en enero, cuando se firmó un acuerdo entre la Organización Panamericana de la Salud (OPS), el Gobierno de Argentina, Pfizer y Sinergium Biotech para la producción local de la vacuna antineumocócica conjugada 20-valente (PCV20). Gracias a esta colaboración, se podrá adelantar el acceso a la vacuna en casi dos años. Además, esta versión mejorada, que protege contra 20 serotipos (en lugar de 13), brinda una mayor cobertura frente a cepas más peligrosas, especialmente en niños.

El segundo acuerdo se anunció con el Instituto Butantan de Brasil, una de las instituciones científicas más

prestigiosas de América Latina. En conjunto, Pfizer y Butantan impulsarán la producción local de una vacuna dirigida contra el virus respiratorio sincitial (VRS), una de las principales causas de bronquiolitis y neumonía en niños, pero también un riesgo considerable para mujeres embarazadas y adultos mayores. Esta colaboración permitirá avanzar hacia la inmunización de estos dos grupos prioritarios y reforzar la salud materna y neonatal en Brasil.

Vacunas para todos: fortaleciendo la producción local y las alianzas estratégicas en América Latina

Este esfuerzo se alinea con los compromisos de la OPS, que ha anunciado que a partir del primer trimestre de 2025 facilitará a los países de las Américas el acceso a la vacuna contra el VRS, la principal causa de hospitalización pediátrica y muerte por infección respiratoria en los primeros seis meses de vida, a precios asequibles. Esta medida tiene un impacto potencial altísimo, ya que cada año, alrededor de 13 millones de niños nacen en la región, quienes podrían beneficiarse si la vacuna se administra a las personas embarazadas.

Para que estas estrategias sean sostenibles, la OPS cuenta con más de 40 años de experiencia en Fondos Rotatorios Regionales, los cuales realizan compras consolidadas de más de 60 biológicos de calidad a precios accesibles, además de adquirir jeringas, equipos de cadena de frío y otros insumos necesarios, fortaleciendo los programas de inmunización en toda la región.

El valor estratégico de la producción de vacunas en la región representa un valor estratégico incuestionable. No se trata únicamente de acelerar los tiempos de distribución o de reducir la dependencia externa: se trata de construir resiliencia sanitaria, acercar la innovación a las comunidades y generar un impacto social de largo plazo.

Porque la vacunación no es un privilegio, es un derecho. Y garantizar el acceso equitativo no es solo una meta técnica: es una expresión de justicia social. Hoy, América Latina avanza hacia un futuro donde la protección contra enfermedades no dependerá de la capacidad económica o de la ubicación geográfica de las personas.

Si América Latina quiere estar mejor preparada para futuras pandemias y emergencias sanitarias, necesita consolidar capacidades regionales de producción de vacunas, mejorar el acceso a la atención materna y establecer marcos regulatorios que permitan respuestas efectivas e inmediatas.

La colaboración entre gobiernos, organismos de salud, industria y sociedad civil sigue siendo el motor de cambio. Este Día Mundial de la Salud, renovemos nuestro compromiso por una región más saludable, más equitativa y resiliente. Con inversiones estratégicas y alianzas de largo plazo, podemos garantizar que todas las personas, desde los recién nacidos hasta los adultos mayores, accedan a servicios esenciales y vivan con dignidad.

Fuente: Forbes Centroamérica. Disponible en https://n9.cl/3hxd4

Tackling Africa's vaccine supply and demand puzzle

Apr 7. The African Union has embarked on one of its most audacious health security missions: Ensuring that the continent manufactures 60% of its own vaccines by 2040. Africa currently manufactures a lowly 1% of the vaccines. However, since April 2021, when the AU tasked the Africa Centres for Disease Control and Prevention (Africa CDC) to initiate a structure, technocrats have been busy pushing the dream. In the last of our four-part series, The Independent's Ronald Musoke looks at mechanisms that are being advanced to tackle the continent's vaccine supply and demand challenges.

At the second 'Vaccine and Other Health Products Manufacturing Forum' held on Feb.4-6 in Cairo, Egypt, Dr Hisham Stait, the head of the Egyptian Unified Procurement Authority gave a rousing update on Africa's ever-growing commitment to self-sufficiency in manufacturing of vaccines. "The target is not just a strategic ambition but a reflection of our sheer determination to create a resilient healthcare system," he said.

Dr Stait referenced the African Union's vision of producing 60% of Africa's vaccine needs locally by 2040. "The journey toward self-sufficiency in vaccine and health products manufacturing is no longer a vision – it is a necessity inspired by the experience gained from the COVID-19 pandemic," he said.

Egypt continues to lead in the transformation of vaccine production and procurement patterns on the continent. The North African country possesses nearly 20% of Africa's vaccine manufacturing capacity and plans to produce 380 million doses annually in the next five years.

Dr Stait highlighted the unprecedented funding commitments made to support Africa's health products manufacturing sector, including over US$5.5 billion in pledged investments. These commitments, he said, reflect global confidence in Africa's capacity to produce high-quality health products, including vaccines.

The Cairo forum amplified the ongoing debate of the African Union's stance of ramping-up of in-continent health products manufacturing, including vaccines. It noted how Africa continues to suffer outbreaks of Ebola, Mpox, cholera, Marburg, measles, and many others and carries a high burden of infectious diseases with millions of people continuing to suffer from ancient diseases such as tuberculosis, malaria and many others, each year.

According to a recent report by the Tony Blair Institute at the University of Oxford in the U.K, at least 10 million global deaths per year are attributable to diseases with existing or forthcoming adult vaccines and preventative injectable therapies.

The report shows that addressing these could offer more than US$ 3.4 trillion in value for the global economy, including US$1 trillion for developing countries and more than US$ 7 trillion in a pandemic scenario.

Reversing the trend

According to the World Economic Forum, the African market for vaccines and medicines is valued at over US$ 50 billion annually, yet the continent imports most of the healthcare products that it consumes. That includes 99% of vaccines.

At the Cairo Forum, Wamkele Mene, the Secretary-General of the African Continental Free Trade Area (AfCFTA), said Africa must reverse this trend. "This meeting provides an opportunity to refine our strategy, our plan, and our vision for regional manufacturing of essential health products in Africa, particularly in light of policy documents that support our goal of producing 60% of Africa's vaccines by 2040," said Mene.

However, there is also debate of how best the continent should ensure that investments being made don't go to waste with white elephant projects littering the continent. There have also been arguments about whether ongoing investments in vaccine manufacturing plants around the continent are being done cognizant of existing market dynamics.

Expanding vaccine market

According to a brief by the Clinton Health Access Initiative (CHAI), an expanding global market for vaccines – with significant growth forecast for the African continent– means that there is potential to grow a thriving

vaccine industry on the continent. The global non-profit that operates at the intersection between government, business and health, says the African routine vaccine market demand is, for instance, estimated to be worth US$ 1.3 billion annually.

Meanwhile, forecasts based on modelling undertaken by the non-profit show the potential for expansion of the African vaccine market across all existing and projected novel products to be somewhere between US$ 2.8 billion and US$ 5.6 billion within the next 15 years. In terms of the demand for vaccine doses, forecasts also suggest a growth of between 60% and 100%, from a baseline level of 1.3 billion doses in 2020.

Gavi's role in procuring vaccines

Gavi, the Global Vaccine Alliance, is currently the largest single buyer of vaccines for use in Africa, with the vaccine alliance accounting for about half of the total market by value in 2020 and about one-third by volume.

