



## EN ESTE NÚMERO

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

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

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

Última actualización por la OMS: 9 de septiembre de 2022.

Fuente de información utilizada:

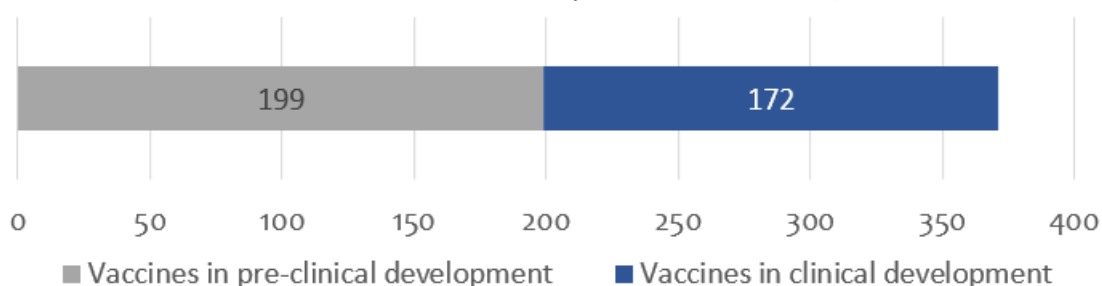


World Health Organization



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172 Vacunas en evaluación clínica y 199 en evaluación preclínica



## Candidatos vacunales en evaluación clínica por plataforma

Platform		Candidate vaccines (no. and %)	
PS	Protein subunit	55	32%
VVnr	Viral Vector (non-replicating)	23	13%
DNA	DNA	16	9%
IV	Inactivated Virus	22	13%
RNA	RNA	40	23%
VVr	Viral Vector (replicating)	4	2%
VLP	Virus Like Particle	6	4%
VVr + APC	VVr + Antigen Presenting Cell	2	1%
LAV	Live Attenuated Virus	2	1%
VVnr + APC	VVnr + Antigen Presenting Cell	1	1%
BacAg-SpV	Bacterial antigen-spore expression vector	1	1%

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## Candidatos vacunales mucosales en evaluación clínica

Desarrollador de la vacuna/fabricante/país	Plataforma de la vacuna	Vía de administración	Fase
University of Oxford/Reino Unido	Vector viral no replicativo	Intranasal	1
CanSino Biological Inc./Beijing Institute of Biotechnology/China	Vector viral no replicativo	Inhalación	4
Vaxart/Estados Unidos	Vector viral no replicativo	Oral	2
Univ. Hong Kong, Xiamen Univ./Beijing Wantai Biol. Pharm./China	Vector viral replicativo	Intranasal	3
Symvivo/Canadá	ADN	Oral	1
Codagenix/Serum Institute of India	Virus vivo atenuado	Intranasal	3
Center for Genetic Engineering and Biotechnology (CIGB)/Cuba	Subunidad proteica	Intranasal	1/2
Razi Vaccine and Serum Research Institute/India	Subunidad proteica	IM e IN	3
Bharat Biotech International Limited/India	Vector viral no replicativo	Intranasal	3
Meissa Vaccines, Inc./Estados Unidos	Virus vivo atenuado	Intranasal	1
Laboratorio Avi-Mex/México	Virus inactivado	IM o IN	2/3
USSF + VaxForm/Estados Unidos	Subunidad proteica	Oral	1
CyanVac LLC/Estados Unidos	Vector viral no replicativo	Intranasal	1
DreamTec Research Limited/Hong Kong	BacAg-SpV	Oral	NA
Sean Liu, Icahn School of Medicine at Mount Sinai	Vector viral replicativo	IN/IM	2/3
Hannover Medical School/Alemania	Vector viral no replicativo	Inhalación	1
ACM Biolabs/Singapur	Subunidad proteica	IN/IM	1
CanSino Biologics Inc.	Vector viral no replicativo	IN	3

## Candidatos vacunales más avanzados a nivel global

Desarrollador de la vacuna/fabricante/país	Plataforma de la vacuna	Fase
Sinovac/China	Virus Inactivado	4
Sinopharm/Beijing Institute of Biological Products/China	Virus Inactivado	4
University of Oxford/AstraZeneca/Reino Unido	Vector viral no replicativo	4
CanSino Biological Inc./Beijing Institute Biotechnology/China (IM e IH)	Vector viral no replicativo	4
Gamaleya Research Institute/Rusia	Vector viral no replicativo	3
Janssen Pharmaceutical Companies/Estados Unidos	Vector viral no replicativo	4
Novavax/Estados Unidos	Subunidad proteica	3
Moderna/NIAID/Estados Unidos	ARN	4
Pfizer/BioNTech Fosun Pharma/Estados Unidos	ARN	4
Anhui Zhifei Longcom Biopharmac./Inst. Microbiol, Chin Acad Sci/China	Subunidad proteica	3
CureVac AG/Alemania	ARN	3
Institute of Medical Biology/Chinese Academy of Medical Sciences	Virus inactivado	3
Research Institute for Biological Safety Problems, Kazakhstan	Virus inactivado	3
Inovio Pharmac. + Intern. Vacc Inst. + Advaccine Biopharm Co., Ltd	ADN	3
Zydus Cadila Healthcare Ltd./India	ADN	3
Bharat Biotech International Limited/India	Virus Inactivado	3
Sanofi Pasteur + GSK/Francia/Gran Bretaña	Subunidad proteica	3
Shenzhen Kangtai Biological Products Co., Ltd./China	Virus Inactivado	3
Clover Biopharmaceuticals Inc./GSK/Dynavax/China/Reino Unido/EE.UU	Subunidad proteica	3
Vaxine Pty Ltd. + CinnaGen Co./Australia, Irán	Subunidad proteica	3
Medigen Vaccine Biol./Dynavax/NIAID/Taiwán/EE.UU	Subunidad proteica	4
Instituto Finlay de Vacunas/Cuba	Subunidad proteica	3
Federal Budget Res Inst State Res Cent Virol Biotechnol "Vector"/Rusia	Subunidad proteica	3
West China Hospital + Sichuan University/China	Subunidad proteica	3
Vaxxinity/EE.UU	Subunidad proteica	3
Univ. Hong Kong, Xiamen Univ. & Beijing Wantai Biological Pharm./China	Vector viral replicativo	3
Acad Milit Sci (AMS) Walvax Biotechnol, Suzhou Abogen Biosci/China	ARN	3
Medicago Inc./Canadá	Partícula similar a virus	3
Codagenix/Serum Institute of India	Virus vivo atenuado	3
Center for Genetic Engineering and Biotechnology (CIGB)/Cuba	Subunidad proteica	3
Valneva, National Institute for Health Research, Reino Unido	Virus inactivado	3
Biological E. Limited/India	Subunidad proteica	3
Nanogen Pharmaceutical Biotechnology/Vietnam	Subunidad proteica	3
Shionogi/Japón	Subunidad proteica	3
Erciyes University/Turquía	Virus inactivado	3
SK Bioscience Co., Ltd./CEPI/Corea del Sur/Noruega	Subunidad proteica	3
Razi Vaccine and Serum Research Institute/Irán, India	Subunidad proteica	3
Bharat Biotech International Limited/India	Vector viral no replicativo (IN)	3
Jiangsu Rec-Biotechnology/China	Subunidad proteica	3
Radboud University/Holanda	Partícula similar a virus	3
Arcturus Therapeutics, Inc./Estados Unidos	ARN	3
Livzon Pharmaceutical/China	Subunidad proteica	3
KM Biologics Co., Ltd.	Virus inactivado	3
Bagheiat-allah University of Medical Sciences/AmitisGen/Irán	Subunidad proteica	3
Laboratorios Hipra, S.A.	Subunidad proteica	3
Sinocelltech Ltd./China	Subunidad proteica	3
Chumakov Federal Scientific Center for Research/Rusia	Virus Inactivado	3
Airlangga University/Indonesia	Virus Inactivado	3
PT Bio Farma/Indonesia	Subunidad proteica	3
AIM Vaccine and Liverna Therapeutics/China	ARN	3
China National Biotec Group Company Limited	Virus inactivado	3



## Noticias en la Web

### Drug regulator recommends manufacture of Biological E's pediatric pneumococcal vaccine

**Sep 1.** The subject expert committee (SEC) of Central Drugs Standard Control Organisation (CDSCO) has recommended for manufacture of pediatric pneumococcal vaccine by Hyderabad based Biological E. Limited followed by review and approval of the Phase 3 infants' clinical trial data.

The vaccine is an investigational 14-valent pediatric pneumococcal vaccine named as polysaccharide conjugate vaccine (PCV14) against *Streptococcus pneumoniae* infection in single dose and

multi dose presentations. The vaccine can be administered to infants at 6, 10 and 14 weeks of age.

*Streptococcus pneumoniae* infection continues to be a leading cause of child mortality under 5 years of age in India and in developing countries. The Biological E. has said that it would be also working with the World Health Organization (WHO) and other global regulatory agencies to make this vaccine available globally.

“The PCV14 vaccine will protect millions of infants worldwide and contribute to the prevention of invasive pneumococcal disease. With this recommendation from SEC and the anticipated formal approval from DCGI thereafter, India will have yet another important lifesaving vaccine for pediatric use,” Mahima Datla, Managing Director, Biological E. Limited said.

Biological E.'s PCV14 contains 14 serotypes, 12 of them same as in Prevnar13 from Pfizer. The US Centers for Disease Control and Prevention defines Serotypes as groups within a single species of microorganisms, such as bacteria or viruses, which share distinctive surface structures.

In addition, Biological E.'s PCV14 has 2 more Serotypes 22F and 33F for which there have been increasing cases of infections globally. Biological E in a statement said that PCV14 vaccine elicited functional immune responses. One month after third dose of vaccination, adequate increase in serotype-specific immune responses were observed for all 14 PCV serotypes.

“The safety analysis revealed that all the adverse events were mild to moderate in their intensity and with no grade-3 and 4 events reported. The safety comparison shows that BE-PCV14 vaccine was well tolerated and found to be safe,” the company statement said.

BE's PCV14 is comparable in terms of serotype coverage for infants to the two pneumococcal conjugate vaccines Prevnar13 and Merck's VAXNEUVANCE which are currently approved globally, the company said.

Fuente: BusinessToday.In. Disponible en <https://bit.ly/3DeXPCY>



## First adapted COVID-19 booster vaccines recommended for approval in the EU

**Sep 1.** EMA's human medicines committee (CHMP) has recommended authorising two vaccines adapted to provide broader protection against COVID-19. Comirnaty Original/Omicron BA.1 and Spikevax bivalent Original/Omicron BA.1 are for use in people aged 12 years and above who have received at least primary vaccination against COVID-19. These vaccines are adapted versions of the original vaccines Comirnaty (Pfizer/BioNTech) and Spikevax (Moderna) to target the Omicron BA.1 subvariant in addition to the original strain of SARS-CoV-2.

Vaccines are adapted (i.e., updated) to better match the circulating variants of SARS-CoV-2. Adapted vaccines can broaden protection against different variants and are therefore expected to help maintain optimal protection against COVID-19 as the virus evolves.

Studies showed that Comirnaty Original/Omicron BA.1 and Spikevax bivalent Original/Omicron BA.1 can trigger strong immune responses against Omicron BA.1 and the original SARS-CoV-2 strain in people previously vaccinated. In particular, they were more effective at triggering immune responses against the BA.1 subvariant than the original vaccines.

**"The adapted COVID-19 vaccines Comirnaty Original/Omicron BA.1 and Spikevax bivalent Original/Omicron BA.1 are now authorised across the EU. This follows a decision from the European Commission issued on 1 September 2022."**

Side effects observed with the adapted vaccines were comparable to those seen with the original ones and were typically mild and short-lived.

The two CHMP opinions will now be sent to the European Commission, which will adopt a final decision.

As the pandemic evolves, the EU's strategy is to have a broad range of adapted vaccines that target different SARS-CoV-2 variants so Member States have a plurality of options to meet their needs when they design their vaccination strategies. This is a key element in the overall strategy to combat the pandemic as it is not possible to predict how the virus will evolve in the future and which variants will be circulating this winter.

Other adapted vaccines incorporating different variants, such as the Omicron subvariants BA.4 and BA.5, are currently under review by EMA or will be submitted soon, and, if authorised, will further extend the arsenal of available vaccines. The clinical data generated with the original/BA.1 bivalent vaccines recommended today will support the evaluation and authorisation of further adapted vaccines.

The original vaccines, Comirnaty and Spikevax, are still effective at preventing severe disease, hospitalisation and death associated with COVID-19 and will continue to be used within vaccination campaigns in the EU, in particular for primary vaccinations.

National authorities in the EU Member States will determine who should receive which vaccines and when, taking into account factors such as infection and hospitalisation rates, the risk to vulnerable populations, vaccination coverage and vaccine availability.

### Evidence supporting use of Comirnaty Original/Omicron BA.1

Comirnaty Original/Omicron BA.1 can be used in people aged 12 years and older, at least 3 months after the last dose of a COVID-19 vaccine.

The CHMP's opinion on Comirnaty Original/Omicron BA.1 is based on 2 studies. One study in adults over 55

years old who had previously received 3 doses of Comirnaty (primary vaccination and a booster) found that the immune response to the Omicron BA.1 subvariant was higher after a second booster dose of Comirnaty Original/Omicron BA.1 than after a second dose of the original Comirnaty vaccine (as measured by the level of antibodies against Omicron BA.1). In addition, the immune response to the original SARS-CoV-2 strain was comparable for both vaccines. The study involved more than 1,800 people, of whom about 300 received Comirnaty Original/Omicron BA.1 in its final composition.

