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

Usted puede realizar sugerencias sobre los contenidos y de esa forma crear una retroalimentación que nos permita acercarnos más a sus necesidades de información.

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CUBA

Vacunas antineumocócicas conjugadas y polisacáridas: breve revisión

La implementación y disponibilidad de las vacunas antineumocócicas son fundamentales en la prevención de infecciones graves causadas por el *Streptococcus pneumoniae*, un patógeno responsable de enfermedades como la neumonía, meningitis y sepsis.

Desde el punto de vista del entorno competitivo, la oferta de vacunas antineumocócicas está soportada fundamentalmente por alrededor de 14 fabricantes con 20 productos comercializados. El mercado está fraccionado en vacunas de tipo polisacáridas y conjugadas. Estas vacunas varían en cuanto a los serotipos o cepas contra los que protegen.

Vacunas antineumocócicas registradas a nivel mundial

Tipo de vacuna	Nombre comercial (si está disponible)	No. de dosis	Fabricante	PQ OMS* (Sí/No)
Conjugadas				
PCV7	Qumi-Vio	2	Instituto Finlay de Vacunas (Cuba)	No
PCV7	Qumi-Vio	1	Instituto Finlay de Vacunas (Cuba)	No
PCV7	Prevnar7	1	Pfizer (Estados Unidos)	Sí
PCV7	---	4	GlaxoSmithKline Biologicals SA (Bélgica)	Sí
PCV10	Vacina pneumocócica 10-valente	1	Bio-Manguinhos/Fiocruz (Brasil)	No
PCV10	Synflorix	1	GlaxoSmithKline Biologicals SA (Bélgica)	Sí
PCV10	Synflorix	2	GlaxoSmithKline Biologicals SA (Bélgica)	Sí
PCV10	Synflorix	4	GlaxoSmithKline Biologicals SA (Bélgica)	Sí
PCV10	Bio-PCV	4	PT Bio Farma (Persero) (Indonesia)	No
PCV10	PNEUMOSIL	1	Serum Institute of India Pvt. Ltd. (India)	Sí
PCV10	PNEUMOSIL	5	Serum Institute of India Pvt. Ltd. (India)	Sí
PCV13	Prevenar 13	1	BioVac (Sudáfrica)	No
PCV13	Prevenar 13	1	Pfizer (Estados Unidos)	Sí
PCV13	Prevenar 13	4	Pfizer (Estados Unidos)	Sí
PCV13	Prevenar 13	1	Sinergium Biotech (Argentina)	No
PCV15	Vaxneuvance	1	Merck Sharp & Dohme LLC (Alemania)	No
PCV20	Prevnar 20	1	Pfizer (Estados Unidos)	No
PCV21	Capvaxive	1	Merck Sharp & Dohme LLC (Alemania)	No
Polisacáridas				
PPSV23	Pneumococcal		Beijing Minhai Biotec Group (China)	No
PPSV23	Pneumococcal		Chengdu Institute of Biological Products Co.,Ltd (China)	No
PPSV23	Pneumovax 23		Chongqing Zhifei (China)	No
PPSV23	Pneumovax 23	1	Merck Vaccines (Alemania)	No
PPSV23	Prodiax23		SK Bioscience Co., Ltd. (Corea del Sur)	No
PPSV23	23-valent Pneumococcal Polysaccharide Vaccine	1	Walvax (China)	No
PPSV23	Pneumo 23	1	Sanofi (Francia)	No

* PQ OMS: Precalificación por la Organización Mundial de la Salud (OMS)

En resumen, existen nueve vacunas antineumocócicas conjugadas de distintas valencias, desde 7 hasta 21, de ellas tres precalificadas por la Organización Mundial de la Salud (OMS). En el caso de las polisacáridas, se dispone de siete vacunas y ninguna precalificada por la OMS.

Desarrollos recientes

En diciembre de 2024, Sanofi amplió su acuerdo con SK Bioscience para desarrollar, licenciar y comercializar PCV de nueva generación para el tratamiento de la ENI en poblaciones de pacientes pediátricos y adultos.

El último acuerdo se basa en la colaboración existente entre estas dos compañías para desarrollar y comercializar una PCV 21-valente (PCV21) para población pediátrica. Según el acuerdo, ambas compañías financiarán conjuntamente todos los costos de investigación y desarrollo para apoyar el lanzamiento de la PCV21 y las vacunas de nueva generación. Una vez registrada la vacuna, Sanofi la comercializará en todo el mundo excepto en Corea del Sur, donde SK Bioscience tendrá la exclusividad comercial.

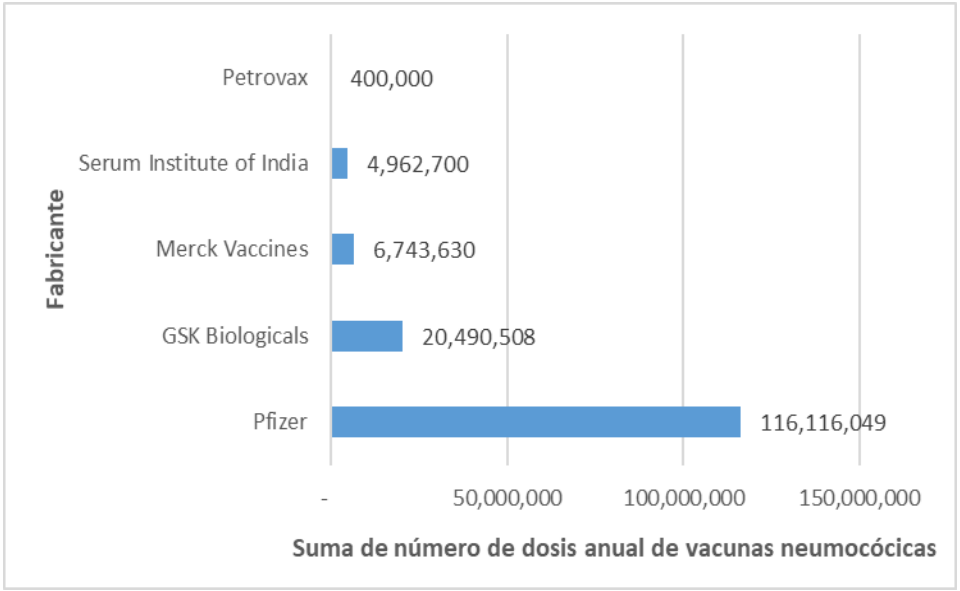
También se está avanzando en una vacuna conjugada de 31 serotipos VAX-31, desarrollada por Vaxcyte, con sede en California, para proporcionar una amplia cobertura frente a la enfermedad neumocócica invasiva (ENI) y la otitis media aguda, que constituyen importantes problemas de salud para los niños menores de cinco años en EE.UU.

Tras la revisión de los datos de seguridad y tolerabilidad de la fase 1, el estudio ha pasado a la fase 2, en la que se seguirán evaluando la seguridad, tolerabilidad e inmunogenicidad de la vacuna en lactantes sanos.

La empresa espera publicar los datos de seguridad, tolerabilidad e inmunogenicidad de la serie de inmunización primaria a mediados de 2026, y los datos de la dosis de refuerzo aproximadamente nueve meses después.

Empresas clave en el mercado de vacunas antineumocócicas

Al analizar el conjunto de datos de compra de vacunas de "Información de mercado para el acceso" (MI4A) publicado en 2024 (5), fueron identificados los fabricantes Pfizer Inc., GlaxoSmithKline Biologicals S.A. (GSK Biologicals), Merck Vaccines y Serum Institute of India Pvt. Ltd. (SIIPL), como actores clave en el mercado de vacunas antineumocócicas en cuanto a número de dosis vendidas.



Cantidad de dosis de vacunas antineumocócicas por fabricante, vendidas en 2023.

Según reportes de mercado de las vacunas antineumocócicas, las siguientes son las empresas que poseen la mayor participación de mercado y dictan las tendencias de la industria:

Valor del mercado global

Según la OMS, el valor de las vacunas antineumocócicas ha seguido creciendo en los últimos años. De acuerdo a un estudio de Future Market Insights que cubre el periodo 2023-2033, se proyecta que el mercado mundial de vacunas antineumocócicas tendrá una tasa de crecimiento compuesta anual (CAGR, por sus siglas en inglés) de ritmo promedio del 4,1 % durante el período de pronóstico. La valoración del mercado fue de 8900 millones de dólares estadounidenses en 2023. Se prevé que el valor de mercado del mercado de vacunas antineumocócicas supere el valor de 13 300 millones de dólares estadounidenses para 2033. Los analistas de Future Market Insights registraron una valoración de mercado histórica de 8500 millones de dólares estadounidenses para el mercado en cuestión durante el año base.

Asimismo, otros estudios de mercado refuerzan esta afirmación, entre ellos el reporte de Grand View Research donde se prevé que crezca a una tasa de crecimiento compuesta anual del 6,21 % entre 2024 y 2030. Por su parte, IMARC Group (29) espera que el mercado alcance los 14 400 millones de dólares en 2032, con una tasa de crecimiento compuesta anual del 4,7 % durante el período 2024-2032. En un informe de Mordor Intelligence (30), se indica que el tamaño del mercado de vacunas antineumocócicas se estima en 8,80 mil millones de dólares en 2024 y se espera que alcance los 11,20 mil millones de dólares en 2029, creciendo a una tasa compuesta anual del 4,83% para el período 2024-2029.

Según los informes revisados anteriormente, este crecimiento está respaldado por factores como:

⇒ Creciente prevalencia de infecciones del torrente sanguíneo, neumonía bacteriémica, meningitis, infección del oído medio y bacteriemia.

⇒ Creciente número de niños menores de 2 a 5 años que poseen un alto riesgo de enfermedades neumocócicas.

⇒ Aumento de la población geriátrica y las complicaciones graves y la contagiosidad de las enfermedades neumocócicas en los adultos mayores.

⇒ Aumento de los programas de concienciación gubernamental sobre los programas de inmunización contra la neumonía.

⇒ Apoyo gubernamental para educar a las personas sobre la vacunación contra la neumonía.

⇒ Introducción de nuevas vacunas para la prevención de enfermedades neumocócicas.

Consideraciones finales

La efectividad de la vacuna antineumocócica polisacárida 23-valente (VPNC23) en adultos es objeto de debate, y los ensayos clínicos y los estudios observacionales muestran resultados contradictorios. Algunos estudios muestran efectividad, mientras que otros no. Una revisión Cochrane estima una eficacia general del 74% en adultos contra la infección neumocócica invasiva (ENI), pero no se observó protección en los grupos de alto riesgo. La eficacia contra la ENI se ha estimado en un 52%.

Por su parte, las vacunas antineumocócicas conjugadas son eficaces para prevenir las formas graves de la enfermedad neumocócica. Reducen la portación nasofaríngea de los serotipos de la vacuna, lo que genera protección directa para las personas vacunadas y protección indirecta (inmunidad de grupo) para las personas no vacunadas.

Desde la introducción de las vacunas antineumocócicas, se ha alcanzado un éxito global, disminuyendo de forma considerable la carga de la ENI.

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Noticias en la Web

EMA Recommends Approval of Capvaxive Pneumococcal Vaccine

Feb 1. The European Medicines Agency (EMA) has recommended granting marketing authorization for the pneumococcal vaccine Capvaxive (pneumococcal polysaccharide conjugate vaccine [21-valent]) intended to prevent invasive disease and pneumonia caused by Streptococcus pneumoniae in people aged 18 years or older.

There are approximately 100 different serotypes of pneumococcal bacteria, which can affect adults differently than children.

Vaccine Overview

The active substance of Capvaxive works by triggering an immune response against 21 serotypes that cause most invasive pneumococcal disease cases.

At its January meeting, the EMA's Committee for Medicinal Products for Human Use accepted immunobridging data demonstrating the vaccine's effectiveness.

Clinical Data and Efficacy

The recommendation was largely based on positive results from a phase 3 randomized, double-blind clinical trial (STRIDE-3), which evaluated the vaccine's safety, tolerability, and immunogenicity. The study found that Merck's Capvaxive was noninferior to Pfizer's Prevenar 20 (pneumococcal polysaccharide conjugate vaccine) for the 10 serotypes common to both vaccines.