Two decades of active market shaping by Gavi has seen expansion to long-term healthy market objectives, including fostering diversification, supply security, healthier demand and innovation.

This has resulted into an increase in the number of manufacturers supplying pre-qualified Gavi-supported vaccines, from five in 2001 to 18 in 2021 (with more than half based in Africa, Asia and Latin America). Prices for the most common vaccines for lower-income countries, already at a significant discount, have continued to decline.

Gavi has worked with the private sector to create favourable market conditions for the pharmaceutical industry to offer vaccines to lower-income countries at lower prices. This has been done by aggregating, pooling and financing demand to enable a layered or tiered pricing, whereby low-income countries are charged less than higher-income countries for the same or similar products. This has meant that lower-income countries such as Uganda now pay less for their routine vaccines than high-income countries.

Much of the remaining "non-Gavi" market share is accounted for by other pooled procurement, with alliance partner, UNICEF, responsible for managing perhaps as much as 90% of vaccine procurement in Africa by volume.

However, the proportion of vaccine doses consumed in Africa that are Gavi-supported is projected to fall significantly by 2040, largely as a result of countries transitioning from Gavi support to self-financing a greater proportion of their vaccine spend.

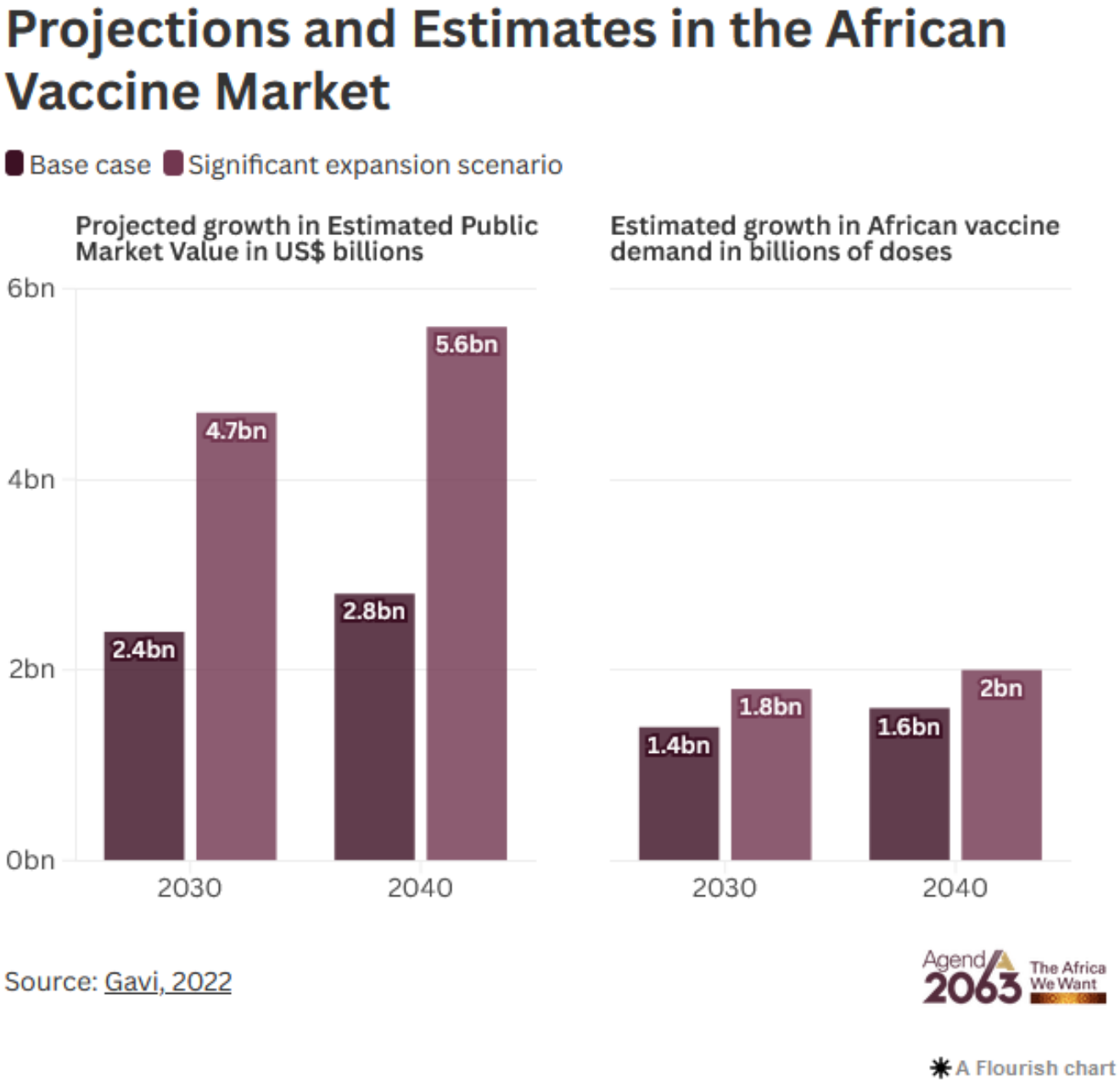
Experts at CHAI note that as unsubsidised demand becomes increasingly dominant, continued downward price-pressure will be critical if high levels of access are to be maintained across the continent.

This shows a critical role for all those involved, including the African Union, in shaping markets to ensure existing low-cost manufacturers remain viable, while at the same time, encouraging low-cost models of production on the African continent, notes the CHAI brief.

"We are very supportive of a vibrant, sustainable commercial vaccine sector on the continent. Africa's aspirations for self-sufficiency in vaccine manufacturing can only be achieved with African leadership, full commitment, and stronger capacity on the continent," Dr Sania Nishtar, the Chief Executive Officer of Gavi, said during the Cairo forum.

Dr Nishtar said it will take a multi-sectoral effort, with governments creating the right policy environment for manufacturers and investors to ensure the success of local vaccine manufacturing. She emphasised that

governments must build the necessary capacity at the regulatory level, develop human resources, secure raw materials, sustain manufacturing and create appropriate demand in Africa. “When the next pandemic happens, we must make sure we are not at the end of the queue,” she said.



The Gavi model has country choice at its core, with African countries exercising product choice over approximately 700 million doses of vaccines worth about US$1 billion by 2030. Working closely with the African Union and implementing countries, it will be possible to send clearer demand signals to the market around the willingness of actors to select and procure from African suppliers.

Experts at CHAI say collective action could help provide an important signal of future demand to new manufacturers, while still being consistent with Gavi’s operating model and the principle of country choice. The experts say African countries themselves could, for example, provide new continental suppliers with increased demand assurances over the vaccines they intend to select through Gavi. “This would represent a significant volume of doses per year over the next 20 years.”