Further data from a study involving over 600 people aged between 18 and 55 years who had previously received 3 doses of Comirnaty showed that the immune response to Omicron BA.1 was higher in people who received a booster with a vaccine containing only the Omicron BA.1 component than in those given a booster with the original Comirnaty vaccine.

Based on these data, it was concluded that the immune response to Omicron BA.1 following a booster with Comirnaty Original/Omicron BA.1 in people aged 18 to 55 years would be at least equal to that in people aged over 55. Further, based on previous data in younger people, it was also concluded that the immune response to a booster dose with Comirnaty Original/Omicron BA.1 in adolescents would be at least equal to that in adults.

### **Evidence supporting use of Spikevax bivalent Original/Omicron BA.1**

Spikevax bivalent Original/Omicron BA.1 can be used in adults and adolescents from the age of 12 years, at least 3 months after primary vaccination or a booster dose with a COVID-19 vaccine.

The CHMP's opinion on Spikevax bivalent Original/Omicron BA.1 is based on data from a study involving more than 800 adults aged 18 years and above. The study found that a booster dose of Spikevax bivalent Original/Omicron BA.1 induced a stronger immune response against the SARS-CoV-2 strain and the Omicron subvariant BA.1 compared with a booster dose of the original Spikevax vaccine. The study compared the level of antibodies in people previously vaccinated with a primary series and booster dose of Spikevax, and who were given a second booster dose of either Spikevax or Spikevax bivalent Original/Omicron BA.1. It was also concluded that Spikevax bivalent Original/Omicron BA.1 could be used as a first booster after primary vaccination and that the immune response induced by a booster dose of Spikevax bivalent Original/Omicron BA.1 in adolescents aged 12-17 years would be at least equal to that in adults, given that previous data with Spikevax have shown a comparable effect.

### **How the adapted vaccines work**

The adapted vaccines work in the same way as the original vaccines.

Both adapted vaccines work by preparing the body to defend itself against COVID-19. Each vaccine contains molecules called mRNA which have instructions for making the spike proteins of the original SARS-CoV-2 and the Omicron subvariant BA.1. The spike protein is a protein on the surface of the virus which the virus needs to enter the body's cells and can differ between variants of the virus. By adapting vaccines, the aim is to broaden protection against different variants.

When a person is given one of these vaccines, some of their cells will read the mRNA instructions and temporarily produce the spike proteins. The person's immune system will then recognise those proteins as foreign and activate natural defences — antibodies and T cells — against them.

If, later on, the vaccinated person comes into contact with the virus, the immune system will recognise the spike protein on its surface and be prepared to attack it. The antibodies and immune cells can protect against COVID-19 by working together to kill the virus, preventing its entry into the body's cells and destroying infected cells.

The mRNA molecules from the vaccines do not stay in the body but are broken down shortly after vaccination.

### More about the procedures

The companies marketing Spikevax and Comirnaty submitted applications (called variation applications) to change the current marketing authorisations of the authorised vaccines Comirnaty and Spikevax and include the use of adapted vaccines. These applications included data on the quality and safety of the adapted vaccines, and their ability to trigger immune responses against various strains of SARS-CoV-2. The review was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use. The CHMP opinion has been forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

Fuente: European Medicines Agency. Disponible en <https://bit.ly/3xdD4Ug>

## La ciencia y la innovación acercan más a BioCubaFarma y a la Universidad Central de Las Villas

**2 sep.** Varios proyectos encaminados a facilitar el desarrollo conjunto de la ciencia y la innovación en el campo de la biotecnología y la agricultura acaban de ser concretados entre la Universidad Central «Marta Abreu» de Las Villas (UCLV) y el grupo empresarial BioCubaFarma, lo cual constituye un paso sustancial en la integración entre la academia y el sistema empresarial cubano.

Entre los campos del conocimiento que más se benefician de esta colaboración figuran la biomedicina y la producción agropecuaria, según afirmó la doctora Dagmar García Rivera, Directora de Investigaciones del Instituto Finlay de Vacunas, quien destacó el potencial de la UCLV para el fomento de la ciencia y la innovación.

Al respecto señaló que fueron identificados tres proyectos fundamentales, uno de los cuales puede impactar a más corto plazo, relacionado con el desarrollo de la Furvina, entre los productos líderes del Centro de Bioactivos Químicos, que es un ingrediente farmacéutico activo que posee una doble acción, antifúngica y antibacteriana, en fase avanzada de investigación y aprobación.

Mencionó también el área de la producción de fitomedicamentos –a partir de plantas medicinales–, en lo que la UCLV tiene más de 20 años de experiencia de trabajo;





además de otras sustancias que pueden ser extraídas y estudiadas a fin de ser empleadas como adyuvantes para su uso en vacunas humanas y veterinarias.

De igual manera, los principales esfuerzos en el terreno agropecuario se centrarán en la obtención de semillas y su mejoramiento genético en siembras como el frijol y la caña de azúcar, así como en la producción de los medios de cultivos más empleados en la red de biofábricas de Cuba.

Al referirse a las potencialidades de la Marta Abreu de Las Villas, la viceministra de Educación Superior, Alicia Alonso Becerra, destacó que esta tiene la ventaja de ser una de las más multidisciplinarias del país, con capacitados especialistas en todas las ramas, a lo que se suma el hecho de tener la Sociedad Interfaz de Ciencia y Tecnología.

Luego de rubricarse la firma de los seis primeros acuerdos, el doctor Eduardo Martínez Díaz, presidente de BioCubaFarma, reconoció la importancia de estos proyectos, cuyo objetivo es cerrar ciclos y facilitar la introducción en la práctica de tecnologías y productos, entre otras ventajas.

Fuente: Granma. Disponible en <https://bit.ly/3DkNWUj>

## South Africa Reaches Deal With India to Boost Domestic Vaccine Production

**Sep 2.** The Serum Institute of India signed a deal this week with South Africa's Aspen Pharmacare to make four vaccines used in Africa.

The deal has been hailed as saving local vaccine production, which was at risk of shutting down after receiving no orders for a COVID vaccine. But medical aid group Doctors Without Borders says more efforts are needed for vaccines to be fully produced in Africa for Africans.



*GCIS/Flickr. A worker at the Aspen Pharmacare sterile manufacturing facility in Gqeberha in the Eastern Cape province in South Africa on March 29, 2021.*

Four routine pediatric vaccines -- pneumococcal vaccine, rotavirus vaccine, polyvalent meningococcal vaccine and hexavalent vaccine -- will be made in South Africa with products from bulk drug substances supplied by India's Serum Institute.

In addition to the 10-year agreement, South Africa's Aspen Pharmacare also anticipates receiving grant funding from the Bill & Melinda Gates Foundation and the Coalition for Epidemic Preparedness Innovations, CEPI.

"The partnership represents an important step for preventing the kinds of gross inequities of access to life-saving vaccines that emerged during the COVID pandemic," said CEPI's chief executive officer, Richard Hatchett. "We are proud to be part of an effort that will secure critically needed vaccine manufacturing



capacity in Africa, for Africa so that it can be ready when it faces future epidemic or pandemic threats."

But Candice Sehoma with Doctors Without Borders' Access Campaign in South Africa is calling for more than just fill-and-finish deals.

"I think it's a great step towards realizing the improvements in the African continent's manufacturing capacity, particularly looking at vaccines. And actually looking into routine vaccines. I think that, for me, is a great step," Sehoma said. "But I think, definitely, we could do with a lot more and even a full sharing of technology, so that we don't find ourselves waiting in line for vaccines that are coming from high-income countries."

Petro Terblanche, managing director of the South African company Afrigen, which reproduced Moderna's MRNA COVID vaccine, says Aspen's deal with the Serum Institute may not be healthy for other companies on the continent, as it could drown out local competition.

"So, the manufacturing capacity and the technology capabilities and the reach of the Serum Institute is very dominant, it is very, very powerful. However, if Serum Institute is prepared to do partnerships with Africa and South Africa for end-to-end manufacturing and technology transfer to Africa, it's a positive development," Terblanche said.

Meanwhile, Dr. Ahmed Oghwell Ouma, deputy director of the Africa Centres for Disease Control and Prevention, says the agreement is an important step for African vaccine manufacturing.

"It has responded to African Union heads of state and government calls that 30 percent of our continent's requirements for human vaccines be procured from Africa manufacturers. And we look forward to this being motivation for more expanded manufacturing of vaccines here on the continent of Africa," Ouma said.

According to the Africa CDC, less than 1% of vaccines currently used on the continent are locally manufactured.

Aspen's Group Communications Consultant Shauneen Beukes says they cannot comment on calls for the full African production of vaccines at this stage.

Fuente: All Africa. Disponible en <https://bit.ly/3BGzIMx>

## **New omicron boosters are now available, but it's unclear how effective they will be**

**Sep 3.** The U.S. authorized the first major makeover of the COVID-19 vaccines this week in an effort to stem an expected tide of infections and hospitalizations this fall.

But it's unclear how much protection the new booster shots will provide. The Food and Drug Administration and the Centers for Disease Control and Prevention cleared the shots without any data from clinical trials that are testing the reformulated doses in humans.

The new boosters, authorized for people ages 12 and older, target the highly contagious and immune-evasive omicron BA.5 subvariant that has caused a wave of breakthrough infections over the summer. The shots also target the original strain of the virus that first emerged in Wuhan, China, in 2019.

The nation's top health officials acted with urgency this summer to ensure the new boosters would roll out in time for the fall. They are worried that the waning effectiveness of the old vaccines is creating an opening for omicron to cause another wave of hospitalizations this winter as people spend more time indoors where the airborne virus spreads more easily.

Deaths and hospitalizations have climbed since April among the elderly, the most vaccinated age group in America, as omicron has continued to mutate into more and more transmissible subvariants that dodge the protection of the original vaccines, according to Heather Scobie, a CDC epidemiologist.

Dr. Peter Marks, who heads the FDA office that reviews vaccines, said the new boosters aim to restore the high levels of protection that vaccines demonstrated in early 2021. But Marks acknowledged that the federal government's experts simply do not know yet whether the boosters will meet the high bar set by those doses.

"We don't know for a fact yet whether we will get to that same level, but that is the goal here. And that is what we believe the evidence that we've seen helps point to," Marks told reporters during a news conference after the FDA authorization Wednesday.

The FDA will conduct surveillance to see whether the boosters meet that goal, Marks said. When Pfizer's and Moderna's shots were authorized in December 2020, they provided more than 90% protection at preventing Covid.

Marks told reporters it will likely take at least another couple of months before human data on the BA.5 boosters is available to the public. But he said the FDA used basically the same process to authorize the new boosters that it has relied on for years to switch the virus strains in flu shots.

"We're pretty confident that what we have is very similar to the situation that we've done in the past with influenza changes where we don't do clinical studies for them in the United States," Marks said. "We know from the way the vaccine works, and from the data that we have, that we can predict how well the vaccine will be working."

The new boosters could prevent 2.4 million infections, 137,000 hospitalizations and 9,700 deaths if a new variant doesn't emerge, according to a projection by a team of scientists that forecasts the trajectory of the pandemic, called the Covid-19 Scenario Modeling Hub.

But that projection is based on optimistic assumptions about booster coverage and efficacy, according to the scientists. The model assumes that the shots will prove 80% effective at preventing illness and the public will broadly embrace the new boosters. There is no efficacy data on the new shots and it's unclear how strong public demand will be for them.

The CDC estimates that an early fall vaccination campaign with boosters could save the U.S. between \$63 billion and \$109 billion in medical costs by preventing hospitalizations and ICU admissions.

Pfizer and Moderna were originally developing new boosters to target the first version of omicron, BA.1, that caused the massive wave of infection and hospitalization last winter. But keeping up with the rapid evolution of the virus has proved challenging.



*A woman receives a Pfizer vaccination booster shot at Eugene A. Obregon Park in Los Angeles. Gary Coronado | Los Angeles Times | Getty Images*

By the time the nation's top health leaders moved in earnest in April to get new boosters ready, more transmissible subvariants had already driven omicron BA.1 out of prevalence. In June, the FDA asked the vaccine makers to switch gears and target omicron BA.5 after it rose to dominance.

This decision did not leave enough time for Pfizer and Moderna to complete human clinical trials on the new boosters before a fall vaccine rollout.

As a consequence, the FDA and the CDC are relying on human data from the clinical trials of the BA.1 shots to understand how the BA.5 boosters might perform. They also relied on data from studies in which the BA.5 boosters were tested in mice.

The CDC's independent advisory committee backed the shots on Thursday in an overwhelming vote.

But several members of the panel also had reservations about the lack of human data.

"I really do struggle with a vaccine that has no clinical data that's reported for humans, for those that would be actually receiving the vaccine," said Dr. Oliver Brooks, a committee member and the chief medical officer at Watts HealthCare Corp. in Los Angeles.

Dr. Pablo Sanchez, the only CDC committee member who voted against the shots, called the decision to recommend the new boosters without human data premature.

"There's a lot of vaccine hesitancy already — we need the human data," said Sanchez, a professor of pediatrics at Ohio State University.

Dr. Doran Fink, deputy head of the FDA's vaccine review division, told hesitant committee members that the new booster shots use the exact same manufacturing process as the old vaccines and contain the same total amount of mRNA, the code that instructs human cells to produce the proteins that provoke an immune response to defend against Covid.

Fink said the BA.1 and the BA.5 shots are similar enough to use data from the BA.1 human trials to get a good idea of how the new BA.5 boosters will perform.

Pfizer and Moderna presented data at the CDC meeting which showed that the BA.1 shots triggered a stronger immune response in humans than the old vaccines. The mouse studies from both companies on the BA.5 shots also showed a stronger immune response.