Side Effects and Availability

Common side effects of Capvaxive are pain at the injection site, fatigue, headache, and myalgia.

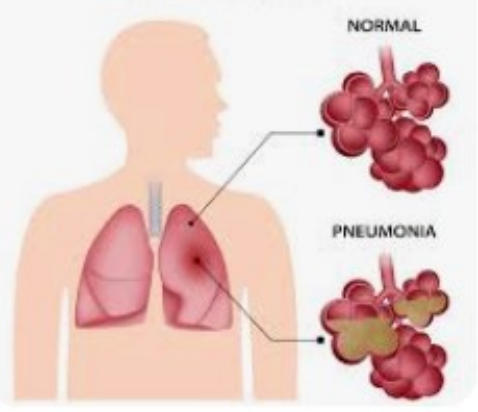
The vaccine is supplied as a solution for injection in a prefilled syringe.

The EMA's recommendation will now be sent to the European Commission for final approval. If authorized for EU use, it will mark the fourth approval for Capvaxive in this indication. The vaccine was greenlit in the United States and Canada in 2024 and in Australia earlier this month.

Fuente: Medscape. Disponible en https://lc.cx/AruRpb

Addressing Burden Of Childhood Pneumonia

Feb 2. Childhood pneumonia remains a significant global health challenge, particularly in low- and middle-income countries (LMICs). Despite advances in vaccines, antibiotics, and public health measures, pneumonia continues to be the leading infectious cause of mortality in children under five. According to the World Health Organization (WHO), pneumonia accounts for nearly 14 per cent of deaths in children under five, with the highest burden in sub-Saharan Africa and South Asia. While high-income countries have largely controlled childhood pneumonia through vaccination and healthcare access, LMICs still struggle with late diagnoses and inadequate treatment.



The epidemiology of childhood pneumonia is influenced by a combination of biological, environmental, and socioeconomic factors. Despite being preventable and treatable, pneumonia continues to claim over 800,000 young lives annually. The disease disproportionately affects children in poor and marginalised communities, where healthcare access, nutrition, and living conditions are suboptimal. Pneumonia is a respiratory infection that inflames the lungs, leading to difficulty in breathing, fever, cough, and chest pain. It can be caused by bacteria, viruses, or fungi, with the most common bacterial pathogens being Streptococcus pneumoniae and Haemophilus influenzae type b (Hib). Viral causes include respiratory syncytial virus (RSV), influenza, and adenoviruses.

Vaccination

Children under five, particularly newborns and malnourished infants, are at the highest risk of severe pneumonia. Risk factors include poor nutrition, lack of vaccination, air pollution, weak immune systems, and delayed treatment. The disease is most deadly when compounded by other illnesses, such as diarrhoea, malaria, and measles. Vaccination is the most effective way to prevent pneumonia-related deaths. The pneumococcal conjugate vaccine (PCV) and Hib vaccine have dramatically reduced pneumonia cases worldwide. However, many children in LMICs still lack access to these vaccines due to affordability and distribution challenges.

Other important vaccines that help prevent pneumonia include measles vaccine, as measles weakens the immune system and increases pneumonia risk. Pertussis (whooping cough) vaccine, which prevents severe respiratory infections. Influenza vaccine reduces the risk of viral pneumonia, and RSV vaccines and monoclonal antibodies are emerging tools to prevent severe RSV-related pneumonia. Governments must strengthen immunisation programmes to ensure universal vaccine coverage, particularly in rural and underserved areas. International organisations, such as Gavi, the Vaccine Alliance, play a crucial role in making vaccines affordable and accessible to low-income nations.

Malnutrition weakens a child's immune system, making them more susceptible to infections, including pneumonia. Exclusive breastfeeding for the first six months provides essential antibodies that protect against respiratory infections. Breastfeeding also ensures optimal lung development and strengthens the child's immune system. After six months, a balanced diet rich in vitamins and minerals especially vitamin A, zinc, and iron is crucial for immunity and lung health. Zinc supplementation, in particular, has been shown to reduce pneumonia incidence in young children. Governments and NGOs must invest in nutrition programmes to combat childhood malnutrition, focusing on educating mothers about proper infant feeding and ensuring access to nutritious food.

Another significant risk factor for childhood pneumonia is air pollution. Children exposed to indoor air pollution which is mainly caused by burning biomass fuels (wood, charcoal, dung), tobacco smoke, and poor ventilation are at higher risk of respiratory infections. Outdoor air pollution, particularly in urban areas with high levels of particulate matter (PM2.5) and toxic gases, further exacerbates lung diseases. Delayed diagnosis and treatment are major contributors to pneumonia mortality.

Many children in LMICs lack access to healthcare, leading to severe complications before they receive medical attention. Community health programmes can play a vital role in early detection and treatment of pneumonia.

It is essential to training community health workers to recognise pneumonia symptoms (fast breathing, chest in-drawing, fever). Hence, expanding access to antibiotics and oxygen therapy, especially in rural clinics and improving referral systems for severe cases to reach hospitals quickly significantly reduces mortality. Governments should strengthen primary healthcare systems to ensure every child has timely access to pneumonia treatment.

Poor hygiene increases the spread of pneumonia-causing pathogens. Simple measures like handwashing with soap can significantly reduce the risk of respiratory infections. Improved sanitation and clean water access further contribute to disease prevention such as by promoting handwashing habits, especially before eating and after using the toilet and encouraging the use of clean drinking water to prevent infections that weaken immunity. Thus, school-based hygiene programmes have crucial role to educate children about infection prevention. Governments and NGOs should invest in sanitation infrastructure and public awareness campaigns to improve hygiene practices.

Poverty

Poverty is a major determinant of childhood pneumonia risk. Children from low-income families often lack proper nutrition, clean air, vaccines, and healthcare access. Reducing pneumonia mortality requires broader efforts to tackle poverty and improve living conditions. Therefore, it is imperative to expand universal healthcare coverage to ensure affordability of pneumonia treatment. Investing in education programmes for maternal and child health helps reduce pneumonia incidence. Improving housing conditions to reduce overcrowding and pollution exposure brings significant reduction.

Childhood pneumonia is a preventable tragedy that still claims hundreds of thousands of lives each year. By expanding vaccination programmes, improving nutrition, reducing pollution, ensuring early treatment, and promoting hygiene, we can drastically reduce pneumonia-related deaths. Governments, NGOs, and global organisations must prioritise pneumonia prevention as part of broader child health strategies. Every child deserves the right to breathe freely, and it is our collective responsibility to make that a reality.

Fuente: The Rising Nepal. Disponible en https://lc.cx/wWU6Cq

MRK Gets Positive CHMP Nod for 21-Valent Pneumococcal Jab Capvaxive

Feb 3. Merck MRK announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of its 21-valent pneumococcal conjugate vaccine (PCV), Capvaxive, for the prevention of invasive pneumococcal disease ("IPD") and pneumococcal pneumonia in individuals aged 18 years and above.

The European Commission will now review the CHMP's opinion and a final decision from the regulatory body is expected by the second quarter of 2025.

The FDA approved Capvaxive for 21 serotypes, which account for 84% of all IPDs in older adults, in June 2024.

Capvaxive targets serotypes that account for approximately 84% of all IPD in older adults (50 years and older) in the United States, including eight serotypes not covered by currently licensed vaccines.

In the past year, shares of Merck have plunged 21.7% compared with the industry's decrease of 2.6%.

Title	High	Low	Median	Cumulative Return	Annualized Return	Start Date	End Date
MERCK & CO INC (MRK) % Gr	5.37%	-24.27%	-6.20%	-21.68%	-21.68%	02-05-2024	01-31-2025
Large Cap Pharma Market (ZSI225M) % Gr	18.14%	-8.83%	4.90%	-2.55%	-2.55%	02-05-2024	01-31-2025

Image Source: Zacks Investment Research.

More on the CHMP Opinion for MRK's Capvaxive

The latest CHMP recommendation for Capvaxive was based on data from multiple phase III studies.

Among them are data from the phase III STRIDE-3 study, which evaluated Capvaxive compared to PCV20 (pneumococcal 20-valent conjugate vaccine) in adults aged 18 years and above who had not previously received a pneumococcal vaccine.

It also included data from the phase III STRIDE-4, STRIDE-5, STRIDE-6, STRIDE-7 and STRIDE-10 studies, which investigated Capvaxive in vaccine-naïve and vaccine-experienced adults.

A potential approval in the EU will mark the fourth authorization of Capvaxive for the prevention of IPD and pneumococcal pneumonia in adults.

Along with the United States, Capvaxive is also approved in Canada and in Australia. A regulatory filing seeking approval for Capvaxive is currently under review in Japan.

MRK markets another PCV vaccine, Vaxneuvance, which is approved for 15 serotypes in older adults.

Other Drugmakers in the PCV Space

Pfizer PFE is a key player in the PCV vaccine space.

PFE markets Prevnar 20, which is approved for the prevention of IPD caused by 20 serotypes in individuals aged six weeks and older. PFE also markets Prevnar 13, which contains 13 serotypes and has the FDA's approval for use in individuals aged six weeks and older. In the first nine months of 2024, Pfizer recorded $4.8 billion from combined sales of Prevnar 13 and Prevnar 20.

Fuente: Barchart. Disponible en https://lc.cx/2Qc4Ea

Butantan Institute says its dengue vaccine protects against serotype 3

Feb 5. The state of São Paulo is preparing to face yet another outbreak of dengue: Butantan Institute has already begun to produce the first batch of tetravalent vaccines, comprising 1 million doses, and on January 23 the state government announced the creation of a center for emergency operations, as well as the transfer of BRL 228 million to cities statewide to support the fight against dengue and other diseases caused by arboviruses (transmitted by arthropods, such as mosquitoes and ticks).

Butantan Institute has started producing the four types of active pharmaceutical ingredient (API) required for the vaccine's final formulation (photo: Butantan Institute)

A cause of concern is the reappearance of dengue serotype 3 after 17 years without circulation of this viral variant, potentially leading to fresh outbreaks of the disease, as the population is not immune to this specific strain. Dengue types 1 and 2 continue to circulate in Brazil.

"We've begun to produce the inputs [active pharmaceutical ingredients, or APIs] for each of the four viral serotypes. Production is continuous because the composition of the vaccine includes all four APIs. It makes sense to process all these stages together so that as soon as our vaccine is approved we can rapidly have doses ready for the population," said Gustavo Mendes, Butantan Institute's head of regulatory affairs, quality and clinical trials.

Butantan Institute expects ANVISA, Brazil's regulator of vaccines, medical drugs and devices, and healthcare procedures, to license its vaccine soon, having filed for approval in December 2024.

The results of the phase 3 clinical trial of the vaccine, known as Butantan-DV, were published in the New England Journal of Medicine last year, showing 79.6% overall two-year efficacy (89.5% for DENV-1 and 69.6% for DENV-2). The vaccine is designed to combat all four serotypes, but the researchers were unable to assess its efficacy against types 3 and 4 because no cases of disease caused by them were detected during the trial.

According to Mendes, the team responsible for conducting the clinical trial had previously done several in vitro studies and comparisons of the different viral subtypes to extrapolate the efficacy data from types 1 and 2 to types 3 and 4 in their presentation of the results.

"The extrapolation is based on the comparability of the four serotypes. This methodology is accepted by the scientific community and the regulators. We discussed this information with ANVISA before. So far we haven't been asked by ANVISA to do a phase 3 trial focusing on types 3 and 4, but post-vaccination monitoring and testing [i.e. phase 4 trials] are part of the regulatory requirements in Brazil," he said.

Constant monitoring after approval of a vaccine is a mandatory part of pharmacovigilance, a set of activities designed to detect and prevent unforeseen adverse effects, which can occur in mass vaccination campaigns, and to investigate possible cases of vaccine inefficacy. No phase 4 trials focusing on dengue virus serotypes 3 and 4 have been scheduled so far, however.

Mendes said Butantan Institute has put together a team to investigate these cases if they happen, but reaffirmed the technical and scientific argument that it is possible to extrapolate the efficacy results obtained so far for types 3 and 4 even though none of the participants in the trial was infected by them.

As soon as ANVISA licenses the vaccine, Butantan Institute will request approval of its price from the Drug Market Regulation Chamber (CMED). Delivery of the vaccine free of charge via the national health service (SUS) will then be considered by the National Commission for Health Technology Incorporation (CONITEC), a multisectoral agency linked to the Ministry of Health.