Fuente: The Independent. Disponible en https://n9.cl/yrsse

Costa de Marfil: La Alianza Gavi apoya la mayor campaña de vacunación contra el virus del papiloma humano

7 abr. Gavi, la Alianza para las Vacunas, en colaboración con el Gobierno de Côte d'Ivoire, apoya el lanzamiento de la mayor campaña de vacunación contra el virus del papiloma humano (VPH) realizada hasta la fecha en el país. La campaña, que se desarrollará del 7 al 13 de abril, se dirigirá a 3,5 millones de niñas de entre 10 y 18 años, tanto escolarizadas como no escolarizadas, y estará dedicada a todas aquellas que no han recibido la vacuna, incluso durante la pandemia de Covid-19. Así lo informa Gavi en un comunicado de prensa. Cada año, 348 mujeres en todo el mundo pierden la vida trágicamente debido al VPH: el 90 por ciento de estas muertes ocurren en países de África y Asia. En 2019, Côte d'Ivoire dio un paso importante para revertir esta tendencia al introducir la vacuna contra el VPH en todo el país a través de su programa de inmunización sistemática, poniéndola a disposición de las niñas de forma gratuita por primera vez. La cobertura de vacunación ha aumentado de forma constante desde entonces, y la campaña de hoy ayudará a acercar al país a un futuro en el que el cáncer de cuello uterino ya no sea una amenaza. Con 17 muertes futuras evitadas por cada XNUMX niñas vacunadas en los países donde trabaja Gavi, la vacuna contra el VPH tiene el potencial de transformar la lucha contra esta enfermedad mortal. Costa de Marfil y Gavi compartirán los costos del suministro de vacunas y la logística operativa, de acuerdo con el innovador modelo de cofinanciación de Gavi, que ayuda a los países a financiar progresivamente una parte mayor de sus programas de vacunación hasta que sean totalmente autofinanciados.

De cara al futuro, entre 2026 y 2030, Gavi se propone ampliar la protección vital a otros 120 millones de niñas, salvando potencialmente 1,5 millones de vidas y transformando las perspectivas sociales, sanitarias y económicas de las mujeres jóvenes a nivel mundial. Sin embargo, para hacer realidad esta visión y proteger el progreso alcanzado hasta ahora, Gavi debe asegurar la financiación necesaria para su próximo período estratégico de cinco años, que comienza en 2026. El director regional de Gavi para África occidental y central, Marthe Sylvie Essengue EloumaComentó sobre este hito: "Para las jóvenes de Costa de Marfil, recibir la vacuna contra el VPH esta semana representa una oportunidad para protegerse de una enfermedad mortal, llevar una vida más sana, continuar su educación y alcanzar sus sueños sin la amenaza inminente del cáncer de cuello uterino. Cada dos minutos, una mujer muere de cáncer de cuello uterino, y esta semana, más de tres millones de niñas recibirán la herramienta más poderosa para prevenir esta tragedia. Felicitaciones al Gobierno de Costa de Marfil por liderar esta iniciativa vital. La urgencia de la vacunación contra el VPH es crucial, especialmente porque las niñas de las comunidades más vulnerables son las que más sufren. Con vacunas seguras y eficaces disponibles, esfuerzos como este son cruciales para proteger vidas y permitir que las jóvenes contribuyan con éxito a sus comunidades, pero solo son posibles con una financiación sostenida para la inmunización", concluyó.

Fuente: Agenzia Nova News. Disponible en https://n9.cl/ysj3e

COVID-19 vaccination induces long-lasting antibody B-cell responses, researchers find

Apr 8. Three doses of COVID-19 mRNA vaccination induce long-lasting antibody and memory B-cell responses, according to a study of 113 health care workers in Catalonia who were followed for three years. The study, led by ISGlobal in collaboration with the Fundación Privada Daniel Bravo Andreu (FPDBA) and published in Cell Reports, also shows that exposure to the virus prior to vaccination differentially imprints the immune systems without compromising the quality of the antibody response.

Memory B cells are essential for maintaining a long-term immune response: they rapidly proliferate upon antigen reencounter and differentiate into antibody secreting cells. "There is the belief that vaccine-induced antibodies to SARS-CoV-2 decay rather rapidly, but recent evidence suggests that they remain quite stable over time," says Gemma Moncunill, senior co-author of the study, together with ISGlobal colleague Carlota Dobaño.

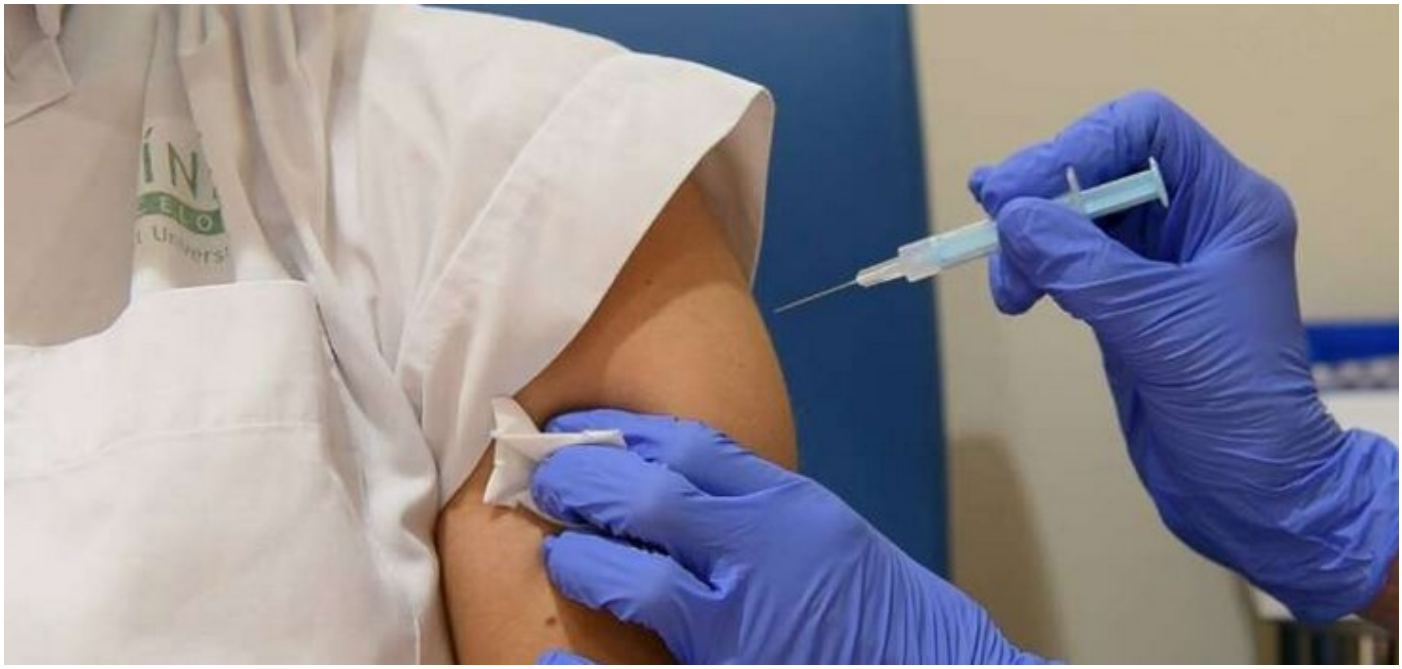
As part of the European END-VOC project, the research team evaluated the durability and quality of SARS-CoV-2 antibody and memory B-cell responses in 113 individuals from a cohort of health care workers (COVIDCatCentral) who were followed over 3 years since the start of the pandemic.

Durable B-cell responses

The findings reveal that individuals -whether or not they had been infected by SARS-CoV-2 before their first vaccine dose- developed comparable antibody and memory B-cell responses nearly a year and a half after completing a three-dose mRNA vaccination.