CDC Director Dr. Rochelle Walensky last week said waiting longer for human data from the BA.5 shots could mean the boosters become outdated if a new variant emerges.

"There's always a question here of being too slow versus too fast," Walensky told "Conversations on Health Care" in a radio interview. "One of the challenges is if we wait for those data to emerge in human data ... we will be using what I would consider to be a potentially outdated vaccine."

Moderna completed enrollment in its clinical trials last week and expects results by the end of the year. Pfizer's clinical trials are ongoing, though the company hasn't provided a time frame on when it will have data.

Brooks questioned why the FDA decided to go with a BA.5 vaccine when clinical data is available for the BA.1 shots that the vaccine makers were originally developing. Canada and the United Kingdom have authorized new booster shots that target omicron BA.1



Fink said the U.S. selected BA.5 based on the advice of the FDA's independent committee, data from South Africa that indicated natural infection from the subvariant provides broader protection than infection from BA.1, and the fact that BA.5 is dominant.

Though the committee members had some hesitation about proceeding without the human data, they agreed the new boosters should have a similar safety profile to the old vaccines because they use the same platform. The Covid vaccines have been administered to millions of people in the U.S. with mostly mild side effects.

The most common side effects from the human trials of the BA.1 shots was pain, redness, swelling at the injection site, fatigue, headaches, muscle pain, joint pain, chills, nausea, vomiting and fever, according to the FDA.

Dr. Sara Oliver, a CDC official, told the committee that the risk of myocarditis, inflammation of the heart muscle, after a BA.5 booster is unknown. But health officials anticipate it will be similar to the risk observed with the old vaccines.

Pfizer's and Moderna's vaccines have been associated with an elevated risk of myocarditis in young men and adolescent boys mostly after the second dose. But the risk of myocarditis is higher from Covid infection than vaccination, according to the CDC.

Dr. Grace Lee, the CDC committee chair, sought to reassure the public that there's a robust surveillance system to monitor safety, and that the panel will meet again if any new concerns emerge.

"I just want to make sure that the members of the public are aware that we're continuing to monitor closely," Lee said. "We have systems and teams that are continuing to monitor and to meet."

Fuente: CNBC. Disponible en <https://cnb.cx/3U0PQPX>

## CanSino's inhaled COVID-19 vaccine gets emergency use approval in China

**Sep 4.** China's CanSino Biologics Inc. said on Sunday that its recently developed COVID-19 vaccine has been approved by the country's drug regulator for emergency use as a booster, potentially benefiting its business.

The inhaled version of Cansino's adenovirus-vectored COVID-19 vaccine has obtained the green light from the National Medical Products Administration, the company said in a filing on Sunday.

"The approval will have a positive impact on the company's performance if the vaccine is subsequently purchased and used by relevant government agencies," CanSino said.

The company cautioned, however, that it will face fierce competition from other vaccines



in China that have also obtained government approval or are in clinical trials.

China granted emergency use authorisation to Livzon Pharmaceutical Group Inc's COVID-19 vaccine as a booster, Livzon said on Friday, one of just two new products against the disease the country had cleared in more than a year.

Cansino also said it was uncertain when its vaccine would be able to go to market, since additional administrative approvals are still needed, while sales would depend on the COVID-19 situation at home and abroad, as well as China's vaccination rate.

China has seen a recent flare-up in COVID outbreaks. The southern tech hub of Shenzhen imposed a weekend lockdown in most parts of the city on Saturday, while the southwestern metropolis of Chengdu put its 21 million people under lockdown on Thursday.

Mainland China reported 1,848 new coronavirus cases for Sept. 3, including both symptomatic and asymptomatic infections, compared with 1,988 new cases a day earlier.

Fuente: REUTERS. Disponible en <https://reut.rs/3eDFHII>

## Swissmedic autoriza la vacuna Novavax Nuvaxovid™ COVID-19 Vaccine para adolescentes de 12 a 17 años

**5 sep.** Novavax, Inc. (Nasdaq: NVAX), una empresa de biotecnología dedicada a desarrollar y comercializar vacunas de nueva generación contra enfermedades infecciosas graves, ha anunciado hoy que Swissmedic, la Agencia Suiza de Productos Terapéuticos, ha ampliado su autorización temporal de la vacuna Nuvaxovid™ (NVX-CoV2373) COVID-19 en Suiza para la inmunización activa para prevenir la enfermedad por coronavirus 2019 (COVID-19) causada por el coronavirus del síndrome respiratorio agudo severo 2 (SARS-CoV-2) en adolescentes de 12 a 17 años y como dosis de refuerzo heteróloga y homóloga para adultos mayores de 18 años.

"Nos complace ofrecer la primera vacuna de COVID-19 basada en proteínas para su uso tanto en adolescentes como en dosis de refuerzo en adultos en Suiza", dijo Stanley C. Erck, presidente y consejero delegado de Novavax. "Mientras seguimos explorando las mejores prácticas para el tratamiento de la COVID-19 a largo plazo, tenemos ensayos en curso que exploran aún más la eficacia y seguridad de Nuvaxovid como refuerzo y los datos preclínicos sugieren que nuestra vacuna induce una respuesta inmune contra las variantes de Omicron, incluyendo la BA.4/5."

### Adolescentes de 12 a 17 años

La autorización para los adolescentes de 12 a 17 años se basa en los datos de la ampliación pediátrica en curso del ensayo de fase 3 PREVENT-19 con 2.247 adolescentes de 12 a 17 años en 73 centros de Estados Unidos para evaluar la seguridad, efectividad (inmunogenicidad) y eficacia de Nuvaxovid. En la ampliación pediátrica, Nuvaxovid alcanzó su objetivo principal de eficacia y demostró una eficacia clínica global del 80% en un momento en el que la variante Delta era la cepa de SARS-CoV-2 predominante en Estados Unidos.

Los datos preliminares de seguridad de la expansión pediátrica mostraron que la vacuna fue generalmente bien tolerada. Los acontecimientos adversos graves y severos fueron escasos en número y equilibrados entre los grupos de vacuna y placebo, y no se consideraron relacionados con la vacuna. La reactogenicidad local y sistémica fue en general menor o similar a la de los adultos, después de la primera y segunda dosis.

Las reacciones adversas más comunes observadas fueron sensibilidad/dolor en el lugar de la inyección, dolor de cabeza, mialgia, fatiga y malestar. No hubo un aumento de la reactogenicidad en los adolescentes más jóvenes (12 a <15 años) en comparación con los adolescentes mayores (15 a <18 años). No se observó ninguna nueva señal de seguridad en la parte controlada con placebo de la expansión pediátrica.

### **Refuerzo en adultos mayores de 18 años**

La autorización de la dosis de refuerzo en adultos mayores de 18 años está respaldada por los datos del ensayo de fase 2 de Novavax realizado en Australia, de otro ensayo de fase 2 realizado en Sudáfrica y del ensayo COV-BOOST patrocinado por el Reino Unido. Como parte de los ensayos de fase 2, se administró una dosis única de refuerzo de Nuvaxovid a participantes adultos sanos aproximadamente seis meses después de su serie de vacunación primaria de dos dosis de Nuvaxovid. La tercera dosis produjo un aumento de la respuesta inmunitaria comparable o superior a los niveles asociados a la protección en los ensayos clínicos de fase 3. En el ensayo COV-BOOST, Nuvaxovid indujo una respuesta significativa de anticuerpos cuando se utilizó como tercera dosis heteróloga de refuerzo.

En los ensayos patrocinados por Novavax, tras el refuerzo, las reacciones locales y sistémicas tuvieron una duración media de aproximadamente dos días. La incidencia de eventos de grado 3 o superior se mantuvo relativamente baja. Los informes de seguridad de los acontecimientos de reactogenicidad mostraron una incidencia creciente en las tres dosis de Nuvaxovid, a menudo observada con el aumento de la inmunogenicidad. Los acontecimientos adversos atendidos médicamente, las afecciones médicas potencialmente inmunomediadas y los acontecimientos adversos graves se produjeron con poca frecuencia tras la dosis de refuerzo y estuvieron equilibrados entre los grupos de vacuna y de placebo

En la población de 12 a 17 años, NVX-CoV2372 también ha sido autorizada en la Unión Europea, Reino Unido, Australia, Nueva Zelanda, Japón, Tailandia, India, y Corea del Sur. La vacuna también ha sido autorizada en Japón, Australia, y Nueva Zelanda como refuerzo. Nuvaxovid está siendo revisado activamente para ambas indicaciones en otros mercados.

Swissmedic concedió una autorización temporal en abril de 2022 para el uso de Nuvaxovid en adultos mayores de 18 años.

### **Nombre comercial en EE.UU.**

El nombre comercial Nuvaxovid™ aún no ha sido aprobado por la Administración de Alimentos y Medicamentos de los Estados Unidos

### **Uso autorizado**

Nuvaxovid está indicado para la inmunización activa para prevenir la COVID-19 causada por el SARS-CoV-2 en individuos de 12 años o más. El uso de esta vacuna debe ser conforme a las recomendaciones oficiales.

### **Información de seguridad importante: Suiza**

- Nuvaxovid está contraindicado en personas con hipersensibilidad al principio activo o a cualquiera de los excipientes.
- Se han notificado casos de anafilaxia con la administración de las vacunas de COVID-19, incluyendo



Nuvaxovid. En caso de reacción anafiláctica tras la administración de la vacuna, debe disponerse de un tratamiento médico adecuado y de supervisión. Se recomienda observación durante al menos 15 minutos y no se debe administrar una segunda dosis de la vacuna a quienes hayan experimentado anafilaxia a la primera dosis de Nuvaxovid.

- Se han notificado casos muy raros de miocarditis y pericarditis tras el uso de Nuvaxovid. Los profesionales sanitarios deben estar atentos a los signos y síntomas de miocarditis y pericarditis. Se debe instruir a los vacunados (incluidos los padres o cuidadores) para que busquen atención médica inmediata si desarrollan síntomas indicativos de miocarditis o pericarditis, como dolor torácico (agudo y persistente), dificultad para respirar o palpitaciones tras la vacunación. Los profesionales sanitarios deben consultar a orientadores y/o especialistas para diagnosticar y tratar esta afección.
- Reacciones relacionadas con la ansiedad, incluyendo reacciones vasovagales (síncope), hiperventilación o reacciones relacionadas con el estrés pueden ocurrir en asociación con la vacunación como una respuesta psicógena a la inyección de la aguja. Es importante que se tomen precauciones para evitar lesiones por desmayo.
- La vacunación debe posponerse en personas que sufran una enfermedad febril grave o una infección aguda. La presencia de una infección menor y/o fiebre baja no debe retrasar la vacunación.
- Nuvaxovid debe administrarse con precaución en personas que reciban tratamiento anticoagulante o que padezcan trombocitopenia o cualquier trastorno de la coagulación (como la hemofilia), ya que en estas personas pueden producirse hemorragias o hematomas tras la administración intramuscular. • La eficacia de Nuvaxovid puede ser menor en individuos inmunodeprimidos.
- La administración de Nuvaxovid durante el embarazo sólo debe considerarse cuando los beneficios potenciales superen los posibles riesgos para la madre y el feto.
- Los efectos con Nuvaxovid pueden afectar temporalmente a la capacidad de conducir o utilizar máquinas.
- Se desconoce la duración de la protección proporcionada por la vacuna, ya que aún se está determinando en los ensayos clínicos en curso. Las personas pueden no estar totalmente protegidas hasta siete días después de su segunda dosis. Como ocurre con todas las vacunas, la vacunación con Nuvaxovid puede no proteger a todos los receptores de la vacuna.
- Reacciones adversas muy comunes ( $\geq 1/10$ ) y comunes ( $\geq 1/100$  a  $< 1/10$ ) observadas durante los estudios clínicos en personas mayores de 12 años fueron dolor de cabeza, náuseas o vómitos, mialgia, artralgia, sensibilidad/dolor en el lugar de la inyección, pirexia. La fiebre se observó con mayor frecuencia en los adolescentes de 12 a 17 años en comparación con los adultos, siendo la frecuencia muy común después de la segunda dosis en el caso de adolescentes.

Para obtener más información sobre Nuvaxovid, incluido el Resumen de las Características del Producto con el Prospecto, las instrucciones de notificación de efectos adversos, o para solicitar información adicional, visite el siguiente sitio web: [Swissmedic](#)

### **Acerca de Nuvaxovid™ (NVX-CoV2373)**

Nuvaxovid es una vacuna basada en proteínas diseñada a partir de la primera secuencia genética del SARS-CoV-2, el virus que causa la enfermedad de la COVID-19. La vacuna fue creada utilizando la

tecnología de nanopartículas recombinantes de Novavax para generar antígenos derivados de la proteína espiga (S) del coronavirus y está formulada con Matrix-M™, el adyuvante basado en saponinas patentado de Novavax, para mejorar la respuesta inmune y estimular altos niveles de anticuerpos neutralizantes. Nuvaxovid contiene antígenos de proteína purificados y no puede replicarse ni causar la COVID-19. Nuvaxovid está empaquetada como una formulación líquida lista para usar en un vial que contiene diez dosis. El régimen de vacunación requiere dos dosis de 0,5 ml (5 mcg de antígeno y 50 mcg de adyuvante Matrix-M) administradas por vía intramuscular con 21 días de diferencia. La vacuna se almacena entre 2° y 8° Celsius, lo que permite utilizar los canales de suministro de vacunas y de cadena de frío existentes. El uso de la vacuna debe estar de acuerdo con las recomendaciones oficiales.