Production process

If Butantan-DV is approved, it will be the first single-dose dengue vaccine in the world. The institute plans to produce around 1 million doses in 2025, mostly for purchase and distribution by the Ministry of Health via the national vaccination program (PNI), and plans to produce 100 million more doses by end-2027.

"We've been discussing technical aspects of the production process with ANVISA for a long time, so we believe the production technique won't be affected even if ANVISA requires changes to optimize the process," Mendes said.

He also explained that ANVISA does not prohibit production of a vaccine before it is licensed. Doing so risks a major financial loss, as any batches produced will have to be destroyed if the regulator rejects the license application.

"If I produce a vaccine that expires a year or 18 months from now, for example, it's risky unless I'm absolutely certain of fast-track approval. For this reason, we're producing the APIs but not the final formulation," he said.

The production process for Butantan-DV comprises two distinct stages. The first is production of the four serotypes separately. They are then combined in the final formulation.

ANVISA has not yet concluded its analysis of the licensing request. The procedure typically takes about 90 days. Butantan Institute's application was filed on December 16, so a final decision by the regulator should be announced around mid-March.

A decade and a half of studies

Development of the tetravalent dengue vaccine began in 2010, with support from FAPESP. The initial inspiration was a formulation created by researchers affiliated with the U.S. National Institutes of Health (NIH). The NIH conducted the phase 1 clinical trial in 2010-12. The phase 2 trial was conducted in Brazil (2013-15). A phase 3 trial began in 2016, also in Brazil, and ended in 2024, when all 16,235 volunteers completed the five-year follow-up period.

The results attest to the safety of the vaccine for people aged 2 to 59, regardless of whether they have ever been infected by the virus. Butantan Institute is now waiting for ANVISA's approval of a clinical trial involving the over-60s, a particularly vulnerable age group, and expects to begin in the coming months.

Challenges for 2025

São Paulo State Governor Tarcísio de Freitas stated on January 22 that combating dengue is the first challenge of the year. He highlighted the development of the vaccine by Butantan Institute, but warned that it will not be available on a large scale until next year and preventing infection must therefore remain the top priority.

"We have the current challenge from the climate, which favors vector proliferation. The second problem is that many people had dengue last year, and repetition favors the development of severe dengue. Lastly, a different serotype is circulating this year. We must combat the vector and get organized with the tools we have now. We all have to do our homework – citizens and municipal governments, which must be effective in keeping the mosquito at bay, and the state government, which will provide full support," Freitas said.

Fuente: Agencia FAPESP. Disponible en https://lc.cx/_yfiHT

Propuesta para incluir la vacuna antineumocócica en el Programa Ampliado de Inmunizaciones de Vietnam

7 feb. El Ministerio de Salud acaba de proponer añadir la vacuna neumocócica al Programa Ampliado de Inmunización y, al mismo tiempo, poner la enfermedad neumocócica en la lista de enfermedades infecciosas que requieren vacunación obligatoria para los niños.

Noticias médicas del 5 de febrero: Proponen incluir vacuna antineumocócica en Programa Ampliado de Inmunizaciones

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El Ministerio de Salud propone incluir la vacuna antineumocócica en el Programa Ampliado de Inmunizaciones.

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Este es uno de los contenidos importantes del proyecto de modificación y complemento a la Circular No. 10/2024/TT-BYT sobre la lista de enfermedades infecciosas y vacunas obligatorias.

El Ministerio de Salud está elaborando modificaciones y adiciones a la Circular No. 10/2024/TT-BYT, emitida el 13 de junio de 2024, sobre la lista de enfermedades infecciosas, sujetos y alcance del uso obligatorio de vacunas y productos biológicos médicos.

Según el proyecto, el Ministerio de Salud propone añadir la enfermedad neumocócica a la lista de enfermedades infecciosas que requieren vacunación obligatoria para los niños. La vacunación antineumocócica sería un paso importante para reducir las enfermedades infecciosas que pueden causar complicaciones graves.

De acuerdo con la Circular No. 10/2024/TT-BYT, actualmente hay 11 enfermedades infecciosas que requieren vacunación obligatoria en el Programa Ampliado de Inmunización, entre ellas la hepatitis B, la tuberculosis, la difteria, la tos ferina, el tétanos, la poliomielitis, la meningitis causada por Haemophilus influenzae tipo b, el sarampión, la encefalitis japonesa B, la rubéola y la diarrea causada por el rotavirus.

El Ministerio de Salud dijo que las vacunas neumocócicas se implementarán a nivel nacional para niños bajo la dirección del Ministerio, con base en la Resolución No. 104/NQ-CP del 15 de agosto de 2022 del Gobierno sobre la hoja de ruta para aumentar el número de vacunas en el Programa Ampliado de Inmunización para el período 2021-2030.

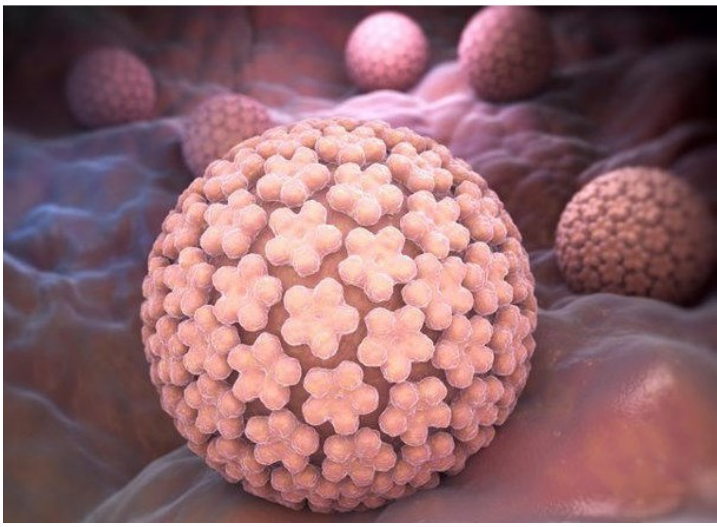
Según el plan, la vacuna antineumocócica se incluirá oficialmente en el Programa Ampliado de Inmunización a partir de 2025, junto con la vacuna contra el rotavirus. Se espera que a partir de 2026 se introduzca en el programa la vacuna contra el cáncer de cuello uterino, y a partir de 2030 se implementará la vacuna contra la gripe estacional.

La introducción de la vacuna antineumocócica en el Programa Ampliado de Inmunización es un paso importante en la estrategia para prevenir enfermedades infecciosas graves, especialmente en los niños.

El neumococo es la causa de muchas enfermedades graves, como meningitis, neumonía, otitis media y complicaciones que pueden poner en peligro la vida si no se tratan a tiempo. Con la introducción de esta vacuna en el Programa de Inmunización, el Ministerio de Salud espera reducir la incidencia de la enfermedad y proteger la salud pública, especialmente a los niños.

Fuente: VIETNAM.VN. Disponible en https://lc.cx/yLa2OS

La OPS anuncia la disponibilidad de la vacuna VPH9 contra el virus del papiloma humano en América a partir de julio



7 feb. "La inclusión de la vacuna VPH9-valente es un avance en la lucha contra los cánceres relacionados con el VPH y una herramienta importante en el trabajo de los países y sus programas de inmunización. Al trabajar juntos, podemos hacer que las vacunas que salvan vidas sean más accesibles para todos y continuar la meta de eliminación del cáncer cervicouterino en 2030", ha afirmado el gerente ejecutivo de los Fondos Rotatorios de la OPS, Santiago Cornejo.

Esta vacuna tiene cinco valencias más que su versión anterior, la cuadrivalente, por lo que se espera que ayude a proteger a la población contra los genotipos más prevalentes en cáncer de cuello uterino, así como reducir la carga de enfermedades relacionadas con el VPH.

Esta inmunización está recomendada para toda la población desde los 9 años hasta los 26 años, dependiendo de los esquemas de cada país, y forma parte de la Iniciativa de Eliminación de la OPS, que busca poner fin a más de 30 enfermedades en el 2030 usando la vacunación como herramienta "clave", y vacunando al 90 por ciento de las niñas antes de los 15 años con al menos una dosis de vacuna contra el VPH.

El Fondo Rotatorio de la OPS permite a los países combinar su poder de compra para negociar mejores precios, así como asegurar un suministro "permanente y oportuno" de sus vacunas y otros insumos relacionados, un enfoque que reduce los costes y "simplifica" el proceso de adquisición para los países participantes.

Todas las vacunas incluidas en el portafolio del Fondo Rotatorio de la OPS son precalificadas por la Organización Mundial de la Salud (OMS) o por una autoridad de referencia, buscando ofrecer tecnologías sanitarias que sean de calidad, seguras y alineadas con criterios técnicos.

Fuente: Europa Press. Disponible en https://lc.cx/wI3uzK

Aprobada la primera vacuna contra el virus sincitial para embarazadas y mayores de 60

7 feb. Las embarazadas pueden ya proteger a sus bebés de hasta 6 meses de la bronquiolitis y otras enfermedades respiratorias vacunándose, entre las 24 y las 36 semanas de gestación, con el primer suero para adultos que acaba de aprobar el Ministerio de Sanidad frente al Virus Sincitial Respiratorio (VRS).

"Abrysvo, nombre comercial de la vacuna, consta de una única dosis que se inyecta en el músculo de la parte superior del brazo y ya está disponible en farmacias por un precio de 234,95 euros con IVA."

La vacuna bivalente de Pfizer contra la proteína F en prefusión (RSVpreF), está también indicada para los mayores de 60 años, pero por ahora el Sistema Nacional de Salud solo la financiará para las embarazadas, ha explicado en la presentación del fármaco el director médico de la compañía, José Chaves.

A la espera de las pautas que aún debe marcar la Comisión de Salud Pública, que debe decidir ahora su incorporación en el calendario vacunal para toda la vida, Abrysvo, nombre comercial de la vacuna, consta de una única dosis que se inyecta en el músculo de la parte superior del brazo y ya está disponible en farmacias por un precio de 234,95 euros con IVA.

"Complementaria" a nirsevimab

Desde octubre, los recién nacidos están siendo inmunizados con nirsevimab, un anticuerpo monoclonal -no vacuna- que está desplomando las tasas de hospitalizaciones por VRS, que supone la segunda causa de muerte en lactantes menores de 12 meses en el mundo.

Se estima que en España, las infecciones por este virus originan entre 7.000 y 14.000 hospitalizaciones anuales, es decir, un 2 % de los casos, sin olvidar que el sincitial puede conllevar secuelas futuras, llegando a tener cuadros parecidos a los de asma en los 5 primeros años de vida.

Esta vacuna, la primera que llega a España para adultos y única que está indicada para mujeres gestantes -la otra que desarrolla GSK es solo para mayores-, viene a ser nueva herramienta con la que recibirán una protección pasiva a través de la placenta de sus madres.

Según María María Garcés, pediatra del centro de salud Nazaret (Valencia) y miembro del Comité Asesor de Vacunas de la Asociación Española de Vacunología (CAV-AEP), no debe hay "ninguna interferencia" entre ambos fármacos, que incluso "pueden ser complementarios".

Un escudo vital para los bebés

"Hasta hace unos años, vacunar a una mujer embarazada era un tema tabú, pero gracias a la evidencia científica, los avances y la industria se ha visto la importancia de que se vacunen, lo primero para que se protejan ellas mismas de enfermedades diversas, y luego al feto", ha señalado Inmaculada Cuesta, enfermera, matrona y secretaria de la Asociación Nacional de Enfermería y Vacunas (Anenvac).

Cuando una mujer se vacuna, genera unos anticuerpos que transfiere al feto a través de la placenta. "Es un

acto altruista que hace la mujer en beneficio de su hijo", al que regala "un escudo vital" contra el VRS en sus primeros seis meses de vida.

Dado que la protección del lactante frente al VRS depende de esa transferencia de anticuerpos, Abrysvo se debe administrar entre las semanas 24 y 36 de embarazo; lo importante, ha querido dejar claro la experta, es que las mujeres en la edad fértil lleguen al embarazo con todo su calendario vacunal completo, más aún si son mujeres con algún factor de riesgo.