"Over time, we saw a progressive increase in the proportion of memory B cells recognizing the receptor-binding domain (RBD) of the Spike protein, pointing to their continuous selection upon exposure to evolving variants," says Luis Molinos-Albert, first author of the study.

Notably, these RBD-reactive B cells were associated with lower breakthrough infections in individuals who had not been infected before vaccination. Meanwhile, individuals who had been exposed to the virus prior to vaccination developed an atypical subset of memory B cells that remained stable over time.



"This is probably due to the different environment generated by primary mRNA vaccination as compared with viral infection," says Dobaño, "but we still do not know whether this subset is detrimental or beneficial," she adds.

Overall, the study findings show that both groups (previously exposed or not exposed) could develop efficient memory responses, but that having been infected first leaves a distinct imprint on the immune system. "Our data highlight the durability of SARS-CoV-2 immune responses, but they also suggest that updated vaccines to target new variants could further enhance immunity, especially in those previously infected," concludes Moncunill.

Switch to IgG4 antibodies upon repeated vaccination

In a related study published in the Journal of Infection using the same cohort, the research team found an increase in a certain subclass of virus-specific antibodies known as IgG4 after three mRNA doses.

Vaccinated people with the highest levels of IgG4 and IgG2 antibodies, which have a lower capacity to neutralize the virus and activate other immune functions, had a higher risk of breakthrough infections.

Fuente: Medical Xpress. Disponible en https://n9.cl/ecads

Will SK Bioscience be ranked as a leader in the global vaccine industry this year?

Apr 8. The company is conducting global phase 3 clinical trials of the 21-valent pneumococcal protein conjugation vaccine "GBP410" and is simultaneously pursuing improvements in the performance of IDT Biologika, a German biopharmaceutical development and production (CDMO) company acquired last year. The industry predicts that if these two projects are successfully completed, they will be able to become global pharmaceutical companies.

A bird's-eye view and expected image of SK Bioscience Songdo Global R&PD Center, which is scheduled to be completed at the end of this year. SK Bioscience

"GBP410" is being developed in collaboration with Sanofi and has recently been approved by the U.S. Food and Drug Administration (FDA) for a phase 3 clinical trial plan (IND) and is conducting clinical trials in the U.S., Europe, and Asia for about 7,700 infants, children, and adolescents aged 6 weeks or older. Previously, it demonstrated an immunogenicity equivalent to that of the control vaccine (Privena 13) in phase 2 clinical trials. In particular, no serious abnormal cases have been reported, so safety has been secured. This global phase 3 clinical trial is actually the last gateway to the global market launch and will be conducted by comparing immunogenicity and safety with existing licensed vaccines.

GBP410 is a multivalent vaccine that expands the scope of prevention, including more serotypes than conventional vaccines, and the medical community is counting on the effectiveness of preventing pneumococcal infections in infants and adolescents.

An industry official said, "We know that we have secured positive data so far," adding, "Development is

actually only a matter of time," based on the average probability of success in phase 3 clinical trials in vaccine development exceeding 80%. According to Grand View Research, a global market research firm, the global pneumococcal vaccine market is expected to grow at an annual average of 5.6% from about $7.5 billion (11.137 trillion won) in 2023, reaching $11 billion by 2030.

For this reason, global companies, including Pfizer and MSD (Merck), which divide the pneumococcal market, are paying attention to the success and commercialization of SK Bioscience's global phase 3 clinical trials.

SK Bioscience is working hard to strengthen the global production capacity of Germany's IDT Biologica, which was incorporated into a family last year. IDT Biologica, headquartered in Desauroslau, close to the German capital Berlin, has specialized in the production of virus-based vaccines and gene therapy drugs since its inception in 1921, with advanced production facilities approved by the U.S. FDA and the European Medicines Agency (EMA).

In particular, SK Bioscience expects to secure a base for mass production of various vaccines, including GBP410, and speed up the establishment of a global supply chain, as it has been evaluated to have built trust by collaborating with global pharmaceutical companies.

Currently, IDT Biologica is expanding its position in the global CDMO market by expanding new customers, securing additional supplies from existing customers, and building synergy with SK Group. SK Bioscience predicted that IDT BioLogica will be able to turn into a surplus early this year by normalizing its management and improving its performance.

SK Bioscience is also actively seeking to secure next-generation vaccine technology. The Japanese encephalitis vaccine candidate 'GBP560' is being developed using mRNA technology and is currently in phase 1 and 2 of global clinical trials. By securing mRNA platform technology, the plan is to establish a system that can quickly respond to new infectious diseases in the future and to preempt competitive advantage in the global vaccine market.

A company official emphasized, "Based on the development of GBP410 and the improvement of IDT Biologica's performance, we will solidify our global market position and lead to continued growth and sales expansion in the future."

Fuente: Maeil Business Newpaper(MK). Disponible en https://n9.cl/ssddi

Cost-Effectiveness of PCV15, 20 Vaccines Expected to Decrease

Apr 10. The cost-effectiveness of pneumococcal conjugate vaccine 15-valent and 20-valent (PCV15 and PCV20) is expected to decrease as adults receive herd immunity from childhood vaccination programs, according to a study published in *Expert Review of Vaccines*. While PCV15 and PCV20 were found to decrease disease incidence and mortality, when used with or without PCV23, these vaccines were likely not cost-effective.

"*Streptococcus pneumoniae* (pneumococcus) is a gram-positive bacterium with 100 known serotypes that causes a wide spectrum of diseases, manifesting either as invasive pneumococcal disease (IPD; e.g. meningitis, bacteremia) or non-invasive disease," wrote authors of the study. "The pathogen remains the leading cause of morbidity and mortality worldwide, including Canada, particularly affecting young children and adults aged ≥65 years. In Ontario, 42% of IPD cases in 2019 were among older adults and 87% of these cases were hospitalized."

In Ontario, where the study was conducted, age- and risk-based guidelines have been offered to help steer pneumococcal vaccination programs. However, pneumococcal disease burden and mortality in Canada continues to be significantly high. Not only are disease-causing serotypes increasing but so is the economic burden of pneumococcal disease.

"The health and economic burden of pneumococcal disease could further increase in the future, not only because of the progressively aging population but also due to the rapid spread of resistant *S. pneumoniae* strains," they continued.1 "Between 2014 and 2018, the proportion of vaccine-preventable (PCV13) multi-drug-resistant (MDR) invasive *S. pneumoniae* infections in Canada increased by 25% (from 9.2% to 11.5%)."

With new PCV combinations releasing on a persistent basis, the 2 newest vaccines that have been approved in Canada were the PCV15 and PCV20 formulas. As these new modes of vaccination have shown the ability to improve both disease burden and mortality, researchers wanted to better understand the economical trade-offs of older adults receiving these vaccines.

PCV15 and 20 could help to address important public health needs by providing broader coverage for serotypes associated with a substantial proportion of pneumococcal diseases. "The National Advisory Committee on Immunization (NACI) in Canada has recommended a single dose of PCV20 for all older adults, with the option of using PCV15 plus [23-valent pneumococcal polysaccharide vaccine] (PPV23) if PCV20 is unavailable and Ontario Immunization Advisory Committee has adopted this recommendation," they wrote. "We conducted a model-based economic evaluation to assess the cost-effectiveness of various pneumococcal vaccination strategies for older adults in Ontario."