Novavax ha establecido asociaciones para la fabricación, comercialización y distribución de Nuvaxovid en todo el mundo. Las autorizaciones existentes aprovechan la asociación de fabricación de Novavax con Serum Institute of India, el fabricante de vacunas más grande del mundo por volumen. Posteriormente se complementarán con datos de sitios de fabricación adicionales a lo largo de la cadena de suministro global de Novavax.

### **Acerca de los ensayos de fase 3 de NVX-CoV2373**

NVX-CoV2373 sigue siendo evaluado en dos ensayos fundamentales de fase 3. PREVENT-19 (el Ensayo de Eficacia de la Vacuna de la Subunidad de Proteínas de PRE Fusión | COVID-19) es un ensayo 2:1 aleatorio, controlado con placebo y ciego por un observador para evaluar la eficacia, seguridad e inmunogenicidad de NVX-CoV2373 con el adyuvante Matrix-M en 29.960 participantes mayores de 18 años en 119 lugares de EE.UU. y México. El criterio de valoración primario de PREVENT-19 fue la primera aparición de COVID-19 sintomática (leve, moderada o grave) confirmada por PCR con inicio al menos siete días después de la segunda dosis en participantes adultos serológicamente negativos (al SARS-CoV-2) al inicio. El criterio de éxito estadístico incluía un límite inferior de 95% CI >30%. Un criterio de valoración secundario fue la prevención de la COVID-19 sintomática y confirmada por PCR. Ambos criterios de valoración se evaluaron al menos siete días después de la segunda vacunación del estudio en voluntarios que no se habían infectado previamente con el SARS-CoV-2. En el ensayo, NVX-CoV2373 alcanzó una eficacia global del 90,4%. En general, fue bien tolerado y provocó una sólida respuesta de anticuerpos tras la segunda dosis en ambos estudios. Los resultados completos del ensayo se publicaron en la revista *New England Journal of Medicine* (NEJM).

La ampliación pediátrica de PREVENT-19 es un ensayo 2:1 aleatorio, controlado con placebo y ciego por un observador para evaluar la seguridad, la efectividad y la eficacia de NVX-CoV2373 con el adyuvante Matrix-M en 2.247 participantes adolescentes de 12 a 17 años de edad en 73 lugares de los Estados Unidos, en comparación con el placebo. En el ensayo pediátrico, NVX-CoV2373 alcanzó su objetivo principal de eficacia (la no inferioridad de la respuesta de anticuerpos neutralizantes en comparación con los participantes adultos jóvenes de 18 a 25 años de edad de PREVENT-19) y demostró una eficacia global del 80% en un momento en que la variante Delta era la cepa predominante que circulaba en EE.UU. Además, las respuestas inmunitarias fueron de dos a tres veces mayores en los adolescentes que en los adultos contra todas las variantes estudiadas.

Además, un ensayo llevado a cabo en Reino Unido con 14.039 participantes de 18 años o más fue diseñado como un estudio aleatorio, controlado con placebo y ciego por un observador, y alcanzó una eficacia global

del 89,7%. El criterio de valoración primario se basó en la primera aparición de COVID-19 sintomática (leve, moderada o grave) confirmada por PCR con inicio al menos siete días después de la segunda vacunación del estudio en participantes adultos serológicamente negativos (al SARS-CoV-2) al inicio. Los resultados completos del ensayo se publicaron en NEJM.

### **Acerca del adyuvante Matrix-M™**

El adyuvante Matrix-M a base de saponina patentado de Novavax ha demostrado un efecto potente y bien tolerado al estimular la entrada de células presentadoras de antígenos en el lugar de la inyección y mejorar la presentación de antígenos en los ganglios linfáticos locales, lo que aumenta la respuesta inmunitaria.

### **Acerca de Novavax**

Novavax, Inc. ( Nasdaq: NVAX) es una empresa de biotecnología que promueve la mejora de la salud a nivel mundial mediante el descubrimiento, el desarrollo y la comercialización de vacunas innovadoras para prevenir enfermedades infecciosas graves. La plataforma de tecnología recombinante patentada de la empresa combina el poder y la velocidad de la ingeniería genética para producir de manera eficiente nanopartículas altamente inmunogénicas diseñadas para atender las necesidades urgentes de salud en todo el mundo. La vacuna COVID-19 de Novavax, NVX-CoV2373, ha recibido la autorización de múltiples autoridades reguladoras de todo el mundo, incluidas las de Estados Unidos, la Comisión Europea y la Organización Mundial de la Salud. La vacuna está siendo revisada por múltiples agencias reguladoras de todo el mundo, incluso para indicaciones y poblaciones adicionales como los adolescentes y como refuerzo. Además de su vacuna COVID-19, Novavax también está evaluando actualmente un candidato a vacuna combinada contra la gripe estacional-COVID en un ensayo clínico de fase 1/2, que combina NVX-CoV2373 y NanoFlu\*, su candidato a vacuna tetravalente contra la gripe en investigación, y también está evaluando una vacuna basada en la cepa Omicron (NVX-CoV2515), así como una vacuna bivalente basada en la cepa Omicron / original. Estas vacunas candidatas incorporan el adyuvante Matrix-M, propiedad de Novavax, a base de saponina, para mejorar la respuesta inmunitaria y estimular altos niveles de anticuerpos neutralizantes.

Fuente: PR Newswire. Disponible en <https://prn.to/3U1zJkZ>

## **BioVaxys anuncia la síntesis completa de su vacuna candidata Pan-Sarbecovirus**

**6 sep.** BioVaxys Technology Corp. anunció que Millipore-Sigma, el fabricante por contrato para su programa preclínico de vacunas virales, ha completado la bioproducción y detección de endotoxinas de liberación por lotes de BVX-1021, la vacuna de la compañía para el SARS-CoV, que se está utilizando en colaboración con la Universidad Estatal de Ohio (OSU) para desarrollar una vacuna contra el sarbecovirus. El siguiente paso es medir el desarrollo de anticuerpos neutralizantes contra los sarbecovirus luego de la inmunización de los animales de estudio con BVX-1021, seguida de la administración de una vacuna contra el SARS-CoV-2, en este caso con BVX-0320, la vacuna de la empresa candidata contra la COVID-19.

En junio, la compañía reveló que se determinó que los rendimientos de la proteína recombinante SARS-1 obtenida de un proveedor chino para la bioproducción de BVX-1021 contenían la presencia de un subproducto agregado de proteína natural además de la proteína SARS-1. Aunque no es probable que haya afectado los estudios de anticuerpos neutralizantes, la compañía consideró prudente sintetizar BVX-1021



utilizando un nuevo lote de proteína SARS-1 recombinante del proveedor que eliminó el agregado de proteína extraña. Un brote de la COVID-19 en agosto en un proveedor de los reactivos necesarios para el control de calidad/control de calidad final provocó un pequeño retraso en la liberación final de BVX-1021.

BVX-1021 es objeto de una colaboración de investigación en curso entre OSU y BioVaxys que está evaluando el enfoque novedoso de la compañía para una "vacuna universal" que pueda tratar una amplia gama de sarbecovirus. Se trata de una familia de virus que incluye el SARS-CoV-2 y variantes emergentes, el SARS-CoV-1 y una amplia gama de otros virus zoonóticos potencialmente peligrosos. La colaboración, que comenzó a principios de este año, está evaluando la combinación de BVX-0320 y BVX-1021 de BioVaxys en un modelo de cobaya. Los principales criterios de valoración del estudio son el desarrollo de anticuerpos neutralizantes de virus contra el virus vivo SARS-CoV-2 y otros sarbecovirus, incluidos los coronavirus relacionados con el SARS de murciélagos y pangolines.

Los murciélagos son un reservorio importante de muchas cepas de SARS, y se han identificado varias cepas en civetas de palma, que probablemente fueron antepasados de SARS-CoV-1 ("SARS-1") (Journal of Virology. 84 (6): 2808– 19, 2010). La presencia de anticuerpos neutralizantes en el modelo animal sugeriría fuertemente que BVX-1021 conferiría una respuesta inmunitaria adicional en todos los sarbecovirus en aquellas personas completamente vacunadas contra la COVID-19, así como en aquellas con inmunidad natural.

El director general y responsable de operaciones de BioVaxys, Kenneth Kovan, comentó: "Ahora que se ha sintetizado BVX-1021 utilizando la proteína SARS1 purificada, OSU ahora puede completar los estudios de anticuerpos neutralizantes. Salvo circunstancias imprevistas, anticipamos los datos del estudio en septiembre".

### **Acerca de BioVaxys Technology Corp.**

Con sede en Vancouver, BioVaxys Technology Corp. (www.biovaxys.com) es una compañía de biotecnología en etapa clínica registrada en la Columbia Británica que está desarrollando plataformas de vacunas virales y oncológicas, así como inmunodiagnósticos. La compañía está avanzando en las vacunas para el SARS-CoV-2, el SARS-CoV-1 y una vacuna contra el sarbecovirus basada en su tecnología de proteína viral haptenizada, y está planeando un ensayo clínico de su vacuna de células autólogas haptenizadas utilizada en combinación con inhibidores del punto de control anti-PD1 y anti-PDL1 que se desarrollarán inicialmente para el cáncer de ovario en estadio III/estadio IV. También se encuentra en desarrollo CoviDTH®, un diagnóstico para evaluar la presencia o ausencia de una respuesta inmune de células T al SARS-CoV-2, el virus que causa la COVID-19. BioVaxys tiene dos patentes estadounidenses emitidas y múltiples solicitudes de patentes estadounidenses e internacionales relacionadas con sus vacunas contra el cáncer, vacunas antivirales y tecnologías de diagnóstico. Las acciones ordinarias de BioVaxys cotizan en la CSE con el símbolo bursátil "BIOV" y se negocian en la Bolsa de Frankfurt (FRA: 5LB) y en Estados Unidos (OTCQB: BVAXF)

The logo for BioVaxys, featuring the word "BIOVAXYS" in a bold, teal, sans-serif font.

Fuente: PR Newswire. Disponible en <https://prn.to/3qqEabL>

## Pfizer isn't sharing Covid vaccines with researchers for next-gen studies

**Sep 6.** Researchers studying next-generation vaccines to fight an evolving COVID-19 threat are running into problems getting existing vaccines to use in their research.

Because Pfizer and Moderna hold the patents for the current vaccines, researchers would likely have to get the companies' permission to use them for research into products like nasal or pan-coronavirus vaccines. Right now, Pfizer isn't sharing its vaccines for research purposes, a spokesperson confirmed to STAT. Moderna didn't comment when we asked.



Pfizer's stance is legal and in line with the company's commercial interests, said Ana Santos Rutschman, a professor of law at Villanova University.

"If you use this thing that has been patented, what you're doing doesn't matter. Even if you're trying to cure cancer, the law is pretty rigid," she said.

But some university researchers argue the posture slows global progress toward more effective vaccines in the future, especially since the United States has already wasted tens of millions of doses of the COVID-19 vaccines.

Yale University virologist and immunologist Akiko Iwasaki has designed a study of nasal vaccines against COVID-19, which she argues could provide better protection against infection and transmission than shots alone. The ideal study would be conducted on subjects that have already had a primary vaccine series, to simulate real-world scenarios. She inquired with Pfizer about obtaining some vaccine to use in her study of nasal vaccines, but has not received any.

"In order for us to develop a better vaccine, we need a comparator. For that reason, everyone who's doing research in this area is in the same boat, we don't have access to do a comparison," Iwasaki said.

Iwasaki brought the issue up briefly at the White House's summit on the future of Covid vaccines on July 26, and presidential science adviser Francis Collins said at the time that he "would not have thought of that" hurdle.

California Institute of Technology professor Pamela Bjorkman said her lab has had similar troubles obtaining existing COVID-19 vaccines that would otherwise be discarded in order to research a vaccine candidate that could provide protection against a variety of COVID-19 variants.

"Whatever policy prevents using such vials does a great disservice to global efforts to develop new and improved vaccines," Bjorkman said.

When asked whether Pfizer has provided any vaccines for research purposes, spokesperson Sharon Castillo said, "We are not accepting or reviewing applications for possible clinical research that studies the COVID-19 vaccine."

Another Pfizer spokesperson also said the company has its own "extensive studies" of the vaccine underway, and will continue to share information from those studies as it becomes available.

Fuente: STAT News. Disponible en <https://bit.ly/3d5JGNP>

## Varios biomarcadores predicen la progresión de la infección por SARS-CoV-2

**6 sep.** Después de dos años de pandemia, la COVID-19 se mantiene como una amenaza global inminente. Aunque la mayoría de las infecciones permanecen asintomáticas o solo causan síntomas leves, los casos graves aún causan una morbilidad y mortalidad significativas.

Sobre la base del conocimiento actual, la hiperinflamación desempeña un papel fundamental en la progresión de la enfermedad y el deterioro clínico, lo que sugiere que las mediciones de biomarcadores basados en el sistema inmunitario representan herramientas prometedoras para la detección temprana de la probabilidad de deterioro. Estos parámetros pueden estar disponibles en cuestión de minutos a través de pruebas en el punto de atención y la información proporcionada por los biomarcadores inmunitarios podría facilitar y acelerar el trabajo de diagnóstico.

Los microbiólogos médicos de la Universidad de Saarland (Homburg, Alemania), reclutaron en un estudio a 132 pacientes (edad media 64 años, 40,2 % mujeres) que tenían una infección confirmada por reacción en cadena de la polimerasa (PCR) con SARS-CoV-2 (excepto los controles), durante la segunda y tercera ola pandémica experimentada en Alemania (diciembre de 2020 a julio de 2021). El grupo de control estaba formado por 27 adultos (edad media 47,1 años, rango 22-83; 19 [70,4 %] mujeres), compuesto por 19 adultos en el grupo 1 y ocho adultos en el grupo 2. Se analizaron de rutina hisopos nasofaríngeos, muestras de sangre y RT-PCR para el SARS-CoV-2 al ingreso y regularmente durante la estancia en el hospital para tener en cuenta los cambios dinámicos en los niveles de biomarcadores a lo largo del tiempo.