El VRS también es cosa de mayores

Pero el VRS no es exclusivo de los pequeños, ha aclarado Ángel Gil, profesor de Medicina Preventiva y Salud Pública de la Universidad Rey Juan Carlos de Madrid, sino que también impacta en los adultos a partir de los 65 años, sobre los que hay un infradiagnóstico pese a que en ellos hay más mortalidad intrahospitalaria relacionada con casos de este virus -8 %- que con la gripe.

El 90 % de la población de esta edad tiene una enfermedad crónica asociada, que se convierten en dos a los 75 y en al menos 3 cuando se cumplen los 80, por lo que su protección frente a cualquier enfermedad respiratoria "resulta esencial".

Gil ha querido insistir en que la vacuna no evitará la infección, pero sí las hospitalizaciones y las muertes, al igual que ocurre con otras como la covid o la gripe.

Se puede poner con la de la gripe

Según su prospecto, Abrysvo se puede poner paralelamente con la vacuna de la gripe estacional. Como todo medicamento, tiene efectos adversos, siendo los más comunes en mujeres embarazadas el dolor en la zona del pinchazo, de cabeza, muscular y náuseas.

Mientras que en los mayores, los más frecuentes fueron la fatiga, el dolor de cabeza, en la zona de la inyección y mialgia.

Con estas dos indicaciones ya aprobadas, la compañía farmacéutica ha iniciado dos ensayos clínicos adicionales para evaluar Abrysvo en niños con mayor riesgo de contraer enfermedad por VRS, cuya edad va desde los 2 años hasta los 18.

Fuente: El Correo de Andalucía. Disponible en https://lc.cx/uBjKKk

AIM Vaccine submits mRNA RSV vaccine for FDA clinical trials

Feb 10. AIM Vaccine Co., Ltd., a leading PRC vaccine company, announced today that its independently developed mRNA RSV (respiratory syncytial virus) vaccine has recently been submitted for clinical trials to the U.S. Food and Drug Administration (FDA). The vaccine has demonstrated significantly higher humoral and cellular immunity compared to internationally marketed products. If the product progresses smoothly, it will accelerate AIM Vaccine's international expansion and contribute to substantial performance growth.

In preclinical animal trials, third-party testing results showed that AIM Vaccine's mRNA RSV vaccine achieved significantly higher levels of specific IgG antibody titers, live-virus neutralizing antibody potency, and specific T -cell immunity compared to internationally marketed mRNA RSV control vaccines.

This announcement highlights AIM Vaccine's innovative capabilities and underscores the acceleration of its

internationalization efforts, which have been recognized by multiple institutions.

Recently, FOSUN INTERNATIONAL SECURITIES initiated coverage of AIM Vaccine, assigning a "Buy" rating with a 12-month target price of HKD 11.0. The report cited the company's strong product pipeline, technological leadership, and potential for international growth as key factors. Similarly, SDICSI released a research report predicting that AIM Vaccine will launch 1-2 products annually over the next three years. If the products in development gain approval and progress smoothly in international markets, they are expected to drive new performance growth and expand market potential. SDICSI also assigned a "Buy" rating with a target price of HKD 9.5.

FOSUN INTERNATIONAL SECURITIES's analysis indicates that the Chinese vaccine market is evolving in line with global trends, where high-value products and leading companies dominate. With its differentiated advantages, AIM Vaccine is poised to secure a leading position in the domestic market while achieving scalable expansion internationally. Additionally, the company's comprehensive and iterative product portfolio is expected to enhance its market share, pricing power, and profitability, further supporting long-term growth.

The report also emphasized that AIM Vaccine, with its diversified product portfolio, technological strengths, and global expansion strategy, presents an attractive investment opportunity for investors. With a series of high-value products set to launch and profitability expected to rebound from 2025 onwards, the company is positioned for strong growth and potential valuation reassessment.

Globally, there are currently no approved antiviral drugs for RSV available for clinical use. Vaccination for active immune prophylaxis remains the most effective means to prevent severe RSV infections. No RSV vaccines have been approved for marketing in PRC. In 2023, global sales of RSV vaccines reached USD 2.46 billion, and according to industry consultants, the market size is expected to grow to approximately USD 16.7 billion by 2030.

The mRNA vaccine field is still wide open with plenty of opportunities, as there are few competitors globally. AIM Vaccine is one of the earliest companies in PRC to develop mRNA vaccine products and is among the first domestic vaccine enterprises to obtain independent patents for mRNA technology. The company has established a mature mRNA vaccine R&D system and has developed multiple mRNA candidate vaccines, including vaccines for shingles, rabies, and influenza, in addition to the mRNA RSV vaccine.

Fuente: News Medical Life Sciences. Disponible en https://lc.cx/vASHQm

Larga lista de mujeres científicas en Cuba

11 feb. Cerca de 51 mil mujeres en Cuba desempeñan hoy actividades de ciencia y tecnología, lo cual representa la mayor cantidad en los últimos años, de acuerdo con la Oficina Nacional de Estadística e Información (ONEI).

Pero no son solo cifras, detrás de los números existen nombres como el de Rosa Elena Simeón, presidenta de la Academia de Ciencias de Cuba (ACC) durante años y la primera en ocupar el cargo de ministra de Ciencia, Tecnología y Medio Ambiente, quien dirigió el combate a la fiebre porcina africana y examinó un novedoso método de análisis acerca de la inseminación artificial en sementales.

Otra de las figuras más reconocidas es Concepción Campa Huergo, la líder de la investigación que permitió desarrollar la única vacuna con eficacia probada que existe en el mundo para combatir la meningitis B y C, que se lleva aplicando desde 1988 en muchos países del mundo, con gran efectividad.

Alargan la lista las ganadoras del premio Sofía Kovalievskaia en su séptima edición: Beatriz Marcheco Teruel, genetista clínica y Directora del Centro de Genética médica; Martha Ana Castro Peraza, del Instituto de Medicina Tropical Pedro Kourí (IPK); y Mayra Paulina Hernández Sánchez, del Instituto de Ciencia y Tecnología de Materiales.

Este galardón es conferido desde 2005 por la Fundación que lleva el nombre de la célebre científica y feminista rusa del siglo XIX por emplear de manera original y creativa modelos matemáticos y computacionales para dar solución a problemas concretos demandados por la sociedad.

Durante la pandemia de COVID-19, muchas científicas permanecieron en la primera fila de enfrentamiento, participaron en el desarrollo de nuevos proyectos de investigación y colideraron los ensayos de los candidatos vacunales del país.

Dos de los ocho académicos cubanos seleccionados en 2020 para participar en el Panel Internacional de expertos como Grupo Asesor para el enfrentamiento de la COVID-19, eran féminas.

Una de ellas, Tania Crombet Ramos, directora de investigaciones clínicas del Centro de Inmunología Molecular y una de las líderes de la vacuna CimaVax-EGF contra el cáncer de pulmón, fue elegida miembro de la Academia Mundial de Ciencias a partir de 2022.

Guadalupe Guzmán Tirado, titular de investigación y diagnóstico del IPK, es la otra académica escogida y, aunque su trabajo se centra en el estudio del dengue, investigó sobre la neuropatía epidémica, el zika, la influenza pandémica y el virus SARS-CoV-2.

Asimismo, la especialista en enfermedades infecciosas fue escogida entre 45 mujeres de ciencia de 37 países para el premio internacional L'Oréal-Unesco "La Mujer y la Ciencia", reconocimiento que enaltece el prestigio de la Isla a nivel global, gracias a sus investigaciones que permiten comprender y tratar mejor el dengue.

Al IPK pertenece también la doctora Sonia Resik Aguirre, jefa del departamento de virología, quien lideró los estudios de intervención sanitaria con la vacuna Abdala y contribuyó a la investigación sobre la poliomielitis en Cuba.

Destacada por su amplia trayectoria en el desarrollo de vacunas, Dagmar García Rivera, directora de investigaciones del Instituto Finlay de Vacunas y una de las líderes de las vacunas Soberana 01, Soberana 02 y Soberana Plus y del proyecto de la Quimi-Vio, la vacuna heptavalente contra neumococos.

Por su labor, García Rivera ha recibido en tres ocasiones el premio de la Academia de Ciencias de Cuba (ACC) y mereció en 2019 la condecoración Carlos J. Finlay.

Sobresale, también, la doctora Marta Ayala Ávila, directora del Centro de Ingeniería Genética y Biotecnología, en el esfuerzo por lograr candidatos contra la pandemia del coronavirus y la doctora Miladys Limonta Fernández, gerente del proyecto vacunas COVID-19 del centro.

El país caribeño es una de las siete naciones que alcanzan la paridad de género en la investigación científica

y una presencia significativa de mujeres entre los autores de relevantes publicaciones, innovaciones, patentes de invención y premios, según el informe de la Organización de Naciones Unidas para la Educación, la Ciencia y la Cultura.

La ONEI reportó que hasta 2022 las mujeres constituían el 53.8 por ciento de la fuerza laboral dedicada a este tipo de actividades, número que refleja un avance positivo hacia la equidad de género en un sector crucial para el desarrollo económico y social del país.

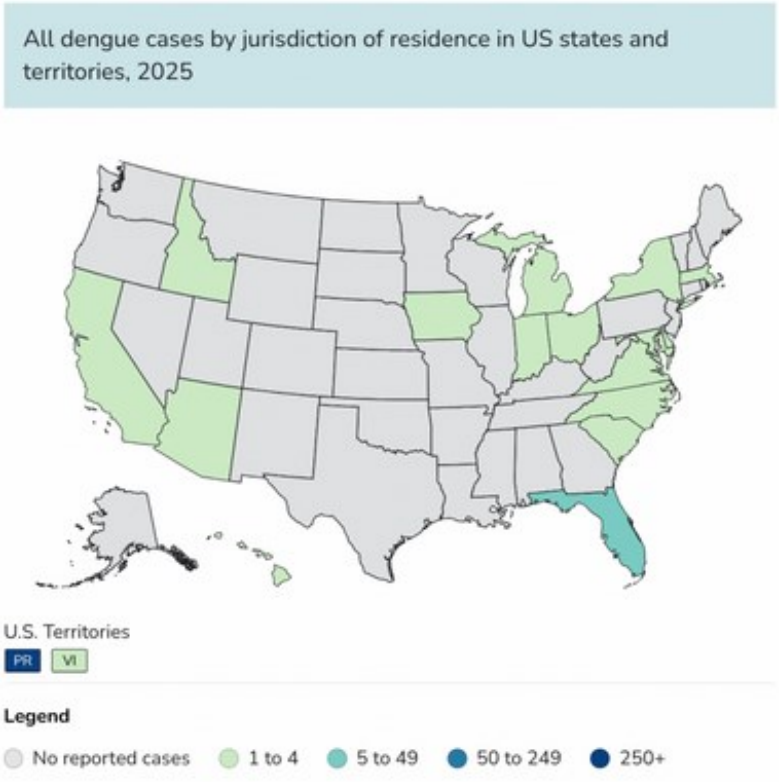
Representan, además, el 69,6 por ciento del sector de la salud pública y de las diez invenciones cubanas que han recibido la Medalla de Oro de la Organización Mundial de la Propiedad Intelectual, en seis son ellas las autoras principales.

Las científicas cubanas han desempeñado un papel fundamental en la investigación médica y biotecnológica, en el éxito de la nación caribeña en el enfrentamiento a la COVID-19, en la búsqueda de soluciones sostenibles para los desafíos ambientales y sociales y en el posicionamiento de Cuba como referente en ciencia y tecnología a nivel internacional.

Fuente: Prensa Latina. Disponible en https://lc.cx/1ESsnp

Will Dengue Passive Immunization Become Available in the USA

Feb 12. As travelers in the United States prepare for another year of record-setting Dengue fever outbreaks, a human monoclonal antibody (mAb) candidate from a Bethesda, MD-based company may soon obtain U.S. FDA approval.



As of February 12, 2025, the National Institutes of Health and AbViro LLC phase IIa clinical trial is exposing healthy volunteers in Maryland and Vermont to a weakened strain of the Dengue virus. The study will compare three AV-1 dose levels in adults challenged with DENV-3, the most infectious Dengue virus strain.

This study launched in early January 2025 and is expected to be completed this Fall.

If successful, the AV1 vaccine candidate could become the first dengue fever treatment approved by the FDA. Previously, the Dengvaxia® vaccine was approved but has since been withdrawn from the U.S. market.