Researchers explored pneumococcal vaccines in 5 different forms: (1) PCV15 alone, (2) PCV20 alone, (3) PCV15 in series with PPV23, (4) PCV20 in series with PPV23, and (5) PPV23 alone. They created a microsimulation model that would place patients 65 and older throughout a variety of health states for 1 full year. Those states included "healthy," sequelae due to [pneumococcus] infection, and death.

"We conducted a cost-utility analysis using an individual-level state transition model to compare one dose of PCV (alone or in series with PPV23) with PPV23 only," stated the authors. "We estimated incremental cost-effectiveness ratios (ICERs) expressed in costs per quality-adjusted life year (QALY) from the health care payer perspective, discounted at 1.5% annually."

Overall, when PCV 15 and PCV20 were separated, both vaccines were more effective than the current PPV23 vaccination program in Ontario. "Use of PCV15 alone resulted in a decrease of 36 IPD episodes and 15 deaths over the lifetime of 100,000 individuals when compared to PPV23-only. Likewise, use of PCV20 alone instead of PPV23 could prevent 46 IPD episodes and 18 deaths," they continued.

However, vaccinating older adults with PCV15 or PCV20 only reduced disease burden and mortality at a higher cost than the currently accepted immunization program in Ontario. Moreover, they found similar reductions in cost-effectiveness when PCV15 and PCV20 were used in conjunction with PPV23.

"Our study found that PCV15/20 vaccines (alone or in series with PPV23) may become less economically attractive for older adults in the long-term when considering their potential use in childhood vaccination programs and associated indirect (herd immunity) effects, which is consistent with results of the Public Health Agency of Canada modeling study and the systematic review," added the authors. "Similarly, other studies

generally reported higher ICERs when indirect effects were considered. This demonstrates the need to consider comprehensive pneumococcal vaccination program options across age and risk groups when developing recommendations."

With newly manufactured pneumococcal vaccines appearing regularly, the available options for patients may cause complexities in their perceptions of cost-effectiveness, disease outcomes, and mortality. However, the development of new vaccines may translate to better uptake and decreased pneumococcal disease burden, as childhood disease burden declined upon US acceptance of PCVs in 2000.

But as herd immunity is expected to protect adults later in their lives, the use of these vaccines may decrease in cost-effectiveness, highlighting the importance of consistently updating PCV evidence and providing education through literature and clinical studies.

"Vaccinating older adults with PCV15/20 likely reduces burden of pneumococcal disease and would be cost-effective initially but is expected to be less economically attractive in the longer term when herd immunity benefits from childhood vaccination programs are considered," concluded authors of the study.

Fuente: Drug Topics. Disponible en https://n9.cl/zfu6f

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Patentes registradas en Patentscope

Estrategia de búqueda: (Vaccine) AND DP:([01.04.2025 TO 10.04.2025]) *as the publication date 33 records.*

1.WO/2025/072259COADMINISTRATION OF TETRAVALENT DENGUE VACCINE WITH HPV VACCINE

WO - 03.04.2025

Clasificación Internacional A61K 39/12Nº de solicitud PCT/US2024/048306Solicitante TAKEDA VACCINES, INC.Inventor/a LEFEVRE, Inge

The invention relates to a HPV vaccine composition and a dengue vaccine composition for use in a method of preventing an HPV-associated disease and dengue disease in a subject or in a subject population, the method comprising concomitantly administering the HPV vaccine composition and the dengue vaccine composition, wherein the dengue vaccine composition is a tetravalent dengue composition comprising live, attenuated DENV-1, DENV-2, DENV-3 and DENV-4 strains and wherein the method provides combined vaccine efficacy against all four serotypes of the dengue virus and non-inferiority of the immune respone to the HPV vaccine composition compared to a mono-administratrion of the HPV vaccine composition.

2.WO/2025/067162DENDRITIC CELL VACCINE FOR CLEAR CELL RENAL CELL CARCINOMA AND USE THEREOF AND PREPARATION METHOD THEREFOR

WO - 03.04.2025

Clasificación Internacional A61K 39/00Nº de solicitud PCT/CN2024/120744Solicitante KOUSAI (SHANGHAI) BIO CO., LTD.Inventor/a LIU, Helen

The present invention relates to the technical field of cellular immunology. Provided are a dendritic cell vaccine for clear cell renal cell carcinoma and the use thereof and a preparation method therefor. The dendritic cell vaccine comprises a vaccine obtained by means of co-culturing an OS-RC-2 whole cell lysate with a dendritic cell. The dendritic cell vaccine is used in the preparation of a drug for treating clear cell renal cell carcinoma. The method for preparing the dendritic cell vaccine comprises: the induction of an immature dendritic cell (imDC): transferring a $CD14^+$ cell solution into a well plate, adding human recombinant GM-CSF into a six-well plate, and adding human recombinant IL-4 to induce and prepare the immature dendritic cell; and the induction of a mature dendritic cell: co-culturing an OS-RC-2 whole cell lysate with the imDC of the above-described step, adding TNF-α, LPS and Poly(I:C) to stimulate the maturation of the immature dendritic cell, thereby preparing a dendritic cell vaccine. The use of the OS-RC-2 whole cell lysate as an antigen to prepare a DC vaccine can effectively activate T cells and other immune cells, and enhance antigen presentation and T-cell activation, thereby promoting immune-mediated killing of tumors.

3.WO/2025/074921VIRUS PRODUCTION METHOD

WO - 10.04.2025

Clasificación Internacional C12N 7/00Nº de solicitud PCT/JP2024/034139Solicitante KYOTO BIKEN LABORATORIES, INC.Inventor/a IGARASHI Tatsuhiko

The present invention relates to: a virus production method comprising a step for mixing a virus-infected cell and a non-infected cell and co-culturing the same to proliferate a virus; a virus strain for vaccination characterized by having 0.6 times or more of the expression level of the membrane surface glycoprotein gp51 as compared with the expression level of the capsid protein p24; and a vaccine composition characterized by comprising the vaccine virus strain that has been inactivated.

4.WO/2025/076477STAPHYLOCOCCUS AUREUS VACCINE COMPOSITIONS

WO - 10.04.2025

Clasificación Internacional A61K 39/085Nº de solicitud PCT/US2024/050130Solicitante THE REGENTS OF THE UNIVERSITY OF CALIFORNIAInventor/a HAJAM, Irshad Ahmed

Provided herein, inter alia, are vaccine compositions including a non-toxin Staphylococcus aureus antigen and an IL-17 activating adjuvant. The vaccine compositions are contemplated to induce a potent immune response against Staphylococcus aureus.

5.WO/2025/073055VACCINE DELIVERY METHOD AND COMPOSITION FOR USE THEREOF

WO - 10.04.2025

Clasificación Internacional A61K 39/00Nº de solicitud PCT/CA2024/051320Solicitante NANOVATION THERAPEUTICS INC.Inventor/a PAWAR, Grishma

Provided is a method for inducing an immune response in a subject to treat or prevent a disease or disorder, the method comprising administering a vaccine comprising a lipid nanoparticle encapsulating nucleic acid encoding an antigenic protein, peptide or fragment thereof, a neutral lipid content of from 30 mol% to 70 mol%, a sterol or derivative thereof and an ionizable cationic amino lipid at between 5 and 50 mol%, and a hydrophilic polymer-lipid conjugate that is present at a lipid content of 0 mol% to 5 mol%, wherein the administering of the lipid nanoparticle results in the immune response against the antigenic protein, peptide or fragment thereof expressed by the mRNA in the subject, wherein each mol% is measured relative to a total lipid content of the lipid nanoparticle. The disclosure further provides vaccine compositions and use of such compositions to induce an immune response in a subject.