Los investigadores utilizaron una plataforma novedosa, MeMed Key (MeMed, Tirat Carmel, Israel), que mide los niveles circulantes de las tres proteínas inmunitarias de respuesta del huésped: ligando inductor de apoptosis relacionado con TNF (TRAIL), proteína 10 inducida por interferón gamma (IP-10) y proteína C reactiva (PCR). El método se basa en un inmunoensayo quimioluminiscente. Los niveles de TRAIL, IP-10 y PCR se midieron en el sitio de estudio en muestras de suero.

Los científicos realizaron un total de 899 mediciones. Entre los pacientes con COVID-19, los niveles de TRAIL fueron significativamente más bajos (49,5 frente a 87 pg/mL), mientras que IP-10 y PCR mostraron niveles significativamente más altos (667,5 frente a 127 pg/mL) y 75,3 frente a 1,6 mg/L que los controles sanos. TRAIL arrojó una correlación inversa con la duración de la estancia en el hospital y en la unidad de cuidados intensivos (UCI), la Puntuación de Fisiología Aguda Simplificada II y la Puntuación Nacional de Alerta Temprana, y la IP-10 mostró una correlación positiva con la gravedad de la enfermedad. La regresión





multivariable reveló que la obesidad (relación de probabilidad ajustada [aOR] 5,434), PCR (aOR 1,014) y la IP-10 pico (aOR 1,001) fueron predictores independientes de mortalidad en la UCI.

Los autores concluyeron que TRAIL e IP-10 mostraron una correlación significativa con la gravedad de la COVID-19, y que los niveles de PCR e IP-10 se asociaron con resultados adversos de la COVID-19. Esto sugiere que la inclusión de estos marcadores en modelos de evaluación de riesgo multivariable podría ser una herramienta prometedora en el manejo de pacientes con COVID-19. El estudio fue publicado el 1 de septiembre de 2022 en la revista *International Journal of Infectious Diseases*.

Fuente: LabMedica. Disponible en <https://bit.ly/3BbMMrL>

## La Comisión Europea adquiere más de 170.000 dosis de la vacuna contra la viruela del mono

**7 sep.** La Comisión Europea adquirió este miércoles más de 170.000 dosis de la vacuna de tercera generación contra la viruela que comercializa la farmacéutica Bavarian Nordic's, para hacer frente al actual brote de la viruela del mono.

La Autoridad de Preparación y Respuesta Sanitaria (HERA) obtuvo 170.920 dosis de la vacuna, según informó este miércoles Bruselas en un comunicado, por lo que desde que estalló el brote, la Comisión ha comprado ya 334.540 en nombre de todos los países de la Unión Europea.

El Ejecutivo comunitario distribuirá las dosis a los países de la UE antes de que acabe el año, de forma proporcional a su población, como ha hecho durante la pandemia de coronavirus.

"Aunque hemos visto disminuir el número de casos de viruela del simio en la UE durante las últimas semanas, la amenaza no ha pasado y no podemos bajar la guardia. Debemos continuar manteniendo el ritmo de nuestros esfuerzos para proteger a nuestros ciudadanos, especialmente a los más vulnerables", dijo la comisaria europea de Sanidad, Stella Kyriakides.

Según los datos ofrecidos por la Comisión, desde que empezó el brote de viruela del mono se han detectado 18.463 casos en los países del Espacio Económico Europeo (EEE), que incluye a los 27 Estados de la UE más Noruega, Islandia y Lichtenstein.

Fuente: HERALDO SALUDABLE. Disponible en <https://bit.ly/3d8HhBZ>

## Nigeria, Cuba To Collaborate In Vaccine Production

**Sep 7.** Nigeria is set to enter into a partnership with the Republic of Cuba to produce vaccines collaboratively.

The Minister of Science, Technology and Innovation, Sen. Adeleke Mamora revealed this when he received the Ambassador of The Republic of Cuba, Mrs. Clara Pulido, who paid him a courtesy visit in his office in Abuja.

Mamora noted that the collaboration will ensure that companies producing vaccines in the Republic of Cuba can be established in Nigeria for fruitful bilateral relationship.

The minister conceded that, although Cuba has done so much in the primary health sector, Nigeria is replicating the same for her growth and development.

He expressed the willingness of the Federal Government to collaborate with the Republic of Cuba in vaccine production, to tap into Cuba's wealth of experience to achieve Nigeria's quest for health for all in the country.

"Vaccine production," the minister said, "will play a key role in tackling the emerging and re-emerging diseases in country, such as malaria, Lassa fever, monkey pox, as all diseases have been declared emergencies globally."

Mamora further revealed that Nigeria is making serious efforts in producing vaccines locally, to enable the country prevent childhood diseases such as polio, tetanus and tuberculosis.

In a statement by the ministry's deputy director, press and public relations, Atuora Obed, Mamora said "the knowledge and experience of those who are ahead of us in vaccine technology is something we must learn through technology transfer".

Pulido said the visit was to felicitate the minister on his appointment and resumption of duty and to seek the ministry's collaboration in vaccine production for betterment of the society.

Fuente: Science Nigeria. Disponible en <https://bit.ly/3U04iHU>

## Cuba en el avance de candidatos vacunales contra el dengue

**8 sep.** Cuba centra esfuerzos en el avance de candidatos vacunales que inducen la respuesta inmunológica celular contra los cuatro serotipos del virus del dengue, estrategia que chequeó en el Centro de Ingeniería Genética y Biotecnología (CIGB), Eduardo Martínez Díaz, presidente de BioCubaFarma, según el perfil de Facebook de esa organización.

Igualmente, explicó el directivo que desde hace tiempo se labora en varios proyectos relacionados con esa enfermedad, que, se han acelerado en la actualidad, a partir de un pedido del Primer Secretario del Partido y Presidente de la República, Miguel Díaz-Canel Bermúdez.

El experto explicó que las investigaciones están a cargo del CIGB con el Instituto de Medicina Tropical Pedro Kourí (IPK), y destacó que cuentan con trabajos basados en la bioinformática y el estudio de la interacción del virus con su receptor.

Es a partir de esos conocimientos que se están diseñando moléculas que tengan un efecto antiviral específico contra el dengue; que eviten, por ejemplo, la entrada del virus a la célula.



Fuente: Radio Rebelde. Disponible en <https://bit.ly/3U6Vd07>

## U.S. starts enrollment in trial testing Siga's antiviral for monkeypox

**Sep 9.** The National Institutes of Health (NIH) said on Friday it had started enrolling monkeypox patients in a late-stage study testing Siga Technologies Inc's (SIGA.O) antiviral pill Tpoxx against the disease.

The oral and intravenous formulations of Tpoxx are approved by the U.S. Food and Drug Administration for the treatment of smallpox, but does not yet have clearance to treat monkeypox.

It is, however, currently accessible by clinicians for treating monkeypox under a compassionate use request.

The NIH aims to enroll more than 500 patients, including both adults and children, who will then be randomized to receive either Tpoxx or placebo pills for 14 days.

Investigators will evaluate if participants receiving Tpoxx heal more quickly compared to placebo, as well as provide critical data on the optimal dosing and safety of the drug in children and people who are pregnant.

The United States has recorded more than 21,000 confirmed cases of monkeypox, according to data from the Centers for Disease Control and Prevention.

Fuente: Reuters. Disponible en <https://reut.rs/3LbnYEU>



## Vacuna cubana Soberana recibe opinión técnica favorable en México

**10 sep.** El Comité de Moléculas Nuevas (CMN) de la Comisión Federal para la Protección contra Riesgos Sanitarios (Cofepris) de México, emitió un voto favorable a la vacuna cubana Soberana 02.

La información aparece hoy publicada por Cofepris en un comunicado luego de una reunión la víspera para llevar a cabo la 165 Sesión Extraordinaria de la CMN.

Es la segunda vacuna latinoamericana en someterse a consideración del CMN y el resultado representa un paso previo a la autorización de uso de emergencia en el país, subraya el comunicado.

Agrega que en esa sesión fue expuesta la información técnico-científica para evaluación de la vacuna Soberana para adultos, recibiendo una opinión técnica favorable.

En esta ocasión, añade, se presentó la evidencia para el uso de la vacuna Soberana como primo



vacunación en adultos, es decir, para población que no ha sido inmunizada anteriormente.

Este producto consiste en un conjugado de proteína de dominio de unión a receptor de la proteína S de SARS-CoV-2 (RBD) recombinante con toxoide tetánico, e hidróxido de aluminio como adyuvante.

Cabe resaltar, expresa Cofepris, que esta vacuna, presentada por Neuronic Mexicana S.A. de C.V. e Instituto Finlay de Vacunas, es la segunda de origen latinoamericano en ser evaluada ante este grupo de expertos, seguida de Abdala, también de Cuba, primer biológico hispanoamericano contra Covid-19, presentado el 31 de agosto de 2021.

La Cofepris precisa que el CMN es un órgano auxiliar de consulta que forma parte de agencia reguladora; emite opiniones no vinculantes sobre medicamentos e insumos para la salud, basándose en la evidencia científica y médica presentada, por lo que este paso no representa la autorización final para uso de emergencia.

Fuente: EIPaís.cr. Disponible en <https://bit.ly/3L75MMm>

## Vacunas Covid: un nuevo hallazgo podría eliminar la necesidad de tantas dosis de refuerzo

**11 sep.** Las nuevas vacunas contra la COVID-19 ya son eficaces contra las nuevas variantes de Ómicron, un aspecto que preocupaba a los expertos, debido a la facilidad con la que mutaba el virus. Las principales agencias de medicamentos ya las han aprobado, por lo que estas comenzarán a inocularse a partir de este mismo otoño.

Sin embargo, los científicos siguen preocupados de que estas nuevas vacunas pierdan efectividad en un futuro contra las variantes que aún están por llegar. Por eso, el descubrimiento de un grupo de investigadores de Tel Aviv (Israel) podría dar un giro radical a esta preocupación.

Y es que este grupo de científicos ha hecho un nuevo hallazgo sobre el virus y la gente que ya lo ha padecido que eliminaría la necesidad de vacunarse con dosis de refuerzo actuales y abriría la puerta a poder dejar de hacerlo con las dosis que se fabricarían por nuevas variantes aún inexistentes.

Importante descubrimiento sobre los anticuerpos

Según el estudio publicado en la revista 'Nature Communications Biology', el equipo ha demostrado que los anticuerpos aislados del sistema inmunitario de los pacientes que se han recuperado de la COVID-19 son eficaces para neutralizar todas las cepas conocidas del virus, incluidas las variantes Delta y la última, Ómicron.

¿Y cómo es posible esto? Porque el estudio es una extensión de otro que ya se realizó en octubre de 2020, en pleno momento crítico de la pandemia de la COVID-19. En ese momento, se secuenciaron todas las células del sistema inmunitario B de la sangre de los que se han recuperado de la primera cepa y se





aislaron nueve anticuerpos. Ahora, algunos de esos anticuerpos pueden neutralizar las nuevas variantes Delta y Ómicron.

### ¿Evitaría las dosis de refuerzo antes nuevas variantes aún no aparecidas?

Tal y como explica la doctora Natalia Freund, principal autora del estudio, los anticuerpos más eficaces eran los que se unían a la proteína espiga del virus. "En el estudio actual, demostramos que otros dos anticuerpos que se unen a la proteína viral de la espiga en una zona diferente de la región en la que se concentraban son en realidad muy eficaces para neutralizar las variantes", asegura la experta.

### Los investigadores identificaron dos anticuerpos:

- TAU-1109: eficaz para neutralizar la cepa Ómicron es del 92% y para la cepa Delta del 90%.
- TAU-2310: neutraliza la variante Ómicron con una eficacia del 84%, y la variante Delta con una eficacia del 97%.

"Por razones que no comprendemos del todo, el nivel de anticuerpos contra la COVID-19 disminuye después de tres meses, por lo que vemos personas que se reinfectan incluso después de haber sido vacunadas tres veces. Por lo que el tratamiento dirigido con anticuerpos y su entrega en altas concentraciones puede servir como sustituto eficaz para los refuerzos de las vacunas", afirma, para concluir que "es posible que al usar este tratamiento no se tenga que proporcionar dosis de refuerzo a toda la población cada vez que haya una nueva variante".

Fuente: ONDA CERO. Disponible en <https://bit.ly/3eH3rf1>



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## Patentes registradas en Patentscope

Estrategia de búsqueda: *Vaccine in the title or abstract AND 20220901:20220911 as the publication date.*

58 records

1. [20220280631](#) VIRAL PANDEMIC VACCINE

US - 08.09.2022

Int.Class [A61K 39/12](#) Appl.No 17194308 Applicant Henry J. Smith Inventor Henry J. Smith

This invention teaches a means of rapidly producing a vaccine following a viral outbreak and using said vaccine to prevent the outbreak from becoming a pandemic. Said vaccine is composed of multiple immunostimulatory agents (agonists) incorporated in liposomes. Each agonist will bind to its specific cellular receptor and induce the cell to produce type 1 interferons which has strong anti-viral activity. The agonists are Poly IC, ssRNA, CpG-ODN and MPL-A incorporated in a liposomal vaccine. Using multiple different agonists in the vaccine will elicit a stronger innate immune response than using a single agonist. This vaccine can be enhanced by combining a viral antigen with the agonists in the liposome. Said enhanced vaccine will provide immediate and prolonged immunity to viral infection by stimulating both the innate immune response and the adaptive immune response against the virus.