Furthermore, the market-leading second-generation vaccine, Qdenga, is not approved in the U.S.

Currently, no approved Dengue vaccines or mAb are available in the U.S.

National Institute of Allergy and Infectious Diseases director Jeanne Marrazzo commented in a media release, "When caring for a patient who is critically ill with Dengue, healthcare providers have few options other than providing supportive care. We must find safe and effective therapeutics to provide much-needed relief to people suffering from Dengue."

While vaccines are designed to stimulate the body's immune system for many years, therapeutic mAbs provide rapid protection following injection.

Another mAb is being developed in India in a phase 3 study.

Dengushield, developed by Serum Institute of India Pvt. Ltd., is a highly potent inhibitor of all four types of dengue viruses. In a phase 1 study announced in February 2024, this mAb was found safe and well tolerated. It showed a dose-proportionate increase in pharmacokinetic exposure.

To alert international travelers to their Dengue risk, the CDC has issued Travel Health Advisories in 2025. Previously, the WHO classified Dengue as a grade 3 emergency, with an estimated 4 billion people at risk globally.

Within the U.S., Miami, Florida, and San Juan, Puerto Rico, are leaders in reporting locally acquired dengue cases.

Without an approved preventive vaccine or a mAb, the CDC suggests avoiding mosquito bites as the best defense against contracting Dengue in 2025.

Fuente: Vax Before Travel. Disponible en https://lc.cx/pX1DWR

FDA suspende ensayos de vacuna contra el VRS tras detectar infecciones respiratorias severas en niños

13 feb. La Administración de Alimentos y Medicamentos de Estados Unidos (FDA) ha suspendido los ensayos clínicos de vacunas contra el virus respiratorio sincitial (VRS) en niños menores de 5 años que no habían estado previamente expuestos al virus.

La decisión se tomó tras la detección de un aumento en los casos graves de infección respiratoria en un ensayo clínico, lo que ha generado preocupación en la comunidad médica y científica.

Preocupaciones de seguridad y riesgo de enfermedad intensificada

Uno de los principales detonantes de la suspensión fue un informe de la FDA en el que se identificó un riesgo de enfermedad respiratoria intensificada asociada a la vacuna (Vaerd, por sus siglas en inglés).

Según datos recopilados por la FDA, en lactantes de entre cinco y ocho meses se notificaron cinco casos graves de VRS en el grupo vacunado. Foto: Shutterstock.

Este fenómeno ocurre cuando la respuesta inmunitaria inducida por la vacuna no es lo suficientemente fuerte como para ofrecer protección efectiva contra la infección, lo que paradójicamente puede aumentar la gravedad de la enfermedad en los individuos vacunados.

En particular, la farmacéutica Moderna ya había pausado en julio los ensayos en fase 1 de su vacuna experimental ARNm-1365-P101 después de detectar un incremento de infecciones graves en el grupo vacunado en comparación con el grupo placebo.

Según datos recopilados por la FDA, en lactantes de entre cinco y ocho meses se notificaron cinco casos graves de VRS en el grupo vacunado, mientras que en el grupo placebo solo se reportó un caso.

Además, se observó que la respuesta inmune de los niños que habían recibido previamente el anticuerpo monoclonal nirsevimab parecía debilitarse tras la vacunación, lo que plantea nuevas interrogantes sobre la interacción entre ambas estrategias de inmunización.

Medidas y próximos pasos

Ante estos hallazgos, la FDA ha señalado la necesidad de realizar más estudios preclínicos y continuar con la monitorización de los ensayos clínicos para evaluar con mayor precisión los riesgos y beneficios de la vacuna en esta población.

La agencia ha instado a las compañías farmacéuticas a revisar sus protocolos y a desarrollar estrategias que minimicen la posibilidad de efectos adversos graves.

El impacto del VRS y la respuesta internacional

El virus respiratorio sincitial es una de las principales causas de hospitalización y mortalidad en niños pequeños, especialmente en lactantes. Se estima que provoca anualmente alrededor de 3 millones de hospitalizaciones y entre 50.000 y 100.000 muertes en menores de 5 años en todo el mundo.

Debido a su alta carga de enfermedad, la búsqueda de vacunas efectivas y seguras ha sido una prioridad en salud pública.

A nivel internacional, el Centro Europeo para la Prevención y el Control de Enfermedades (ECDC) ha comenzado a incluir el VRS en su protocolo de estudios de eficacia vacunal, el cual hasta ahora se había centrado en infecciones respiratorias como la gripe estacional y la COVID-19.

Esta nueva iniciativa permitirá recopilar datos estandarizados en distintos países europeos y comparar la efectividad de las diferentes estrategias de inmunización contra el VRS, lo que facilitará una mejor comprensión del impacto y la carga de la enfermedad.

Un reto para el futuro de la vacunación contra el VRS

A pesar de estos contratiempos, los expertos siguen destacando la importancia de desarrollar una vacuna segura y efectiva contra el VRS, especialmente para los grupos de mayor riesgo, como los bebés prematuros y los niños con enfermedades respiratorias preexistentes.

La suspensión temporal de los ensayos clínicos en EE.UU. no significa el fin de la investigación, sino una pausa para reevaluar los riesgos y garantizar la seguridad de los pacientes antes de avanzar a nuevas fases de estudio.

Mientras tanto, los esfuerzos para mitigar la carga del VRS continúan con estrategias como el uso de anticuerpos monoclonales, medidas de prevención en poblaciones vulnerables y el monitoreo de la circulación del virus en distintas regiones del mundo.

Fuente: MSP Medicina y Salud Pública. Disponible en https://lc.cx/0vSq-x

Bio Farma Partners with MSD, Transfers PCV15 Vaccine Production Technology

Feb 14. MSD (trade name of Merck & Co., Inc., Rahway, NJ, USA) and Bio Farma signed a framework agreement focused on technology transfer partnership to produce 15-valent Pneumococcal Conjugate Vaccine (PCV15) locally in Indonesia.

The collaboration focuses on the development of locally produced PCV15 for the prevention of invasive pneumococcal disease, an infection caused by bacteria called streptococcus pneumoniae.

The partnership is in line with Asta Cita Indonesia: Towards Indonesia Emas 2045, which focuses primarily on strengthening the resilience of the health system.

The agreement was signed in Jakarta by George Stylianou, Managing Director of MSD Indonesia, and Shadiq Akasya, President Director of Bio Farma, witnessed by the Minister of Health of the Republic of Indonesia, Budi Gunadi Sadikin, Deputy Minister of State-Owned Enterprises of the Republic of Indonesia, Aminuddin Ma'ruf, and President of MSD Asia Pacific, David Peacock.

Pneumonia is the leading cause of illness and death in infants and children in Indonesia, accounting for around 14.5% of infant deaths and 5% of deaths in children under five years of age 1. PCV15 specifically includes protection against serotypes 22F and 33F, and has demonstrated superior immunogenicity for serotype 3 compared to other PCV vaccines 2. Streptococcus pneumoniae serotypes 3, 22F, and 33F are recognized as causes of pneumonia in various populations 3.

Minister of Health of the Republic of Indonesia, Budi Gunadi Sadikin said that vaccination is an important component in fighting pneumonia, and PCV15 will play an integral role in preventing the life-threatening disease of our children.

“This partnership not only supports our health transformation, whose third pillar focuses on health resilience in line with the vision of Indonesia Emas 2045 to improve the quality of life of the Indonesian people through the provision of adequate health services, but is also an important step towards improving our vaccination capabilities. This encourages the acceleration of improving health services and protecting future generations,” said Budi.

"The positive impact of this collaboration on health services underscores MSD's commitment to addressing Indonesia's pressing health challenges," he added.

President of Asia Pacific, MSD David Peacock stated that this partnership agreement builds on MSD's existing partnership with Bio Farma, which allows us to expand our PCV production and supply in Indonesia.

"At MSD, we are committed to increasing access to life-saving vaccines and addressing the burden of pneumococcal disease in Indonesia," said David.

David emphasized that today's collaboration reflects MSD's dedication to supporting Indonesia's aspirations to create a sustainable health environment and build a strong vaccination infrastructure.

"We hope to strengthen long-term cooperation with Bio Farma and improve the quality of health of Indonesia's future generations," he said.

Recognizing the heavy burden of pneumococcal disease in Indonesia, local production of PCV15 underscores a proactive approach to improving healthcare services. PCV15 protects against 15 strains of S. pneumoniae, including those associated with critical illness.

This agreement is also a significant step by State-Owned Enterprises (SOEs) in supporting Asta Cita Indonesia, especially in strengthening downstream processing and industrialization to increase domestic value.

Deputy Minister of State-Owned Enterprises of the Republic of Indonesia Aminuddin Ma'ruf said that this partnership marks an important achievement in the effort to make Indonesia a world vaccine production center. This initiative is in line with the government's direction in strengthening the independence of the national health industry while building a more competitive pharmaceutical ecosystem.

Collaboration with global biopharmaceutical companies such as MSD will not only enhance our local capabilities but also ensure that Indonesia is able to meet international standards. The Ministry of SOEs continues to encourage strategic collaborations that accelerate innovation, increase the competitiveness of the national pharmaceutical industry, and ensure access to quality health services for all Indonesians.

This partnership continues the success of the technology transfer partnership between MSD and Bio Farma for the local production of the 4-valent Human Papillomavirus (HPV) vaccine, NUSAGARD® which was launched in August 2023. The experience gained from the local production of the 4-valent HPV vaccine has contributed greatly to the current PCV15 technology transfer efforts, strengthening Bio Farma's capabilities in producing high-quality vaccines domestically.

Meanwhile, Bio Farma President Director Shadiq Akasya said that this partnership agreement not only increases the capability of vaccine production in Indonesia, but also reflects our commitment to supporting Asta Cita Indonesia and contributing to improving the health of the Indonesian people, through the ability to produce innovative vaccines locally,"

"We are very excited to work with MSD, a leading global biopharmaceutical company, in achieving our goals. The continued partnership with MSD will continue to strengthen our vaccination capabilities, so that we can meet the health needs of **the community** and for a healthier future," concluded Shadiq.

Fuente: PORTAL JABARPROVGOID. Disponible en https://lc.cx/5WLtIR

FDA Approves GSK's Penmenvy Vaccine Targeting Meningococcal Serogroups A, B, C, W, and Y

Feb 14. GSK plc announced that the US Food and Drug Administration (FDA) has approved Penmenvy (Meningococcal Groups A, B, C, W, and Y Vaccine) for individuals aged 10 through 25 years. This vaccine is designed to protect against five major serogroups of Neisseria meningitidis (A, B, C, W, and Y), which cause invasive meningococcal disease (IMD).

MenABCWY combines the protective components of two of GSK's existing vaccines: the meningococcal Group B vaccine Bexsero and the meningococcal (Groups A, C, Y, and W-135) oligosaccharide diphtheria CRM_{197} conjugate vaccine Menveo. The approval of MenABCWY makes it the second pentavalent meningococcal vaccine available, joining Penbraya by Pfizer, which also targets the same five meningococcal serogroups.

In its international, observer-blinded Phase 3 clinical trial (NCT04502693), MenABCWY demonstrated promising results. The study involved 3,650 participants aged 10 to 25 years across the US, Canada, and other countries. The vaccine met all 11 primary endpoints and was shown to be noninferior to the combination of Bexsero and Menveo in terms of immunological effectiveness.

Specifically, MenABCWY produced strong immune responses against a panel of 110 diverse MenB strains,

covering 95% of the circulating strains in the US It was well tolerated, with no major safety concerns, and demonstrated a robust immune response across all five meningococcal serogroups (A, B, C, W, and Y). These results position MenABCWY as a significant tool in reducing the incidence of invasive meningococcal disease, particularly among adolescents and young adults at higher risk.

MenABCWY is administered as two intramuscular (IM) injections, given six months apart, following a dosing regimen similar to Penbraya. The approval of MenABCWY is expected to enhance protection for primary care and pediatric populations, providing an effective option to prevent meningococcal disease in a broader age group.

In the press release, Tony Wood, chief scientific officer at GSK, said, “We are excited about the opportunities ahead to help improve meningococcal vaccination coverage in the United States, especially for IMD caused by serogroup B. Building on our global leadership in meningococcal vaccination and our longstanding commitment to address unmet need in disease prevention, we aim to help protect more teens and young adults at a life stage when they are at an increased risk.”