6.WO/2025/073910A VACCINE FOR PROTECTING A PIGLET AGAINST AFRICAN SWINE FEVER

WO - 10.04.2025

Clasificación Internacional A61K 39/12Nº de solicitud PCT/EP2024/077968Solicitante INTERVET INTERNATIONAL B.V.Inventor/a JOSHI, Jui

The invention pertains to a live attenuated African swine fever virus Georgia 2007 (ASFV-G) Δ9GL/ΔUK strain for use in a vaccine for protecting a piglet against an infection with African swine fever virus (ASFV) by administering the vaccine comprising the live attenuated ASFV-G-Δ9GL/ΔUK strain to a pregnant swine the piglet being part of the progeny of the pregnant swine.

7.WO/2025/073874VACCINE COMPOSITION COMPRISING M2E NANOPARTICLES AND HA1 PROTEIN

WO - 10.04.2025

Clasificación Internacional A61K 39/145Nº de solicitud PCT/EP2024/077908Solicitante INSTITUT NATIONAL DE RECHERCHE POUR L'AGRICULTURE, L'ALIMENTATION ET L'ENVIRONNEMENTInventor/a CHEVALIER, Christophe

The present invenon relates to a vaccine against influenza A viruses, said vaccine comprising HA protein and nanostructures bearing M2e, and its use for vaccinaon against avian influenza, especially in the veterinary field.

8.WO/2025/067013ANTI-SARS-COV-2 VIRUS PROTEIN OR MRNA VACCINE, PREPARATION METHOD THEREFOR, AND USE THEREOF

WO - 03.04.2025

Clasificación Internacional C07K 14/165Nº de solicitud PCT/CN2024/119716Solicitante SHANGHAI RNACURE BIOPHARMA CO., LTD.Inventor/a LIN, Jinzhong

An anti-SARS-CoV-2 virus protein or mRNA vaccine, a preparation method therefor, and a use thereof. The protein has one or more amino acid residues added, deleted, or replaced in the amino acid sequence as shown in SEQ ID NO: 18. The nucleic acid encodes an S protein mutant. Preclinical animal test data shows that the mRNA vaccine has a good protective effect for the current variants of concern (VOC) of the SARS-CoV-2 virus and has broad clinical application prospects.

9.20250108101NON-ONCOLYTIC VIRUS INFECTED DEAD CANCER CELL VACCINE

US - 03.04.2025

Clasificación Internacional A61K 39/00Nº de solicitud 18905433Solicitante Queen's University at KingstonInventor/a Kyle Seaver

A composition includes at least one tumour antigen comprising dead infected tumour cells that were infected and incubated with a non-oncolytic virus prior to cell death and a pharmaceutically acceptable vehicle. The at least one tumour antigen may be a tumour associated antigen (TAA), at least one tumour specific antigen (TSA), or a combination thereof. The composition may be used as a cancer vaccine, a prophylactic cancer vaccine, or as a therapeutic cancer treatment, wherein the composition prevents, inhibits, or slows tumour development.

10.20250108108HYBRID FLU-CORONAVIRUS VACCINE

US - 03.04.2025

Clasificación Internacional A61K 39/215Nº de solicitud 18974619Solicitante THE REGENTS OF THE UNIVERSITY OF CALIFORNIAInventor/a Lbachir BenMohamed

A hybrid vaccine composition that prevents infection or reinfection by both influenza and coronaviruses, comprising at least a portion of a Coronavirus spike(S) protein and at least a portion of at least one influenza hemagglutinin (HA) protein. The portion of the coronavirus spike(S) protein is highly conserved among human and animal coronaviruses. The vaccine composition may comprise a Coronavirus protein comprising either: a structural protein, e.g., a Spike protein, a Nucleocapsid protein, or a combination thereof, or a non-structural protein, e.g., NSP2, NSP3, NSP14, or combination thereof; and at least a portion of at least one influenza hemagglutinin (HA) protein.

11.WO/2025/076013ENGINEERED MIDDLE EAST RESPIRATORY SYNDROME PROTEINS AND RELATED METHODS

WO - 10.04.2025

Clasificación Internacional A61K 39/12Nº de solicitud PCT/US2024/049494Solicitante VACCINE COMPANY, INC.Inventor/a WEIDENBACHER, Payton Anders-Benner

Disclosed herein are engineered Middle East Respiratory Syndrome (MERS) spike proteins and nucleic acids encoding the same. Also disclosed are fusion proteins comprising an engineered Middle East Respiratory Syndrome (MERS) spike protein and a binding partner, and nucleic acids encoding the same. Also disclosed are vaccine compositions comprising any of the aforementioned proteins or nucleic acids. Disclosed are methods of preventing a MERS infection or a disease associated with a MERS infection in a subject comprising administering to the subject an effect amount of said vaccine compositions.

12.WO/2025/076466PIV5-BASED VACCINES WITH MODIFIED ANTIGEN: METHODS OF MAKING AND USING THE SAME

WO - 10.04.2025

Clasificación Internacional A61K 39/155Nº de solicitud PCT/US2024/050117Solicitante CYANVAC LLCInventor/a GINGERICH, Maria, Cristina

The present invention is directed to a recombinant vaccine comprising a PIV5-based viral expression vector having a gene inset and methods of producing and using the same. The recombinant vaccine includes a modified bacterial or viral antigen to enhance the expression of the Antigen on the Surface of cells (AOS) resulting in an increase in the immunogenicity to the antigen.

13.20250108106NANOENCAPSULATED PHARMACEUTICAL COMPOSITION AND USE THEREOF

US - 03.04.2025

Clasificación Internacional A61K 39/215Nº de solicitud 18829855Solicitante Fulgent Genetics, Inc.Inventor/a Lu Lu

This disclosure is directed to a pharmaceutical composition for treating or preventing a disease. The pharmaceutical composition can comprise a polymer-drug nanoaggregate having a polymer and at least one bioactive agent that can comprise STING polypeptide, a nucleic acid encoding said STING polypeptide, a STING inhibitor, a STING activator, a STING agonist, a STING antagonist, a STING modulating molecule, or a combination thereof. The pharmaceutical composition can be a vaccine or an adjuvant for a vaccine. This disclosure is also directed to a method for treating or preventing a disease using the pharmaceutical composition. The disease can include infectious diseases caused by viruses or other pathogens, for example, influenza, rabies, or respiratory illnesses such as severe acute respiratory syndrome (SARS) caused by coronaviruses, such as MERS-CoV, SARS-CoV, and Coronavirus Disease 2019 (COVID-19) caused by the virus SARS-CoV-2 and its variants.

14.WO/2025/072797IMMUNOGENS AND VACCINE COMPOSITIONS AGAINST HIV

WO - 03.04.2025

Clasificación Internacional C07K 14/005Nº de solicitud PCT/US2024/049021Solicitante THE HENRY M. JACKSON FOUNDATION FOR THE ADVANCEMENT OF MILITARY MEDICINE, INC.Inventor/a ROLLAND, Morgane Marie

Disclosed herein Arc modified HIV-1 Env polypeptides comprising at least one modified hypervariable loop and isolated polynucleotides comprising a nucleotide sequence that encodes the modified HIV-1 Env polypeptides. Also disclosed herein are vaccine or immunogenic compositions for inducing an immune response in a subject against HIV, as well as a method of inducing an immune response against HIV in a subject. Further disclosed herein are methods of identifying an antibody against HIV in a sample.