2. [WO/2022/186661](#) MULTIVALENT VACCINE COMPOSITION FOR PREVENTION OF PORCINE MYCOPLASMA AND PORCINE CIRCOVIRUS INFECTION

WO - 09.09.2022

Int.Class [A61K 39/295](#) Appl.No PCT/KR2022/003112 Applicant INNOVAC Inventor HAHN, Tae Wook

The present invention relates to a multivalent vaccine composition for prevention of porcine mycoplasma and porcine circovirus infections and an infection prevention method using same. The multivalent vaccine composition according to the present invention exhibits a reciprocally supplemental effect on immune responses in pigs used as experimental animals and target animals and does not allow for interference between antigens. When inoculated into pigs, the vaccine composition induces high serological levels of



antibody titers and neutralizing antibody titers and produces a high level of IFN- $\gamma$  for Mhp or PCV2 sensitization in PBMC. Thus, the vaccine composition can find advantageous applications for preventing porcine mycoplasma and porcine circovirus infections.

3. [WO/2022/181897](#) RECOMBINANT ADENOVIRUS VACCINE FOR CORONAVIRUS DISEASE 19 (COVID-19), AND COMBINATION THERAPY USING SAME

WO - 01.09.2022

Int.Class [A61K 39/42](#) Appl.No PCT/KR2021/009108 Applicant GENEUIN-TECH CO., LTD. Inventor HAN, Eun Yeong

The present invention relates to a recombinant adenovirus live vaccine for preventing coronavirus disease 19 (COVID-19) infection, which broke out in Wuhan, China in 2019, and to a combination therapy using the recombinant adenovirus live vaccine. The recombinant adenovirus according to the present invention can be used to produce an antibody specific to a novel coronavirus antigen, and thereby develop a COVID-19 vaccine which is fast-acting and harmless to the human body. In addition, the combination therapy of the recombinant adenovirus vaccine and a compound according to the present invention can be used to more effectively and safely prevent or treat not only COVID-19 but also viral diseases such as herpes simplex virus (HSV) infection.

4. [WO/2022/180534](#) VACCINE COMPOSITION COMPRISING A LEISHMANIA HOST CELL EXPRESSING AT LEAST ONE PROTEIN OF THE FAMILY CORONAVIRIDAE

WO - 01.09.2022

Int.Class [C07K 14/005](#) Appl.No PCT/IB2022/051585 Applicant UNIVERSITA' DEGLI STUDI DI MILANO Inventor BANDI, Claudio

The present invention relates to a vaccine composition comprising a host cell belonging to the genus Leishmania, wherein the host cell comprises a polynucleotide coding for at least one protein of a virus belonging to the family Coronaviridae. Furthermore, the invention relates to the medical and veterinary use of the vaccine composition and to a process for preparing the vaccine composition.

5. [WO/2022/179318](#) S PROTEIN R815 SITE-BASED CORONAVIRUS INTERVENTION METHOD AND PRODUCT

WO - 01.09.2022

Int.Class [C07K 14/165](#) Appl.No PCT/CN2022/070763 Applicant INSTITUT PASTEUR OF SHANGHAI, CHINESE ACADEMY OF SCIENCES Inventor MENG, Guangxun

Provided in the present invention are an S protein R815 site-based novel coronavirus intervention method and a product. Particularly, provided in the present invention are an antigen peptide and a vaccine polypeptide of novel coronavirus. Further provided in the present invention are a vaccine composition containing the antigen peptide or the vaccine polypeptide and the use thereof. Experiments show that the antigen peptide or the vaccine polypeptide of the present invention can effectively prevent S protein from producing cell fusion and infection effects, thereby effectively preventing the infection of novel coronavirus.

6. [WO/2022/182940](#) NEURAL CONTROL OF ADAPTIVE IMMUNITY

WO - 01.09.2022

Int.Class [A61K 39/00](#) Appl.No PCT/US2022/017819 Applicant THE FEINSTEIN INSTITUTES FOR MEDICAL RESEARCH Inventor CHAVAN, Sangeeta S.

The present invention provides methods for modulating antigen-specific antibody responses by administering to a mammal a compound that selectively either activates or inhibits a specific subset of sensory neurons that express TRPV1. The methods include providing a vaccine adjuvant in a subject who is being administered an immunogen-specific vaccine, which comprises administering to said subject an immunogen-specific antibody production enhancing amount of a TRPV1 nociceptor agonist. The methods

also include increasing antibody production in a subject to at least one antigen contained in a vaccine that is being administered to said subject, which comprises administering to said subject an antibody-production increasing amount of a TRPV1 nociceptor agonist.

7. [20220280630](#) VACCINE COMPOSITIONS AND METHODS OF SELECTING ANTIGENS

US - 08.09.2022

Int.Class [A61K 39/095](#) Appl.No 17631694 Applicant Trustees of Tufts College Inventor Paola MASSARI

Described herein are vaccine compositions and methods of selecting an antigen or fragment thereof for the preparation of a vaccine composition. The methods and vaccine compositions described herein are based, in part, on the discovery that certain polypeptides not previously identified or considered for potential use as antigens from pathogenic microorganisms (e.g., *N. gonorrhoeae*) can provoke an immune response in a subject. The methods of identifying and selecting the antigens described herein rely, in part, on approaches that identify polypeptides (e.g., hypothetical proteins) predicted to be immunogenic.

8. [4051296](#) FIBROBLAST-DERIVED UNIVERSAL IMMUNOLOGICAL COMPOSITION

EP - 07.09.2022

Int.Class [A61K 35/17](#) Appl.No 20880517 Applicant FIGENE LLC Inventor O'HEERON PETE

Described are means of generating immunological compositions that are universally applicable for induction of immunity to neoplasia regardless of histological origin of tissue. Certain methods concern fibroblasts that are manipulated or dedifferentiated in a manner to induce expression of tumor associated antigens including cancer testis antigens. These cells are used as a source of antigenic stimuli for creation of a cellular vaccine, and/or an exosome vaccine, and/or a lysate-based vaccine.

9. [20220273787](#) CO-ADMINISTRATION OF SEASONAL INFLUENZA VACCINE AND AN ADENOVIRUS BASED RESPIRATORY SYNCYTIAL VIRUS VACCINE

US - 01.09.2022

Int.Class [A61K 39/12](#) Appl.No 17595255 Applicant Janssen Vaccines & Prevention B.V. Inventor Benoit Christophe Stephan CALLENDRET

Methods of inducing a protective immune response against respiratory syncytial virus (RSV) and against influenza virus, without inducing a severe adverse event in human subjects are described. The methods include administering to the subjects an effective amount of an adenoviral vector encoding a recombinant RSV F polypeptide that is stabilized in a pre-fusion conformation, along with an effective amount of an influenza vaccine.

10. [20220280629](#) ANTIMICROBIAL VACCINE COMPOSITIONS

US - 08.09.2022

Int.Class [A61K 39/08](#) Appl.No 17638732 Applicant ONEBIOPHARMA, INC. Inventor Rebecca DABORA

This invention is directed to antimicrobial vaccine compounds and compositions comprising oligosaccharide  $\beta$ -(1 $\rightarrow$ 6)-glucosamine groups having from 3 to 12 glucosamine units linked through a linker group to tetanus toxoid wherein the toxoid is primarily in its monomeric form. This invention is also directed to vaccine compositions that provide natural immunity against microbes possessing a cell wall structure that comprises oligosaccharide N-acetyl- $\beta$ -(1 $\rightarrow$ 6)-glucosamine (PNAG) structures.

11. [WO/2022/180648](#) ACTIVATED-QUENCHED POLYSACCHARIDE AND IMPROVED METHODS FOR QUANTIFICATION OF POLYSACCHARIDE IN A VACCINE COMPOSITION

WO - 01.09.2022

Int.Class [A61K 39/09](#) Appl.No PCT/IN2022/050168 Applicant BIOLOGICAL E LIMITED Inventor BURKI, Rajendar

The present invention provides a novel reference standard, comprising of activated-quenched polysaccharide, for quantifying polysaccharide content in a vaccine composition using nephelometry. The invention also provides a method for preparing the activated-quenched polysaccharide, for use as a reference standard. Further, a nephelometry based method for quantifying the polysaccharides in a multivalent conjugate vaccine is also provided. The reference standard of the present invention, comprising of the activated-quenched polysaccharide, is stable and can be used for accurate quantification of polysaccharides through nephelometry.

12. [20220273788](#) VACCINE

US - 01.09.2022

Int.Class [A61K 39/12](#) Appl.No 17628286 Applicant THE PIRBRIGHT INSTITUTE Inventor Linda Dixon

The present invention provides an African swine fever virus (ASFV) subunit vaccine which comprises: (i) one or more recombinant polynucleotides which encode polypeptides shown as SEQ ID NO: 1, 2 and 3 or an immunogenic fragment thereof; or a variant with at least 70% sequence identity to one of SEQ ID NO: 1, 2 or 3; wherein the total number of different ASFV polypeptides encoded by the one or more recombinant polynucleotides is 10 or fewer; or (ii) recombinant polypeptides shown as SEQ ID NO: 1, 2 and 3 or an immunogenic fragment thereof; or a variant with at least 70% sequence identity to one of SEQ ID NO: 1, 2 and 3; wherein vaccine comprises 10 or fewer different ASFV polypeptides.

13. [20220280441](#) FILM WITH LATERALLY ADJOINED STRIPS FOR ADMINISTRATION OF A VACCINE

US - 08.09.2022

Int.Class [A61K 9/70](#) Appl.No 17752325 Applicant CA Pharma Inc. Inventor Michael Bousfield

A film for administration to a mucosal membrane is provided. The film comprises a first film strip comprising a vaccine in a first film matrix comprising at least one film-forming agent, and at least one of a surfactant, emulsifier and/or a plasticizer, and a second film strip comprising an adjuvant in a second film matrix comprising at least one film-forming agent, and at least one of a surfactant, emulsifier and/or a plasticizer. The first and second strips of the film are laterally adjoined along an edge of the first and second strips to provide a single layer film in which the vaccine and adjuvant are not admixed prior to administration.

14. [20220273790](#) RATIONALLY ENGINEERED CARRIER PROTEINS FOR VACCINES

US - 01.09.2022

Int.Class [A61K 39/385](#) Appl.No 17618122 Applicant Citranvi Biosciences, LLC Inventor Avvari Krishna Prasad

The invention relates to the design of rationally engineered Carrier Proteins (reCaPs) geared towards producing Multifunctional Chimeric recombinant Fusion Proteins (MCFPs) useful as vaccine candidates. The key components of the MCFPs are (i) genetically engineered carrier proteins; (ii) polypeptide antigens; (iii) linker peptides, optionally fused to heterologous T-cell epitopes; (iv) Dual Function Peptides (DFP) which can act as a purification aids as well having the non-covalent affinity to bind to an adjuvant. The present invention also relates to recombinantly expressed Self-Assembling Adjuvanted Nanoparticles (SAANPs), comprising reCaPs fused with various polypeptide and protein antigens, useful as vaccine candidates. The present invention also provides novel 'integrated Multiple Conjugate Antigen displayed Adjuvanted Systems' [iMCAAS], comprising rationally engineered Carrier Proteins, based on 'Self Assembling Adjuvanted Nanoparticles' [SAANPs]. These adjuvanted nanoparticles, eventually provide

stronger antigen-antibody interactions compared to the low affinity interactions provided by the monovalent binding generated by single antigen immunogens.

15. [20220280633](#) VIRUS-LIKE PARTICLE VACCINES

US - 08.09.2022

Int.Class [A61K 39/12](#) Appl.No 17631435 Applicant Verndari, Inc. Inventor Daniel R. Henderson

Provided, herein, in certain embodiments are virus-like particles such as synthetic enveloped VLPs or synthetic membrane VLPs. In some embodiments, the VLPs comprise a lipid bilayer. In some embodiments, the VLPs comprise a purified antigen anchored to the lipid bilayer. Some embodiments relate to vaccines comprising the VLP, methods of using the vaccine, and methods of making the vaccine or VLP.

16. [WO/2022/184287](#) FULLY SYNTHETIC, LONG-CHAIN NUCLEIC ACID FOR VACCINE PRODUCTION TO PROTECT AGAINST CORONAVIRUSES

WO - 09.09.2022

Int.Class [A61K 39/12](#) Appl.No PCT/EP2021/074738 Applicant ROCKETVAX AG Inventor CHRISTEN, Matthias

This invention describes a fully synthetic, long-chain nucleic acid that can be used in biotechnological manufacturing processes to produce envelope proteins, virus envelopes and fragments of virus envelopes of SARS-CoV-2 and related coronaviruses in highly purified form, which, as a vaccine protect against COVID-19 and other viral diseases

17. [20220280628](#) SELF-ADJUVANTING YERSINIA OUTER MEMBRANE VESICLE AS A VACCINE AGAINST PLAGUE, ANTHRAX AND PSEUDOMONAS INFECTION

US - 08.09.2022

Int.Class [A61K 39/02](#) Appl.No 17482527 Applicant Albany Medical College Inventor Wei Sun

A vaccine platform using a *Yersinia pestis* mutant synthesizing an adjuvant form lipid A (monophosphoryl lipid A, MPLA) for the increased biogenesis of bacterial outer membrane vesicles (OMVs). To enhance the immunogenicity of the OMVs, an Asd-based balanced-lethal host-vector system was constructed to oversynthesize the LcrV antigen of *Y. pestis*, raise the amounts of LcrV enclosed in OMVs by Type II secretion system, and eliminate harmful factors like plasminogen activator (Pla) and murine toxin from the OMVs. Vaccination with OMVs containing MPLA and increased amounts of LcrV with diminished toxicity afforded complete protection in mice against subcutaneous challenge and intranasal challenge and was significantly superior to that resulting from vaccination with LcrV/alhydrogel. Additionally, the *Yersinia* OMV can be used as a platform to deliver the heterologous antigens of *Bacillus anthracis*. Vaccination with multiantigenic self-adjuvanting bionanoparticles from *Pseudomonas* was also successfully tested in connection with *Pseudomonas aeruginosa*.