IMD is a serious, often rapidly progressing disease that can lead to death in as little as 24 hours. It is frequently misdiagnosed in its early stages, as its symptoms can resemble those of the flu,1 but can lead to deadly infections like meningitis (brain and spinal cord inflammation) and bloodstream infections.3 Adolescents and young adults, especially those in close living environments such as dormitories, are at higher risk for contracting the disease.

The CDC's Advisory Committee on Immunization Practices (ACIP) will meet on February 26, 2025, to discuss recommendations for the vaccine's use in the target age group.

Fuente: Contagion Live. Disponible en https://lc.cx/G1zMbC

European Commission Approves CSL and Arcturus Therapeutics' KOSTAIVE®, the First Self-amplifying mRNA COVID-19 Vaccine

Feb 14. Global biotechnology leader CSL (ASX: CSL; USOTC: CSLLY) and sa-mRNA pioneer Arcturus Therapeutics (Nasdaq: ARCT) today announced that the European Commission has granted marketing authorization for KOSTAIVE ® (ARCT-154), a self-amplifying mRNA COVID-19 vaccine, for individuals 18 years and older. KOSTAIVE is the first sa-mRNA COVID-19 vaccine to receive approval from the European Commission (EC). KOSTAIVE is currently marketed in Japan against COVID-19.

The European Commission approval follows a positive opinion adopted by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on December 12, 2024. The centralized marketing authorization of KOSTAIVE is valid in all EU member states and in the EEA countries.

"The European Commission's approval marks a significant milestone in our ongoing development program for KOSTAIVE," said Jonathan Edelman, MD, Senior Vice President of the Vaccines Innovation Unit, CSL. "We are actively working to optimize KOSTAIVE's formulation to better meet the needs of healthcare professionals and their patients. As COVID-19 remains an unpredictable global threat, CSL is dedicated to completing these technical enhancements and making this innovative vaccine available in Europe as soon as possible."

The approval is based on positive clinical data from several studies, including an integrated phase 1/2/3 study demonstrating KOSTAIVE's efficacy and tolerability, and Phase 3 COVID-19 booster trials, which achieved higher immunogenicity results compared to a conventional mRNA COVID-19 vaccine comparator. A follow-up analysis evaluating a booster dose of KOSTAIVE also showed that the vaccine elicited

superior immunogenicity and antibody persistence for up to 12 months post-vaccination against multiple SARS-CoV-2 strains in both younger and older adult age groups versus the same mRNA comparator.

"KOSTAIVE and sa-mRNA technology signify a major advancement in vaccine innovation, providing the potential for broader and more enduring protection," said Joseph Payne, CEO of Arcturus. "This approval highlights the clinical promise of KOSTAIVE and its ability to protect against the ever-changing COVID-19 virus."

About sa-mRNA

mRNA vaccines help protect against infectious diseases by providing a blueprint for cells in the body to make a protein to help our immune systems recognize and fight the disease. Unlike standard mRNA vaccines, self-amplifying mRNA vaccines instruct the body to make more mRNA and protein to boost the immune response.

About CSL

CSL (ASX: CSL; USOTC: CSLLY) is a global biotechnology company with a dynamic portfolio of lifesaving medicines, including those that treat haemophilia and immune deficiencies, vaccines to prevent influenza, and therapies in iron deficiency and nephrology. Since our start in 1916, we have been driven by our promise to save lives using the latest technologies. Today, CSL – including our three businesses: CSL Behring, CSL Seqirus and CSL Vifor – provides lifesaving products to patients in more than 100 countries and employs 32,000 people. Our unique combination of commercial strength, R&D focus and operational excellence enables us to identify, develop and deliver innovations so our patients can live life to the fullest. For inspiring stories about the promise of biotechnology, visit CSLBehring.com/Vita and follow us on Twitter.com/CSL.

About Arcturus

Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is a commercial mRNA medicines and vaccines company with enabling technologies: (i) LUNAR® lipid-mediated delivery, (ii) STARR® mRNA Technology (sa-mRNA) and (iii) mRNA drug substance along with drug product manufacturing expertise. Arcturus developed KOSTAIVE®, the first self-amplifying messenger RNA (sa-mRNA) COVID vaccine in the world to be approved. Arcturus has an ongoing global collaboration for innovative mRNA vaccines with CSL Seqirus, and a joint venture in Japan, ARCALIS, focused on the manufacture of mRNA vaccines and therapeutics. Arcturus' pipeline includes RNA therapeutic candidates to potentially treat ornithine transcarbamylase (OTC) deficiency and cystic fibrosis (CF), along with its partnered mRNA vaccine programs for SARS-CoV-2 (COVID-19) and influenza. Arcturus' versatile RNA therapeutics platforms can be applied toward multiple types of nucleic acid medicines including messenger RNA, small interfering RNA, circular RNA, antisense RNA, self-amplifying RNA, DNA, and gene editing therapeutics. Arcturus' technologies are covered by its extensive patent portfolio (over 400 patents and patent applications in the U.S., Europe, Japan, China, and other countries). For more information, visit www.ArcturusRx.com. In addition, please connect with us on Twitter and LinkedIn.

Fuente: CSL Global Newsroom. Disponible en https://lc.cx/pnG4k4

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Estrategia de búqueda: (Vaccine) AND DP:([01.02.2025 TO 14.02.2025]) *as the publication date 45 records.*

1.WO/2025/027616FREEZE-DRIED VIRAL VACCINE COMPOSITIONS AND METHOD OF MANUFACTURING THEREOF

WO - 06.02.2025

Clasificación Internacional A61K 39/12Nº de solicitud PCT/IN2023/050860Solicitante SERUM INSTITUTE OF INDIA PRIVATE LIMITEDInventor/a DHERE, Rajeev Mhalasakant

The present disclosure relates to field of lyophilized/freeze-dried viral vaccine composition and methods for manufacturing and obtaining the vaccine composition comprising live attenuated flavivirus as vaccine antigen selected from a group of yellow fever virus, dengue virus, Japanese encephalitis (JE) virus, Kunjin virus, West Nile (WN) virus, tick-borne encephalitis (TBE) virus, St. Louis encephalitis virus, Murray Valley encephalitis virus, Zika virus vaccine antigen; and stabilizers comprising sugar or sugar alcohol; amino acids; lactalbumin

hydrolysate and gelatin. Post reconstitution, the composition preserves the desired characteristics of the virus, including immunogenicity and stability. The composition of the present disclosure can be safely administered subcutaneously or intramuscularly such that the vaccine composition induces complete immune response to yellow fever virus infectious agent and meets the criterion for the seroprotection for the said immunogenic components comprising yellow fever virus.

2.WO/2025/026435CHIMPANZEE ADENOVIRAL VECTOR-BASED VACCINE LIQUID FORMULATION AND PREPARATION METHOD

WO - 06.02.2025

Clasificación Internacional A61K 39/12Nº de solicitud PCT/CN2024/109553Solicitante CANSINO BIOLOGICS INC.Inventor/a SHAO, Juan

The present invention relates to a vaccine formulation. An effective ingredient is a recombinant chimpanzee adenovirus expressing an antigen protein, and adjuvants are ethanol and glycerol. The present formulation has no animal-derived ingredient and has high safety. The formulation can maintain good stability of a chimpanzee adenoviral vector vaccine liquid formulation. The vaccine formulation can be stably stored for more than 12 months at 2-8°C, the abnormal toxicity test of the vaccine formulation satisfies the standards, and the vaccine formulation is safe to use. The vaccine formulation can be used as a liquid injection and an atomized inhalation formulation at the same time.

3.WO/2025/024973CASTRATION VACCINE HAVING ENGINEERED FERRITIN AND GNRH EXPRESSED IN TANDEM, AND USE

WO - 06.02.2025

Clasificación Internacional C07K 19/00Nº de solicitud PCT/CN2023/109838Solicitante SHENZHEN HERZ LIFE SCIENCE TECHNOLOGY CO., LTDInventor/a ZHA, Lisha

The present invention relates to the technical fields of molecular biology, virology, immunology and medicine, and in particular to a castration vaccine having engineered ferritin and GnRH expressed in tandem, and a use. In the present invention, the engineered ferritin and different quantities of GnRH are linked in tandem and then recombined, so as to construct a GnRH-ferritin nanoparticle castration vaccine. The vaccine is used for castration of animals. Experimental results show that the GnRH and mutant ferritin recombined vaccine has a significantly enhanced immune effect and can significantly reduce testosterone levels and testicular weight, and compared with other combination methods, the nanoparticle castration vaccine having four GnRHs and the mutant ferritin linked in tandem has higher expression, stronger immunogenicity, faster immune response, and significant advantages in effect, and can be widely applied in the technical field of castration of animals.

4.4499138IMPFSTOFFFORMULIERUNGEN MIT KONTROLLIERTER FREISETZUNG

EP - 05.02.2025

Clasificación Internacional A61K 39/12Nº de solicitud 23775643Solicitante MERCK SHARP & DOHME LLCInventor/a BHAMBHANI AKHILESH

The present disclosure provides, among other things, a vaccine composition that includes HPV virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82, where the vaccine composition provides enhanced or comparable HPV vaccine response in comparison to a similar multiple-dose vaccine.

5.WO/2025/032613MRNA VACCINE AGAINST DENGUE, METHOD(S) AND KIT THEREOF

WO - 13.02.2025

Clasificación Internacional A61K 39/12Nº de solicitud PCT/IN2024/051468Solicitante SWETHA, RaghavanInventor/a SWETHA, Raghavan

The present disclosure provides ribonucleic acid vaccine(s) which can effectively neutralize multiple serotypes of Dengue, as well as methods of using the vaccine(s) and composition(s) comprising the vaccines for treating and preventing Dengue. More specifically, the present disclosure provides a messenger ribonucleic acid (mRNA) based vaccine comprising an open reading frame encoding multiple antigenic domains across the four serotypes of the Dengue virus. The mRNA of the present disclosure comprises multiple antigenic domains across the four serotypes of Dengue to produce humoral and cell mediated responses while avoiding potential regions that might influence Antibody dependent enhancement (ADE).

6.WO/2025/029561VACCINE CONTAINING RBD2 OF CDTB COMPONENT FROM BINARY TOXIN CDT OF CLOSTRIDIOIDES DIFFICILE

WO - 06.02.2025

Clasificación Internacional A61K 39/08Nº de solicitud PCT/US2024/039462Solicitante UNIVERSITY OF SOUTH FLORIDAInventor/a SUN, Xingmin

A novel vaccine and methods of preventing and treating *C. difficile* infection in a patient is described. The vaccine is comprised of at least a portion of receptor binding domain 2 (RBD2) protein or a protein comprising at least a portion of receptor binding domain 1 (RBD1) protein and RBD2 protein (RBD1+2) from binary toxin (CDT) of *C. difficile*. Administration of the vaccine, as well as anti-RBD2 or anti-RBD1+2 serum, has been shown to prevent *C. difficile* infection as well as treat existing infections.

7.WO/2025/031347TUMOR VACCINE AND USE THEREOF

WO - 13.02.2025

Clasificación Internacional C12N 15/09Nº de solicitud PCT/CN2024/110057Solicitante SHANGHAI JIAO TONG UNIVERSITYInventor/a YANG, Xuanming

A tumor vaccine, comprising and/or expressing an antigen molecule, a co-stimulatory signal molecule, a cytokine, and an NLRC5 molecule. The tumor vaccine can further comprise and/or express a CIITA molecule. Further provided is a use of the tumor vaccine in preventing and/or treating tumors.