15.WO/2025/067254THERMOSTABLE COXSACKIEVIRUS A6 STRAIN AND USE THEREOF

WO - 03.04.2025

Clasificación Internacional C12N 7/00Nº de solicitud PCT/CN2024/121161Solicitante WUHAN INSTITUTE OF BIOLOGICAL PRODUCTS CO., LTDInventor/a SHEN, Shuo

Provided are a thermostable Coxsackievirus A6 strain and a use thereof. The thermostable Coxsackievirus A6 strain can withstand high-temperature treatment below 55°C, and has a protein amino acid sequence as shown in any one of SEQ ID NOs: 1-4. The virus strain is obtained from a parent strain, which is separated

from human rhabdomyoma cells (RD) and undergoes passage to be adapted to Vero cells, undergoing adaptive passage under a thermal selection pressure of 52-55°C and undergoing limited dilution and purification. The virus strain has thermal stability, high yield, and strong immunogenicity and can be used as an inactivated vaccine candidate strain, and a sequence of the virus strain can be used for subsequent research and development of enterovirus vaccines and related research of enterovirus stability.

16.WO/2025/076210CHLAMYDIA VACCINE COMPOSITIONS

WO - 10.04.2025

Clasificación Internacional C07K 14/295Nº de solicitud PCT/US2024/049776Solicitante VAXCYTE, INC.Inventor/a ROZELLE, James

Provided are chlamydial protease-like activity factor (CPAF) polypeptides conjugated to an adjuvant, such as through click chemistry, and uses thereof. Uses include as vaccines for protection against chlamydia infections.

17.20250109172METHODS OF DETECTION AND REMOVAL OF RHABDOVIRUSES FROM CELL LINES

US - 03.04.2025

Clasificación Internacional C07K 14/005Nº de solicitud 18665250Solicitante Takeda Vaccines, Inc.Inventor/a Joel R. HAYNES

The present disclosure relates to compositions, methods, mixtures, and kits for detecting the presence of, and for removing, a virus from a product produced in an insect cell. The disclosure also relates to proteins, peptides, polypeptides, drug substances, biological products, vaccine antigens, and virus-like particles that are produced in an insect cell and that are free or substantially free of a virus. The disclosure also relates to compositions, methods, assays, and kits for detecting a rhabdovirus in a sample.

18.WO/2025/075855REVERSE GENETICS VECTOR AND ASSOCIATED METHOD OF USE

WO - 10.04.2025

Clasificación Internacional A61K 39/145Nº de solicitud PCT/US2024/048515Solicitante ST. JUDE CHILDREN'S RESEARCH HOSPITAL, INC.Inventor/a PATTON, Christopher

A modified pHW2000 vector comprising an inactive T7 promoter is provided, as is a method for preparing an influenza virus vaccine using the modified vector.

19.318745PSEUDOVIRUS BASED NEUTRALIZATION ASSAY FOR EVALUATING VACCINE IMMUNOGENICITY

IL - 01.04.2025

Clasificación Internacional C07K 14/005Nº de solicitud 318745Solicitante NOVAVAX, INC.Inventor/a CAI, Zhaohui

20.20250109421CHIMERIC PROTEIN PRODUCTION PROCESS, CHIMERIC PROTEIN, GENE, IMMUNOGENIC COMPOSITION AND USES

US - 03.04.2025

Clasificación Internacional C12P 21/02Nº de solicitud 18728712Solicitante UNIVERSIDADE FEDERAL DE MINAS GERAISInventor/a Ricardo TOSTES GAZZINELI

The production process for a chimeric protein with SEQ ID No. 1, using the nucleotide sequence with SEQ ID No. 2; the chimeric protein defined by SEQ ID No. 1, the gene in SEQ ID No. 2 used for its production, immunogenic compositions containing the protein, and the use thereof to prepare vaccines for prophylaxis and prevention of infection and moderate and severe forms of COVID-19. The present technology falls within the field of human health, specifically in the field of preventive measures against infection with SARS-CoV2. It involves the production of a vaccine composition comprising a chimeric protein that prevents high viral loads and moderate and severe clinical forms of the disease by stimulating the immune system.

21.319104A LIVE ATTENUATED SARS-COV-2 AND A VACCINE MADE THEREOF

IL - 01.04.2025

Clasificación Internacional A61K 39/00Nº de solicitud 319104Solicitante FREIE UNIVERSIT?T BERLINInventor/a

22.WO/2025/067282HEAT-RESISTANT COXSACKIEVIRUS A10 THERMOSTABLE STRAIN AND USE THEREOF

WO - 03.04.2025

Clasificación Internacional C12N 7/00Nº de solicitud PCT/CN2024/121251Solicitante WUHAN INSTITUTE OF BIOLOGICAL PRODUCTS CO., LTDInventor/a SHEN, Shuo

A heat-resistant coxsackievirus A10 (CV-A10) thermostable strain and a use thereof. The heat-resistant CV-A10 thermostable strain has the protein amino acid sequence as shown in any one of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6 and SEQ ID NO: 8, and is obtained by adaptively passaging a virus parent strain, which is isolated from an HEV3108 sample of a patient with the hand, foot and mouth disease in Xiangyang city, Hubei province, China 2017, under the selective pressure of thermal treatment at 52°C for half an hour for five consecutive rounds and carrying out plaque cloning purification. The thermal stability of the strain is significantly improved compared with that of the parent strain, the antigen yield and immunogenicity of the strain are not inferior to those of a thermolabile strain, and thus the strain can be used as an inactivated vaccine candidate strain, and the sequence of the strain can be used for subsequent research and development of enterovirus vaccines and related research of enterovirus stability.

23.20250108102NOVEL FRAGMENTED CRS PEPTIDE EXHIBITING IMMUNE ENHANCEMENT ACTIVITY, AND USE THEREOF

US - 03.04.2025

Clasificación Internacional A61K 39/00Nº de solicitud 18266540Solicitante ZYMEDI CO., LTD.Inventor/a Sung Hoon KIM

The present invention relates to a novel fragmented CRS peptide exhibiting immune enhancement activity, and a use thereof, and, more specifically, to a novel peptide consisting of an amino acid sequence of SEQ ID NO: 2, and a use thereof as a vaccine adjuvant and a cancer therapeutic agent. A peptide disclosed in the

present invention is a CRS fragment disclosed for the first time in the present specification and exhibits an anti-cancer activity and immune enhancement activity.

24.20250108168MEDICAL DELIVERY ASSEMBLY

US - 03.04.2025

Clasificación Internacional A61M 5/28Nº de solicitud 18979090Solicitante Koska Family LimitedInventor/a Max Kingsley HANNON

A pre-filled medical delivery assembly assembled and configured to allow delivery of a single dose of a therapeutic agent (e.g., vaccine, drug, medicament, etc.) from a Blow-Fill-Seal (BFS) vial to a patient. The delivery assembly generally includes a modular design consisting of separately constructed components cooperatively arranged and coupled to one another. In accordance with some embodiments, the medical delivery assembly comprises a hub connector that includes at least one alignment track on an interior portion thereof, configured to receive a corresponding wing of a BFS vial which it is designed to couple with.