18. [202217029494](#) CHIKUNGUNYA VIRUS-LIKE PARTICLE VACCINE AND METHODS OF USING THE SAME

IN - 02.09.2022

Int.Class [A61K /](#) Appl.No 202217029494 Applicant EMERGENT TRAVEL HEALTH INC. Inventor ALEXANDER, Jeffery L.

The present disclosure is directed to improved virus-like particle (VLP) compositions and vaccines for use in inducing an immune response and/or protective immunity against a Chikungunya virus (CHIKV) infection in a subject, e.g., by inducing a neutralizing antibody response against CHIKV in a subject within 7 days after administration of a single dose of the composition or vaccine.

19. [20220280619](#) DNA VACCINE AGAINST AMYLOID-BETA AND TAU

US - 08.09.2022

Int.Class [A61K 39/00](#) Appl.No 17734512 Applicant IMMUNOTHERAPY DEVELOPMENT INC. Inventor Yoh MATSUMOTO

An object of the present invention is to provide a vaccine that can simultaneously reduce A $\beta$  deposition and tau deposition in the brain by means of a single molecule. The present invention provides a recombinant vector comprising DNA encoding amyloid- $\beta$ , DNA encoding an immunoglobulin Fc sequence, and DNA encoding tau.

20. [20220273563](#) VACCINE ADJUVANT FORMULATION

US - 01.09.2022

Int.Class [A61K 9/127](#) Appl.No 17570635 Applicant Sumitomo Dainippon Pharma Co., Ltd. Inventor Akihisa Fukushima

The present invention provides a liposome useful as a vaccine adjuvant. More specifically, the present invention provides a liposome which comprises a lipid bilayer comprising dimyristoylphosphatidylcholine and egg phosphatidylglycerol and a conjugated compound in which a low-molecular weight compound enhancing the physiological activity of TLR7 is bound to squalene via a linker, said conjugated compound being encapsulated in the lipid bilayer.

21. [20220282322](#) INDIVIDUALIZED VACCINES FOR CANCER

US - 08.09.2022

Int.Class [C12Q 1/6869](#) Appl.No 17576170 Applicant TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg-Universität Mainz gG Inventor Ugur Sahin

The present invention relates to the provision of vaccines which are specific for a patient's tumor and are potentially useful for immunotherapy of the primary tumor as well as tumor metastases. In one aspect, the present invention relates to a method for providing an individualized cancer vaccine comprising the steps: (a) identifying cancer specific somatic mutations in a tumor specimen of a cancer patient to provide a cancer mutation signature of the patient; and (b) providing a vaccine featuring the cancer mutation signature obtained in step (a). In a further aspect, the present invention relates to vaccines which are obtainable by said method.

22. [20220282264](#) Endotoxin-free Production of Recombinant Subunit Vaccine Components

US - 08.09.2022

Int.Class [C12N 15/75](#) Appl.No 17651476 Applicant Ingenza Ltd. Inventor Ian Fotheringham

An endotoxin-free production of recombinant subunit vaccine components, and production methods thereof, using a synthetic virus-like-particle (VLP) to which is attached (and displayed) a fragment of the coronavirus "spike" protein, the Receptor Binding Domain (RBD) and wherein the VLP is produced very effectively using engineered *B. subtilis*.

23. [WO/2022/183120](#) DEVELOPMENT OF COVID-19 VACCINE USING A DUAL TLR LIGAND LIPOSOME ADJUVANT

WO - 01.09.2022

Int.Class [A61K 9/127](#) Appl.No PCT/US2022/018188 Applicant UNIVERSITY OF VIRGINIA PATENT FOUNDATION Inventor POMÉS, Anna

Disclosed are compositions for eliciting anti-SARS-CoV-2 immune responses in subjects. In some embodiments, the compositions include one or more SARS-CoV-2 antigens and one or more PEGylated liposomal adjuvants, wherein at least one of the PEGylated liposomal adjuvants includes a cholesterol, a



non-PEGylated neutral lipid, and a PEGylated lipid. Also provided are methods for using the presently disclosed compositions for stimulating anti-SARS-CoV-2 immune responses, for inducing anti-SARS-CoV-2 Th1 responses, for stimulating systemic immune responses and/or mucosal immune responses, for inducing anti-SARS-CoV-2 IgA responses, for reducing SARS-CoV-2-induced lung injuries, and for inducing anti-SARS-CoV-2 neutralizing antibodies in subjects in need thereof.

24. [20220281960](#) COMPOSITIONS AND METHODS FOR THE TREATMENT OF TUBERCULOSIS  
US - 08.09.2022

Int.Class [C07K 16/12](#) Appl.No 17627167 Applicant Ramot at Tel-Aviv University Ltd. Inventor Natalia FREUND

A human antibody comprising an antigen binding domain which binds PstS1 of *Mycobacterium tuberculosis* (TB) for use in preventing or treating TB infection in a subject in need thereof is provided. Also provided are vaccine compositions and conjugates of such antibodies.

25. [2022902404](#) Wearable animal vaccine insulation apparatus  
AU - 01.09.2022

Int.Class Appl.No 2022902404 Applicant Fisher, Marnie Inventor Fisher, Marnie

26. [WO/2022/186384](#) VACCINE AGAINST CYPRINID HERPESVIRUS 2  
WO - 09.09.2022

Int.Class [A61K 39/245](#) Appl.No PCT/JP2022/009448 Applicant NATIONAL UNIVERSITY CORPORATION TOKYO UNIVERSITY OF MARINE SCIENCE AND TECHNOLOGY Inventor SANO, Motohiko

The purpose of the present invention is to provide a method for controlling CyHV-2 infectious diseases in fish. The present invention pertains to a composition for use in controlling cyprinid herpesvirus 2 (CyHV-2) infectious diseases in fish, the composition containing attenuated CyHV-2.

27. [20220283161](#) METHODS AND COMPOSITIONS FOR HEPATITIS C VIRUS (HCV)  
US - 08.09.2022

Int.Class [G01N 33/576](#) Appl.No 17630104 Applicant The Johns Hopkins University Inventor Valerie Kinchen

Provided herein are, inter alia, methods, compositions and kits for HCV antigen and vaccine design. Preferred methods include measuring neutralization of HCV pseudoparticles (HCVpp) by antibodies specific for an HCV in the biological sample, generating a neutralizations profile of each biological sample; deconvoluting the HCV-specific neutralizing antibodies by generating reference antibody neutralization profiles; correlating the reference antibody neutralization profiles to the biological sample's neutralization profile; and, identifying the HCV neutralizing antibodies.

28. [3299030](#) PARENTERALE NOROVIRUS-VACCINEFORMULERINGER  
DK - 05.09.2022

Int.Class [A61K 39/125](#) Appl.No 17199372 Applicant Takeda Vaccines, Inc. Inventor RICHARDSON, Charles

The present invention relates to single dose parenteral vaccine compositions comprising mixtures of monovalent Norovirus virus-like particles. Methods of conferring protective immunity against Norovirus infections in a human subject by administering such compositions are also disclosed.

29. [WO/2022/180219](#) OPTIMIZED VACCINE TO ELICIT A T CELL IMMUNITY AGAINST SARS-COV-2  
WO - 01.09.2022

Int.Class [A61K 39/12](#) Appl.No PCT/EP2022/054809 Applicant KOSMATOPOULOS, Kostantinos (Kostas) Inventor KOSMATOPOULOS, Kostantinos (Kostas)

The invention pertains to immunogenic compositions designed to elicit both a humoral and a T-cell immunity against SARS-CoV-2. To this aim, the invention provides modified sequences of the S protein and/or the N protein of SARS-CoV-2, in which each of the introduced modifications is likely to increase the affinity of a cryptic epitope presented by one of the major HLA-I molecules (HLA-A1, -A2, -A3, -A24, -B7, -B35 and Cw7) for this HLA-I molecule.

30. [20220280623](#) NOVEL PEPTIDES AND COMBINATION OF PEPTIDES FOR USE IN IMMUNOTHERAPY AGAINST VARIOUS CANCERS

US - 08.09.2022

Int.Class [A61K 39/00](#) Appl.No 17743778 Applicant Immatics Biotechnologies GmbH Inventor Andrea MAHR

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

31. [4052575](#) USE OF A GRAPE EXTRACT AS A VIRUCIDE AGAINST VIRUSES FROM THE CORONAVIRUS FAMILY

EP - 07.09.2022

Int.Class [A01N 43/16](#) Appl.No 22305245 Applicant BERKEM DEV Inventor MESSAOUDI DAOUIA

La présente invention est du domaine de la désinfection et de l'antisepsie et concerne plus particulièrement l'utilisation d'un extrait de raisin en tant que virucide à l'encontre des virus de la famille des coronavirus, des adénovirus, des norovirus murins, des virus de la vaccine et des poliovirus.

32. [20220282330](#) HLA-H IN MEDICINE AND DIAGNOSTICS

US - 08.09.2022

Int.Class [C12Q 1/6881](#) Appl.No 17625063 Applicant Intellexon GmbH Inventor Wolfgang WÜRFEL

The present invention relates to a nucleic acid molecule, a vector, a host cell, or a protein or peptide, or combinations thereof for use as an immunosuppressant, as a tumor vaccine or as a pregnancy promoter wherein (I) the nucleic acid molecule is (a) encoding a polypeptide comprising or consisting of the amino acid sequence of SEQ ID NO: 1; or (b) consisting of the nucleotide sequence of SEQ ID NO: 2; or (c) encoding a polypeptide which is at least 70%, preferably at least 80% identical, more preferably at least 90% identical, and most preferred at least 95% identical to the amino acid sequence of SEQ ID NO: 1; or (d) consisting of a nucleotide sequence which is at least 70% identical, preferably at least 80% identical, more preferably at least 90% identical, and most preferred at least 95% identical to the nucleotide sequence of SEQ ID NO: 2; or (e) consisting of a nucleotide sequence which is degenerate with respect to the nucleic acid molecule of (d); or (f) a fragment of the nucleic acid molecule of any one of (a) to (e), said fragment comprising at least 150 nucleotides, preferably at least 300 nucleotides, more preferably at least 450 nucleotides, and most preferably at least 600 nucleotides; or (g) corresponding to the nucleic acid molecule of any one of (a) to (f), wherein T is replaced by U; (II) the vector comprises the nucleic acid molecule of (I); (III) the host cell is transformed, transduced or transfected with the vector of (II); and (IV) the protein or peptide being encoded by the nucleic acid molecule of (I).

33. [20220275041](#) MODIFIED IFNL3 POLYPEPTIDES COMPRISING A PHARMACOKINETIC ENHANCING MOIETY AND THEIR USES

US - 01.09.2022

Int.Class [C07K 14/555](#) Appl.No 17269363 Applicant Exalt Therapeutics, LLC Inventor John W. WALLEN, III

Non-human IFNL3 polypeptides and their uses thereof are provided. Exemplary embodiments provide IFNL3 polypeptides which include one or more amino acid substitutions, additions, or deletions with natural or non-naturally encoded amino acids, and/or linkage or fusion to other biologically active molecules including other IFNL3 polypeptides, as well as PK enhancing moieties (PKEMs). Additionally, use of said IFNL3 polypeptides for innate immune system stimulation, as a vaccine adjuvant, as well as treatment or prevention of diseases such as viral and bacterial infections, and inflammation, is also provided.

34. [20220280626](#) CIRCUMSPOROZOITE PROTEINS WITH INCREASED EXPRESSION IN MAMMALIAN CELLS

US - 08.09.2022

Int.Class [A61K 39/015](#) Appl.No 17440597 Applicant Fred Hutchinson Cancer Research Center Inventor Marie Pancera

Mutated and/or truncated malarial circumsporozoite proteins (CSP) and associated nucleic acids that are more stable and highly expressed in mammalian cells are described. The mutated and/or truncated CSP and associated nucleic acids can be expressed to produce malaria vaccine antigens.

35. [20220273782](#) Novel PD-L1 Targeting DNA Vaccine for Cancer Immunotherapy

US - 01.09.2022

Int.Class [A61K 39/00](#) Appl.No 17730909 Applicant Vaximm AG Inventor Heinz Lubenau

The present invention relates to an attenuated strain of *Salmonella* comprising at least one copy of a DNA molecule comprising an expression cassette encoding PD-L1. In particular, the present invention relates to said attenuated strain of *Salmonella* for use in the treatment of cancer.

36. [20220273786](#) ZIKA VIRUS VACCINE

US - 01.09.2022

Int.Class [A61K 39/12](#) Appl.No 17548721 Applicant Valneva Austria GmbH Inventor Jana Barbero Calzado

Described herein are Zika virus vaccines and compositions and methods of producing and administering said vaccines to subjects in need thereof.