8.4499140NEUER MERS-COV-IMPFSTOFF

EP - 05.02.2025

Clasificación Internacional A61K 39/215Nº de solicitud 23713655Solicitante MAX DELBRUECK CENTRUM FUER MOLEKULARE MEDIZIN HELMHOLTZ GEMEINSCHAFTInventor/a DE LA ROSA KATHRIN

The present invention relates to a mutant receptor-binding domain (MERS-mRBD) of MERS-CoV (middle east respiratory syndrome coronavirus) or a fragment thereof and a mutant spike protein (MERS-mSpike) of MERS-CoV or a fragment thereof. Furthermore, the present invention relates to a mutant spike protein (MERS-mSpike) of MERS-CoV or a fragment thereof comprising the MERS-mRBD or the fragment thereof. Furthermore, the present invention relates to a polypeptide or protein comprising the MERS- mRBD or the fragment thereof or MERS-mSpike or the fragment thereof and a nucleic acid comprising a nucleotide sequence encoding for the MERS-mRBD or the fragment thereof or the MERS-mSpike or the fragment thereof. Furthermore, the present invention relates to a vaccine composition comprising one or more MERS-mRBDs or fragments thereof, one or more MERS -mSpikes, one or more polypeptide or proteins and/or one or more nucleic acids according to the present invention. Furthermore, the present invention relates to the one or more MERS-mRBDs or fragments thereof, the one or more MERS-mSpikes, the one or more polypeptides or proteins, the one or more nucleic acids and/or the vaccine composition according to the present invention for use in the prevention and/or treatment of diseases caused by MERS-CoV in a subject.

9.WO/2025/031385IMMUNE-ENHANCING ALUMINUM EMULSION, AND PREPARATION METHOD THEREFOR AND USE THEREOF

WO - 13.02.2025

Clasificación Internacional A61K 9/107Nº de solicitud PCT/CN2024/110337Solicitante XIAMEN UNIVERSITYInventor/a ZHANG, Tianying

An immune-enhancing aluminum emulsion, and a preparation method therefor and a use thereof. Specifically provided are an oil-in-water emulsion containing an inorganic salt and a preparation method for the oil-in-water emulsion. Also provided are a vaccine adjuvant comprising the oil-in-water emulsion, a vaccine composition and a pharmaceutical composition. Also provided is a use of the oil-in-water emulsion as a vaccine adjuvant.

10.20250041406RECOMBINANT MULTIVALENT VACCINE

US - 06.02.2025

Clasificación Internacional A61K 39/215Nº de solicitud 18922463Solicitante SHANGHAI PUBLIC HEALTH CLINICAL CENTERInventor/a Huimin YAN

A recombinant multivalent vaccine including a recombinant protein is provided. The recombinant protein includes, from a N-terminus to a C-terminus, a first antigenic peptide, an N-polypeptide (SEQ ID NO: 1), a second antigenic peptide, a C-polypeptide (SEQ ID NO: 3) and a third antigenic peptide, where the N-polypeptide and the C-polypeptide are intramolecular scaffold-forming polypeptides, forming an intramolecular scaffold NC for supporting and stabilizing conformations of the first antigenic peptide, the second antigenic peptide and the third antigenic peptide. The recombinant multivalent vaccines 3Ro-NC (SEQ ID NO: 17) and 3Rs-NC (SEQ ID NO: 19) are provided to against SARS-COV-2 variants. The 3Ro-NC plus KFD is used as a prophylactic mucosal SARS-COV-2 vaccine to provide protection against Omicron infection in upper and lower respiratory tracts.

11.12215358COXSACKIEVIRUS A6 STRAIN CVA6-KM-J33 AND USE THEREOF

US - 04.02.2025

Clasificación Internacional C12N 7/00Nº de solicitud 18654901Solicitante INSTITUTE OF MEDICAL BIOLOGY, CAMSInventor/a Longding Liu

Provided is a Coxsackievirus A6 (CVA6) strain CVA6-KM-J33 and use thereof, and belongs to the technical field of biomedicine. The present invention provides a CVA6 strain CVA6-KM-J33, which belongs to a CVA6 virus. In the present invention, the strain CVA6-KM-J33 is susceptible to KMB17 cells and can achieve a relatively high titer. The strain has strong virulence, high pathogenicity and lethality to suckling mice, and desirable immunogenicity, and is a highly effective virus strain for CVA6 vaccine development. This strain can be used for immunogenicity evaluation or protective evaluation of CVA6 vaccine to improve the accuracy and reproducibility of vaccine immunogenicity evaluation. This strain can also be used to prepare animal models of Coxsackievirus (CV) infection, and exhibits desirable application prospects.

12.4501947FUSIONSPROTEIN UND IMPFSTOFF

EP - 05.02.2025

Clasificación Internacional C07K 14/165Nº de solicitud 23781006Solicitante UNIV OSAKA RES FOUND FOR MICROBIAL DISEASESInventor/a YOSHIOKA YASUO

The present invention provides a fusion protein which is useful as a vaccine antigen against infectious diseases. A fusion protein including (a) a combination of hemagglutinin and an N-terminal domain of SARS-CoV-2, (b) a combination of PspA and a receptor binding domain of SARS-CoV-2, (c) a combination of hemagglutinin and respiratory syncytial virus G protein, or (d) a combination of PspA and hemagglutinin, is useful as a vaccine antigen against infectious diseases.

13.WO/2025/028848NOVEL VECTOR FOR PRODUCING RECOMBINANT ANTIGEN ASSOCIATED WITH PORCINE WASTING DISEASE, AND VACCINE COMPOSITION USING SAME

WO - 06.02.2025

Clasificación Internacional C12N 15/70Nº de solicitud PCT/KR2024/010092Solicitante CARESIDE CO., LTD.Inventor/a YOU, YoungKook

The present invention relates to: a vector capable of simultaneously producing an antigen of porcine circovirus 2d, recently prevalent in Korea, an antigen of porcine circovirus 2a, which has caused diseases from the past to the present, a porcine circovirus 2 cellular immunity recombinant protein, and a p65 recombinant protein of Mycoplasma hyopneuminiae, which causes porcine mycoplasma pneumonia; a vaccine against PCV2 and Mycoplasma, the vaccine comprising four types of antigens, Mycoplasma hyopneuminiae dead cells, and Mycoplasma hyorhinis dead cells produced by the vector; a method for producing same; and a use thereof.

14.20250041400RSV VACCINE

US - 06.02.2025

Clasificación Internacional A61K 39/155Nº de solicitud 18776466Solicitante AstraZeneca ABInventor/a Jason Paul LALIBERTE

Provided herein is a vaccine against RSV. The vaccine comprises an mRNA encoding a stabilised prefusion RSV F protein immunogen linked to a scaffold based on lumazine synthase.

15.WO/2025/028832IMMUNE ADJUVANT AND VACCINE COMPOSITION CONTAINING POLY-BETA-HYDROXYBUTYRATE NANOPARTICLES

WO - 06.02.2025

Clasificación Internacional A61K 39/39Nº de solicitud PCT/KR2024/009576Solicitante SEOUL NATIONAL UNIVERSITY R&DB FOUNDATIONInventor/a YUN, Cheol Heui

The present invention relates to immune adjuvants and vaccine compositions containing poly-beta-hydroxybutyrate nanoparticles. The nanoparticles based on non-cytotoxic FDA-approved substances according to the present invention have no cytotoxicity, have high biosafety, and can compensate for the disadvantages of BHB. Unlike existing commercialized immune adjuvants, the present invention is a novel nano-sized immune adjuvant based on a bio-derived substance, has versatility with antigens having a protein form without being limited to a specific antigen, and has the convenience of being able to provide an effect in a single mixture form. In addition, the present invention functionally increases the activity of antigen presenting cells (APCs), and induces the activity of follicular helper T cells and germinal center B cells to enhance both effective humoral and cellular immunity, thereby becoming a base substance of a next-generation immune adjuvant.

16.20250041414DENDRITIC CELL CANCER VACCINE AND APPLICATION THEREOF

US - 06.02.2025

Clasificación Internacional A61K 39/00Nº de solicitud 18718623Solicitante SUZHOU ERSHENG BIOMEDICAL CO., LTD.Inventor/a Mi LIU

A dendritic cell cancer vaccine obtained by activating dendritic cells in vitro with delivery particles loaded with cell components is provided, wherein the delivery particles are nanoparticles and/or micronparticles, the cell components are derived from water-soluble components and/or non-water-soluble components of cancer cells and/or tumor tissues, the activating is co-incubating the delivery particles loaded with the cell components with the dendritic cells.

17.20250041405IMMUNOGENIC AND VACCINE COMPOSITIONS AGAINST SARS-COV-2

US - 06.02.2025

Clasificación Internacional A61K 39/215Nº de solicitud 18917802Solicitante Iowa State University Research Foundation, Inc.Inventor/a MICHAEL WAN CHO

Disclosed herein are immunogenic and/or vaccine compositions and methods for treating or preventing Severe acute respiratory syndrome (SARS). The compositions and methods include an immunogenic portion of the receptor-binding domain (RBD) of the SARS-CoV-2-2 (COVID-19) spike protein. In at least particular cases, a mutated version of a portion of the RBD is utilized, such as a deglycosylated, or amino acid substituted mutant of the spike protein.

18.WO/2025/031486RESPIRATORY SYNCYTIAL VIRUS ANTIGENIC POLYPEPTIDE, VACCINE, AND USE

WO - 13.02.2025

Clasificación Internacional C07K 14/135Nº de solicitud PCT/CN2024/111116Solicitante SHENZHEN RHEGEN BIOTECHNOLOGY CO., LTD.Inventor/a HU, Yong

Provided are a respiratory syncytial virus antigenic polypeptide, a vaccine, and a use. First, a respiratory syncytial virus antigenic polypeptide or an immunogenic fragment thereof is provided. Compared with the amino acid sequence of a respiratory syncytial virus wild-type pre-F protein, the amino acid sequence of the respiratory syncytial virus antigenic polypeptide or the immunogenic fragment thereof has one or more mutation sites of amino acid residues at the following positions: positions 174-176, positions 181-184, positions 210-213, and positions 160-161. The improvement of pre-F immunogenicity can be achieved and/or the protein expression level can be improved.

19.20250041278TLR8 AGONIST FOR MODULATING IMMUNE RESPONSE

US - 06.02.2025

Clasificación Internacional A61K 31/4184Nº de solicitud 18696547Solicitante The Children's Medical Center CorporationInventor/a David J. Dowling

Provided herein are uses for an immunostimulatory compound for stimulating an immune response when administered either alone or as an adjuvant in a vaccine. Also provided herein are kits, compositions, and methods of administration for the compound described for proliferative disease, inflammatory disease, autoimmune disease, infectious disease, or chronic disease, in a subject in need thereof. Using the compound as a vaccine adjuvant enables effective immunization in vulnerable populations.

20.WO/2025/029562DNA VACCINES FOR ELICITING T CELL IMMUNITY IN THE LUNG

WO - 06.02.2025

Clasificación Internacional A61K 39/125Nº de solicitud PCT/US2024/039464Solicitante THE JOHNS HOPKINS UNIVERSITYInventor/a MARKHAM, Richard

Provided herein are nucleic acid vaccine constructs comprising synthetic polynucleotides encoding a severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) protein, or a functional portion, fragment, or variant thereof, conjugated to a macrophage inflammatory protein-3 alpha (MIP-3a) or other chemokine that binds to a chemokine receptor 6 (CCR6), or a functional portion, fragment, or variant thereof, or to an antibody, or antigen binding portion thereof, that binds to a CCR6. Methods for making the vaccine constructs and their use in prophylaxis and treatment of SARS-CoV-2 infections are also provided.

21.20250041395RECOMBINANT HEGF-CRM197 TUMOR THERAPEUTIC VACCINE FORMULATION

US - 06.02.2025

Clasificación Internacional A61K 39/00Nº de solicitud 18716125Solicitante SHANGHAI HUIMMUTECH BIOTECHNOLOGY CO., LTDInventor/a Wenyao ZHANG

Provided in the present invention is a recombinant hEGF-CRM197 tumor therapeutic vaccine formulation. Specifically, the formulation of the present invention contains a therapeutically effective amount of a conjugate of a recombinant human epidermal growth factor (hEGF) and a diphtheria toxin mutant (CRM197), a phosphate base buffer solution with the pH in a range of 7.5-8.5, a polysorbate 20 surfactant and optionally a monosaccharide or disaccharide. The protein conjugate molecule in the formulation of the present invention

can break immune tolerance and induce the production of an anti-human epidermal growth factor antibody in the human body; In addition, the protein conjugate molecule produces a lower proportion of polymers, and has a more uniform molecular weight distribution in the buffer, and better stability. Therefore, the formulation of the present invention can achieve large-scale production and can be stably stored for a long time.