25.WO/2025/066863AFRICAN SWINE FEVER VIRUS IMMUNOGEN COMBINATION AND USE THEREOF

WO - 03.04.2025

Clasificación Internacional A61K 39/12Nº de solicitud PCT/CN2024/117421Solicitante SHANGFUSHAFEI (SHANGHAI) BIOTECHNOLOGY CO., LTDInventor/a XU, Jianqing

Provided are an African swine fever virus immunogen combination and a use thereof. An immunogenic composition, comprising: (A) an antibody immunogen group containing immunogens derived from African swine fever virus structural proteins; and (B) a recombinant T cell immunogen group containing immunogens derived from non-structural proteins of African swine fever virus. Also provided are an encoding nucleic acid molecule of the immunogenic composition, a vector and a host cell thereof, a vaccine containing one or more of the foregoing, and a related product. The two immunogen combinations can effectively induce binding antibodies against p72, p54 and p30, as well as activate T cell responses against T antigens, p17 and penton, thereby playing an effective preventive role against African swine fever virus.

26.20250109181LAMP CONSTRUCTS

US - 03.04.2025

Clasificación Internacional C07K 14/705Nº de solicitud 18828394Solicitante Immunomic Therapeutics, Inc.Inventor/a Teri Heiland

The present invention provides improved LAMP Constructs comprising specific fragments of the LAMP lumenal domain to deliver antigens to immune cells for enhanced processing. These LAMP Constructs can be used for the treatment of disease and in particular, allergies, infectious disease, diabetes, hyperproliferative disorders and/or cancer. The improved LAMP Constructs allow for presentation of properly configured three dimensional epitopes for production of an immune response when administered to a subject. The improved LAMP Constructs can be multivalent molecules, and/or can be provided as part of a multivalent vaccine containing two or more LAMP Constructs. The improved LAMP Constructs as described herein can also be used to generate antibodies when administered to a non-human vertebrate.

27.4529471VERFAHREN UND ZUSAMMENSETZUNGEN FÜR EINEN UNIVERSELLEN UND DAUERHAFTEN IMPFSTOFF

EP - 02.04.2025

Clasificación Internacional A61K 47/64Nº de solicitud 23812423Solicitante ZHANG GONGYIInventor/a ZHANG GONGYI

Applicants disclose vaccines effective for broad protection against various viruses as well as methods of making and using those vaccines. The disclosed vaccines induce production of broadly neutralizing antibodies. The presently disclosed vaccines are able to inhibit various influenza and coronavirus viruses. Applicant's methods and compositions are not only useful in creating vaccines with broad activity against a specific virus and existing subtypes but are efficient in generating long-lasting immunity to emergent variants. This can be accomplished using recombinant protein antigens or inactivated virus.

28.WO/2025/075887COMPOSITIONS AND METHODS FOR PREVENTING OR TREATING HEPATITIS C VIRAL INFECTIONS

WO - 10.04.2025

Clasificación Internacional A61K 39/29Nº de solicitud PCT/US2024/049093Solicitante EMORY UNIVERSITYInventor/a AMARA, Rama Rao

Disclosed herein are method of vaccinating or treating a subject for a hepatitis C virus. In certain embodiments, methods comprise administering to a subject a DNA plasmid encoding hepatitis C virus core, E1, E2, and/or p7 proteins. In certain embodiments, methods further comprise administering a recombinant attenuated vaccinia vector encoding hepatitis C virus non-structural NS3, NS4a, NS4b, NS5a and/or NS5b proteins. In certain embodiments, the subject is a human subject.

29.WO/2025/074304COMPOSITIONS AND METHODS FOR IN PLANTA PRODUCTION OF A PORCINE CIRCOVIRUS VACCINE

WO - 10.04.2025

Clasificación Internacional A61K 39/12Nº de solicitud PCT/IB2024/059696Solicitante MAZEN ANIMAL HEALTH, INC.Inventor/a EGELKROUT, Erin M.

Compositions and methods for producing porcine circovirus (PCV) vaccines in plants are provided. Compositions comprising PCV antigens, particularly PCV2 antigens, are provided. Compositions include isolated and recombinant polypeptide sequences expressing at least one PCV2 antigen, recombinant and synthetic nucleic acid molecules encoding at least one PCV2 antigen, constructs or expression cassettes comprising at least one nucleotide sequence encoding a PCV2 antigen, and plants, plant cells, plant parts, and seed transformed with the nucleic acid molecules or constructs comprising the same. Animal feed made from the transformed plants, plant parts, and seed are also encompassed.

30.WO/2025/065909METHOD FOR CONSTRUCTING A PORCINE BONE MARROW MACROPHAGE CELL LINE THAT EXPRESSES CRE GENE AND USE THEREOF

WO - 03.04.2025

Clasificación Internacional C12N 5/10Nº de solicitud PCT/CN2023/138741Solicitante NANJING AGRICULTURAL UNIVERSITYInventor/a QIAN, Yingjuan

The present invention relates to the technical field of biology, in particular to a method for constructing a porcine bone marrow macrophage cell line that expresses a Cre gene and the use of the cell line. The method comprises a method of introducing an SV40LT gene into primary porcine bone marrow macrophages by means of electroporation to immortalize the macrophages, a method of continuously constructing a porcine bone marrow macrophage cell line that stably expresses the Cre gene on the basis of the macrophages, and a method of removing a selectable marker gene from a gene-deleted recombinant virus using the cell line. The used method comprises introducing a transposon system containing a SV40LT gene into primary porcine bone marrow macrophages by means of electroporation, and screening out high-quality immortalized porcine bone marrow macrophages. Continuous introduction of a Cre gene into the immortalized porcine bone marrow macrophages by means of electroporation enables the macrophages to stably express the Cre protein, which can be used for removing a selectable marker gene in the process of constructing a gene-deleted vaccine.

31.318755IMPROVED CORONAVIRUS VACCINE

IL - 01.04.2025

Clasificación Internacional A61K 39/00Nº de solicitud 318755Solicitante ACADEMIA SINICAInventor/a CHI-HUEY WONG

32.WO/2025/072659EFFECTS OF GM-CSF ADDITION ON HUMORAL MODULATION AND FCGR2B BINDING IN ALLERGY, INFECTION AND IMMUNITY

WO - 03.04.2025

Clasificación Internacional A61K 39/12Nº de solicitud PCT/US2024/048838Solicitante PARTNER THERAPEUTICS, INC.Inventor/a JOSHI, Ila

The present disclosure relates to the prevention of a viral infection or an allergic reaction in a subject who has received a vaccine against the virus or the allergen along with granulocyte-macrophage colony-stimulating factor.

33.WO/2025/072522NEOJUNCTION-DERIVED CANCER ANTIGEN EPITOPES, SPECIFIC T CELL RECEPTORS (TCRS) FOR IMMUNOTHERAPY, AND DISCOVERY PLATFORM FOR THE SAME

WO - 03.04.2025

Clasificación Internacional C07K 14/74Nº de solicitud PCT/US2024/048660Solicitante THE REGENTS OF THE UNIVERSITY OF CALIFORNIAInventor/a KWOK, Darwin

Provided herein are peptides derived from neoantigens generated by an aberrant splicing. In addition to its use as a cancer vaccine, the peptide can be used to prime immune cells. T cell receptors, cells containing the same, methods for inducing an immune response and methods of treatment are also provided. A discovery platform for identifying other cancer neoantigens is also described.

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