37. [20220273789](#) THERAPEUTIC VIRAL VACCINE

US - 01.09.2022

Int.Class [A61K 39/245](#) Appl.No 17627998 Applicant GLAXOSMITHKLINE BIOLOGICALS SA Inventor Normand BLAIS

The present invention relates to viral Fc receptor or immunogenic fragments thereof for treating a viral infection in a subject and, in particular, a herpes virus infection. The present invention also relates to a heterodimer comprising or consisting of an Fc receptor from a HSV virus or an immunogenic fragment thereof and a binding partner from said HSV virus or a fragment thereof, for use in therapy.

38. [20220283158](#) METHOD OF IDENTIFYING PEPTIDE ANTIGENS AND USES THEREOF

US - 08.09.2022

Int.Class [G01N 33/564](#) Appl.No 17634164 Applicant HUMANIRAS MIRASOLE S.P.A. Inventor Marinos KALLIKOURDIS

The invention provides a new method for identifying peptide antigens relevant to a non-autoimmune disease involving T cell activation as well as novel peptides identified therefrom. The isolated peptides of the invention are useful in the diagnosis, prevention and/or treatment of a cardiovascular disease, more specifically heart failure (HF). The invention further provides a pharmaceutical composition comprising at least one isolated peptide of the invention and a pharmaceutically acceptable carrier, vehicle, excipient and/or diluent. The pharmaceutical composition of the invention is suitable to be orally administered as a tolerizing vaccine.

39.[20220275068](#)COMPOSITIONS AND METHODS OF USING A HUMANIZED ANTI-DKK2 ANTIBODY  
US - 01.09.2022

Int.Class [C07K 16/18](#) Appl.No 17625683 Applicant YALE UNIVERSITY Inventor Le SUN

The present invention relates to the discovery that inhibition of Dickkopf2 (DKK2) increases CD8<sup>+</sup> cytotoxic T lymphocyte (CTL) activity, attenuates tumor, and hence suppresses tumor formation. Thus, in various embodiments described herein, the methods of the invention relate to methods of treating cancer by administering to a patient an effective amount of a humanized anti-DKK2 antibody, methods for providing anti-tumor immunity in a subject, methods of stimulating a T cell mediated immune response to a cell population or a tissue and suppressing tumor in a subject. Additionally, the current invention includes methods of diagnosing a cancer or a predisposition of developing a cancer or a metastasis and methods for determining the use of immunotherapy treatment or cancer vaccine for treating cancer. Furthermore, the invention encompasses a pharmaceutical composition for treating cancer as well as a kit for carrying out the aforementioned methods.

40.[WO/2022/183689](#)HER2 AFFIBODY RADIONUCLIDE MARKER COMPOSITION AND APPLICATION THEREOF

WO - 09.09.2022

Int.Class [A61K 51/08](#) Appl.No PCT/CN2021/112782 Applicant JIANGSU YUANBEN BIOTECHNOLOGY CO., LTD. Inventor CAI, Jiong

The present invention relates to the fields of radiopharmaceuticals and nuclear medicine, and provides a HER2 affibody 99mTc marker composition and an application thereof. The HER2 affibody 99mTc marker composition in the present invention comprises HEPES, sodium glucoheptonate, vitamin C, cysteine, stannous chloride, and HER2 affibody.

41.[4051318](#)ENGINEERED ANTIBODIES TO HIV ENV

EP - 07.09.2022

Int.Class [A61K 39/42](#) Appl.No 20883493 Applicant INT AIDS VACCINE INITIATIVE Inventor SOK DEVIN

The present disclosure relates to anti-HIV Env antibodies and their use in the treatment or prevention of HIV/AIDS. In one aspect, provided herein are enhanced engineered anti-HIV Env antibodies that were derived from the PGDM1400 parent antibody using directed-evolution and yeast display. In one aspect, provided herein are pharmaceutical compositions comprising the enhanced engineered anti-HIV Env antibodies disclosed herein.

42.[3197487](#)VACCINATION AF IMMUNSVÆKKEDE INDIVIDER

DK - 05.09.2022

Int.Class [A61K 39/145](#) Appl.No 15781436 Applicant Seqirus UK Limited Inventor DEL GIUDICE, Giuseppe

Disclosed herein are methods for enhancing immune responses to a vaccine in immunocompromised individuals, including those receiving a statin therapy. Related products are also provided.

43. [294859](#)METHODS OF INDUCING NEOEPITOPE-SPECIFIC T CELLS WITH A PD-1 AXIS BINDING ANTAGONIST AND AN RNA VACCINE

IL - 01.09.2022

Int.Class [A61K 39/00](#) Appl.No 294859 Applicant GENENTECH, INC. Inventor

44. [295142](#)CORONAVIRUS VACCINE FORMULATIONS

IL - 01.09.2022

Int.Class [A61K 39/00](#) Appl.No 295142 Applicant NOVAVAX, INC. Inventor SMITH, Gale

45. [WO/2022/180263](#)CARRIER PROTEIN FOR PEPTIDE ANTIGEN

WO - 01.09.2022

Int.Class [A61K 39/00](#) Appl.No PCT/EP2022/054911 Applicant CURAVAC EUROPE Inventor

HAVELANGE, Nicolas

Pharmaceutical composition comprising a conjugated peptide of SEQ ID NO: 1 to which multiple peptide epitopes are covalently grafted, kit comprising the elements for producing said conjugated peptide, synthesis method, and vaccine use.

46. [WO/2022/186677](#)METHOD FOR DETECTION OF SARS-CoV-2 MUTATIONS

WO - 09.09.2022

Int.Class [C12Q 1/70](#) Appl.No PCT/KR2022/003219 Applicant SEEGENE, INC. Inventor KIM, Yun Jee

Disclosed herein is a method for detecting SARS-CoV-2 mutations in a sample comprising a nucleic acid molecule. By the method, rapid detection can be made of SARS-CoV-2 variants that has changed in viral characteristics (e.g., infectivity, mortality, vaccine effect, therapeutic effect, etc.), thus early preventing and promptly coping with the spread of infection of SARS-CoV-2 variants.

47. [20220280624](#)VACCINE COMPOSITIONS COMPRISING C-C MOTIF CHEMOKINE 22 (CCL22) OR FRAGMENTS THEREOF

US - 08.09.2022

Int.Class [A61K 39/00](#) Appl.No 17697623 Applicant IO BIOTECH APS Inventor Mads Hald ANDERSEN

The present disclosure relates to CCL22 as a T cell target in cancer immunosuppression.

48. [20220273785](#)MODIFIED BRUCELLA VACCINE STRAIN FOR THE TREATMENT OF BRUCELLOSIS

US - 01.09.2022

Int.Class [A61K 39/02](#) Appl.No 17687313 Applicant CONSEJO SUPERIOR DE INVESTIGACIONES CIENTÍFICAS (CSIC) Inventor María Jesús GRILLÓ DOLSET

The present application provides a modified *Brucella* strain, its use as a medicament, and its use as a medicament for the treatment and/or prevention of brucellosis. The *Brucella* strain has been modified through an inactivation of the wzm gene. Further, the present application provides a pharmaceutical composition which comprises the modified *Brucella* strain, its use as a medicament, and its use as a medicament for the treatment and/or prevention of brucellosis. The present application also provides a kit which comprises the modified *Brucella* strain and a pharmaceutically acceptable carrier or diluent and its use for the treatment and/or prevention of brucellosis.

49. [20220280622](#)NOVEL PEPTIDES AND COMBINATION OF PEPTIDES FOR USE IN IMMUNOTHERAPY AGAINST VARIOUS CANCERS

US - 08.09.2022



Int.Class [A61K 39/00](#) Appl.No 17743685 Applicant Immatics Biotechnologies GmbH Inventor Andrea MAHR

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

50. [20220280636](#) ANTIGENIC GLYCOPROTEIN E POLYPEPTIDES, COMPOSITIONS, AND METHODS OF USE THEREOF

US - 08.09.2022

Int.Class [A61K 39/245](#) Appl.No 17626206 Applicant Arthur FRIDMAN Inventor Arthur Fridman

The disclosure relates to HSV glycoprotein E antigenic peptide constructs and HSV protein vaccines, as well as methods of using the vaccines and compositions comprising the vaccines. The present invention directed to immunogenic polypeptides of use for a vaccine against Herpes Simplex Virus (HSV). The polypeptides are glycoprotein E peptides that are mutated to reduce their binding to antibody Fc domain.

51. [4052724](#) FORMULATIONS FOR NEOPLASIA VACCINES

EP - 07.09.2022

Int.Class [A61K 39/00](#) Appl.No 22162718 Applicant BROAD INST INC Inventor FRITSCH EDWARD F

The present invention relates to neoplasia vaccine or immunogenic composition formulation for the treatment or prevention of neoplasia in a subject.

52. [WO/2022/187230](#) METHODS AND COMPOSITIONS FOR DETECTING AND PRODUCING PORCINE MORBILLIVIRUS AND IMMUNOGENIC COMPOSITIONS THEREOF

WO - 09.09.2022

Int.Class Appl.No PCT/US2022/018319 Applicant IOWA STATE UNIVERSITY RESEARCH FOUNDATION, INC. Inventor LI, Ganwu

Disclosed herein are methods for detecting and producing PoMV. Further, disclosed herein are immunogenic and/or vaccine compositions and methods for treating or preventing PoMV. The compositions and methods include immunogenic portions of PoMV including entry proteins. In at least particular cases, a mutated version of a portion of the PoMV is utilized, such as a deglycosylated, or amino acid substituted mutant of the spike protein.

53. [202117041510](#) VACCINE ADJUVANTS AND FORMULATIONS

IN - 02.09.2022

Int.Class [A61K /](#) Appl.No 202117041510 Applicant CLEVELAND CLINIC FOUNDATION Inventor TUOHY, Vincent, Kevin

Compositions comprising an antigen, a carbohydrate, and a metabolizable oil, methods of administering such compositions to a subject, methods of making such compounds, and related compositions, methods, and uses.

54. [202217028862](#) ENGINEERED ANTIBODIES TO HIV ENV

IN - 02.09.2022

Int.Class [C07K /](#) Appl.No 202217028862 Applicant INTERNATIONAL AIDS VACCINE INITIATIVE Inventor SOK, Devin

The present disclosure relates to anti-HIV Env antibodies and their use in the treatment or prevention of HIV/AIDS. In one aspect, provided herein are enhanced engineered anti-HIV Env antibodies that were derived from the PGDM1400 parent antibody using directed-evolution and yeast display. In one aspect, provided herein are pharmaceutical compositions comprising the enhanced engineered anti-HIV Env antibodies disclosed herein.

55. [WO/2022/183278](#) RECOMBINANT VSV-SARS-COV-2 VACCINE

WO - 09.09.2022

Int.Class [C12N 7/01](#) Appl.No PCT/CA2022/050277 Applicant SUMAGEN CANADA INC. Inventor KANG, Chil-Yong

A recombinant vesicular stomatitis virus (rVSV) carrying one or more genes that encode for the spike protein of SARS-CoV-2 or for both the S protein and the envelope protein of the SARS-CoV-2. Vaccines, regimens and kits having the rVSV are used for the prevention of infections caused by SARS-CoV-2.

56. [WO/2022/180262](#) VACCINE FOR THERAPEUTIC OR PROPHYLACTIC TREATMENT OF MYASTHENIA GRAVIS

WO - 01.09.2022

Int.Class [A61K 39/00](#) Appl.No PCT/EP2022/054909 Applicant CURAVAC EUROPE Inventor HAVELANGE, Nicolas

A pharmaceutical composition for treating myasthenia gravis, comprising a carrier protein of SEQ ID NO: 1 coupled to a plurality of peptide epitopes, the corresponding peptide epitopes, and the method of synthesizing the conjugate.

57. [20220273783](#) NOVEL PEPTIDES AND COMBINATION OF PEPTIDES FOR USE IN IMMUNOTHERAPY AGAINST VARIOUS CANCERS

US - 01.09.2022

Int.Class [A61K 39/00](#) Appl.No 17734997 Applicant Immatics Biotechnologies GmbH Inventor Andrea MAHR

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

58. [WO/2022/182902](#) SEQUENCING POLYCLONAL ANTIBODIES DIRECTLY FROM SINGLE PARTICLE CRYOEM DATA

WO - 01.09.2022

Int.Class [G16B 20/00](#) Appl.No PCT/US2022/017756 Applicant THE SCRIPPS RESEARCH INSTITUTE Inventor WARD, Andrew B.

Provided herein are methods for discovery of epitope specific monoclonal antibodies to pathogens directly from immune sera for immunotherapeutic use. Further provided herein are methods to determine molecular structure of antibodies targeting an antigen from convalescent or vaccinated individuals for the purpose of rational vaccine design.

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

Results Search in US Patent Collection db for: (ABST/vaccine AND ISD/20220901->20220911), 8 records.

PAT. NO.	Title
1 <a href="#">11,435,351</a>	<a href="#">Methods for determining vaccine potency</a>
2 <a href="#">11,434,273</a>	<a href="#">Peptides and combination of peptides for use in immunotherapy against various tumors</a>
3 <a href="#">11,434,261</a>	<a href="#">Optimized Zika virus envelope gene and expression thereof</a>
4 <a href="#">11,434,259</a>	<a href="#">Modified Zika virus NS1 protein with reduced cross-reactive immunogenicity</a>
5 <a href="#">11,433,139</a>	<a href="#">Peptide vaccines against interleukin-31</a>
6 <a href="#">11,433,129</a>	<a href="#">Compositions and methods of manufacturing trivalent filovirus vaccines</a>
7 <a href="#">11,433,124</a>	<a href="#">Peptides and combination of peptides for use in immunotherapy against various cancers</a>
8 <a href="#">11,433,099</a>	<a href="#">Immunotherapy with B*08 restricted peptides and combination of peptides against cancers and related methods</a>

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