22.WO/2025/031378MUTANT OF RSV PRE-FUSION CONFORMATIONAL F PROTEIN AND USE THEREOF

WO - 13.02.2025

Clasificación Internacional C07K 14/135Nº de solicitud PCT/CN2024/110284Solicitante BEIJING NEOCURNA BIOTECHNOLOGY CORPORATIONInventor/a WANG, Yi

Provided is a mutant of a respiratory syncytial virus (RSV) pre-fusion conformational F protein. The mutant comprises an amino acid mutation relative to the amino acid sequence of a wild-type RSV F protein, the amino acid mutation being amino acids at a position 392 and a position 493 or a position near the position 493 being substituted by C, and a disulfide bond being formed between a position 392C and a position 493C or a position near the position 493C after the mutation. Also provided are a related DNA coding sequence, recombinant plasmid and mRNA sequence and a corresponding RSV vaccine. By introducing a disulfide bond at a suitable position, and combining same with cavity filling, electrostatic mutation, proline mutation and the like, the expression and stability of an F protein having pre- and post-fusion conformations and a trimerized conformation are significantly improved, and the conformation of the F protein is significantly inhibited from being converted into the post-fusion conformation. The mutant is also applied to preparation of an RSV vaccine and RSV infection detection.

23.4499139IMMUNOGENE UND IMPFSTOFFZUSAMMENSETZUNGEN GEGEN HIV

EP - 05.02.2025

Clasificación Internacional A61K 39/21Nº de solicitud 23782082Solicitante HENRY M JACKSON FOUND ADVANCEMENT MILITARY MEDICINE INCInventor/a ROLLAND MORGANE MARIE

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

24.20250041397EXPRESSION OF BORRELIA BURGDORFERI OUTER SURFACE PROTEIN A IN PLANTS AND PLANT PRODUCED VACCINE FOR SAME

US - 06.02.2025

Clasificación Internacional A61K 39/02Nº de solicitud 18678214Solicitante Applied Biotechnology Institute, Inc.Inventor/a John Howard

Vaccines and methods of expressing a polypeptide of *Borrelia burgdorferi* are provided in which a protective response to *Borrelia burgdorferi* is produced when administered to an animal. The vaccine provides for expression of the *Borrelia burgdorferi* OspA polypeptide in a plant or plant part, linked to a promoter preferentially directing expression to embryo tissue of the plant or plant part. Further embodiments provide that the polypeptide may be targeted to the apoplast/cell wall or the endoplasmic reticulum. Increased

expression levels in the plant or plant part are obtained. The plant or plant materials in an embodiment may be orally administered.

25.20250041408SMALL MOLECULE IMMUNOPOTENTIATOR CONJUGATES OF NFKB ACTIVATORS AS ADJUVANTS WITH ENHANCED EFFICACY AND REDUCED TOXICITY

US - 06.02.2025

Clasificación Internacional A61K 39/39Nº de solicitud 18709085Solicitante Naorem NIHESHInventor/a Aaron ESSER-KAHN

The present disclosure concerns immunomodulatory compositions and methods of use for enhancing response to an antigen (e.g., in a vaccine), an immunotherapy (e.g., a cancer immunotherapy), or other immune stimulation. The disclosure describes immunomodulators having reduced toxicity and improved immune response compared with existing adjuvants. Further disclosed are methods for improving an immune response to a vaccine antigen, cancer immunotherapeutic, or other immune stimulating agent. The disclosure describes dimeric and polymeric immunomodulators comprising one or more pattern recognition receptor (PRR) agonist moieties and one or more NF-κB inhibitor moieties.

26.WO/2025/027624CYCLIC GLYCOLIPOPEPTIDE VACCINE ADJUVANTS AND THE PROCESS FOR PREPARATION THEREOF

WO - 06.02.2025

Clasificación Internacional A61K 38/00Nº de solicitud PCT/IN2024/050993Solicitante COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH AN INDIAN REGISTERED BODY INCORPORATED UNDER THE REGN. OF SOC. ACT (ACT XXI OF 1860)Inventor/a HALMUTHUR MAHABALARAO, Sampath Kumar

The present invention relates a cyclic glycolipopeptide compounds useful as adjuvants in immunogenic compositions for vaccination. The cyclic glycolipopeptides bear 1,2,3- triazole or C4-homologue moieties on glucose unit of a NOD2 agonistic peptide moiety and have high potential of immuno-modulating properties for use as adjuvants in vaccine formulations. The present invention discloses a process for the preparation of these cyclic glycolipopeptide analogues and their intermediates.

27.20250041324CYCLIC DINUCLEOTIDES AS AGONISTS OF STIMULATOR OF INTERFERON GENE DEPENDENT SIGNALLING

US - 06.02.2025

Clasificación Internacional A61K 31/7084Nº de solicitud 18734176Solicitante Board of Regents, The University of Texas SystemInventor/a Maria Emilia DI FRANCESCO

Disclosed herein are new cyclic dinucleotide compounds and compositions and their application as pharmaceuticals for the treatment of disease. Methods of modulation of immune response to disease, and induce Stimulator of Interferon Genes (STING) dependent type I interferon production and co-regulated genes in a human or animal subject are also provided for the treatment diseases such as cancer, particularly metastatic solid tumors and lymphomas, inflammation, allergic and autoimmune disease, infectious disease, and for use as anti-viral agents and vaccine adjuvants.

28.WO/2025/030097PHARMACEUTICAL COMPOSITIONS FOR DELIVERY OF HERPES SIMPLEX VIRUS ANTIGENS AND RELATED METHODS

WO - 06.02.2025

Clasificación Internacional A61K 39/12Nº de solicitud PCT/US2024/040724Solicitante BIONTECH SEInventor/a SAHIN, Ugur

The present disclosure provides pharmaceutical compositions for delivery of HSV antigens (e.g., an HSV vaccine) and related technologies (e.g., components thereof and/or methods relating thereto).

29.2025200420COMBINATION OF A TLR7 MODULATING COMPOUND AND AN HIV VACCINE

AU - 06.02.2025

Clasificación Internacional Nº de solicitud 2025200420Solicitante Aelix Therapeutics S.L.Inventor/a BRANDER, Christian

30.2025200483CORONAVIRUS VACCINE

AU - 06.02.2025

Clasificación Internacional Nº de solicitud 2025200483Solicitante BioNTech SEInventor/a Güler, Alptekin

31.WO/2025/027551IBV VACCINE WITH HETEROLOGOUS DMV/1639 SPIKE PROTEIN

WO - 06.02.2025

Clasificación Internacional A61K 39/12Nº de solicitud PCT/IB2024/057434Solicitante BOEHRINGER INGELHEIM VETMEDICA GMBHInventor/a KRAEMER-KUEHL, Annika

The present invention relates i.a. to an IBV (infectious bronchitis virus) encoding for a heterologous DMV S (spike) protein or fragment thereof. Further, the present invention relates to an immunogenic composition comprising said IBV encoding for a heterologous DMV S (spike) protein or fragment thereof. Furthermore, the present invention relates to methods for immunizing a subject comprising administering to such subject the immunogenic composition of the present invention. Moreover, the present invention relates to methods of treating or preventing clinical signs caused by IBV in a subject of need, the method comprising administering to the subject a therapeutically effective amount of an immunogenic composition according to the present invention.

32.4499840ZUSAMMENSETZUNGEN UND VERFAHREN ZUR PROTEINEXPRESSION MIT RNA

EP - 05.02.2025

Clasificación Internacional C12N 15/79Nº de solicitud 23718587Solicitante EXCEPGEN INCInventor/a MERTINS BARBARA

The compositions and methods provided herein include a ribonucleic acid (RNA) encoding a nuclear cytoplasmic transport (NCT) inhibitor protein to improve target protein expression, *e.g.*, target protein expression encoded by a DNA vector, an mRNA, a self-amplifying RNA or an RNA comprising an unmodified uridine nucleotide. The compositions and methods provided herein may be used to improve the expression of any target protein, for example a viral protein antigen, *e.g.,* for use in a vaccine.

33.WO/2025/034612VARICELLA-ZOSTER VIRUS MRNA VACCINE

WO - 13.02.2025

Clasificación Internacional A61K 39/12Nº de solicitud PCT/US2024/040864Solicitante MODERNATX, INC.Inventor/a METKAR, Mihir

Provided herein are optimized messenger ribonucleic acid (mRNA) vaccines for varicella zoster virus (VZV). The mRNA vaccines encode one or more VZV antigens, such as gE and variants of gE. Methods of use of the mRNA vaccines are also provided.

34.4499137IMMUNOGENE ZUSAMMENSETZUNGEN ZUR PRÄVENTION VON INFLUENZA A

EP - 05.02.2025

Clasificación Internacional A61K 39/12Nº de solicitud 23716652Solicitante UNIV OXFORD INNOVATION LTDInventor/a GUPTA SUNETRA

The present invention relates to polypeptides and immunogenic compositions, particularly vaccine compositions, for the prevention or treatment of influenza A. The invention also provides nucleic acid molecules and vectors encoding the polypeptides, and methods of using the compositions, nucleic acid molecules and vectors for the prevention or treatment of influenza A.

35.318116REPLICATION INCOMPETENT HERPES SIMPLEX VIRUS TYPE 1 VIRAL VACCINE

IL - 01.02.2025

Clasificación Internacional A61K 39/00Nº de solicitud 318116Solicitante IMMVIRA BIOPHARMACEUTICALS CO., LIMITEDInventor/a Yuanyuan LIU

36.20250041407VARICELLA ZOSTER VIRUS (VZV) VACCINE

US - 06.02.2025

Clasificación Internacional A61K 39/25Nº de solicitud 18416835Solicitante ModernaTX, Inc.Inventor/a Giuseppe Ciaramella

Aspects of the disclosure relate to nucleic acid vaccines. The vaccines include at least one RNA polynucleotides having a open reading frame encoding at least varicella zoster virus (VZV) antigen. Methods for preparing and using such vaccines are also described.

37.WO/2025/030165PHARMACEUTICAL COMPOSITIONS FOR DELIVERY OF HERPES SIMPLEX VIRUS ANTIGENS AND RELATED METHODS

WO - 06.02.2025

Clasificación Internacional A61K 39/245Nº de solicitud PCT/US2024/040874Solicitante BIONTECH SEInventor/a GÜLER, Alptekin

The present disclosure provides pharmaceutical compositions for delivery of HSV antigens (e.g., an HSV vaccine) and related technologies (e.g., components thereof and/or methods relating thereto).

38.317780EPSTEIN-BARR-VIRUS VACCINE

IL - 01.02.2025

Clasificación Internacional A61K 39/00Nº de solicitud 317780Solicitante Bavarian Nordic A/SInventor/a

39.317982A VACCINE COMPOSITION OF CELLS EXPRESSING A LENTIVIRAL VECTOR AND METHODS OF USING

IL - 01.02.2025

Clasificación Internacional A61K 39/09Nº de solicitud 317982Solicitante MERIDIAN THERAPEUTICS, INC.Inventor/a NOONAN, Kimberly, A.

40.WO/2025/028960CONJUGATE FOR ANTIGEN DELIVERY AND USE THEREOF

WO - 06.02.2025

Clasificación Internacional A61K 47/64Nº de solicitud PCT/KR2024/010983Solicitante LG CHEM, LTD.Inventor/a KIM, Dae Hee

The present invention relates to: a conjugate comprising mRNA of an antigen protein and mRNA encoding a carrier protein linked to the 5' end and the 3' end of the mRNA of the antigen protein; and an immunization composition and/or vaccine composition comprising same. The present invention has the effect of stably increasing the expression of the antigen protein.

41.4499662KOMBINATION VON EPITOPEN UND DEREN VERWENDUNG, IMPFSTOFFKONSTRUKT, VERFAHREN ZUR AUSLÖSUNG EINER IMMUNANTWORT, VERFAHREN ZUR IDENTIFIZIERUNG VON EPITOPEN

EP - 05.02.2025

Clasificación Internacional C07K 7/06Nº de solicitud 23773377Solicitante FUND ZERBINIInventor/a KALIL FILHO JORGE ELIAS

The present invention refers to a combination of epitopes comprising at least eight T cell epitopes from the SARS-CoV-2, as well as the use of said combination ("set of epitopes"). Said epitopes are widely recognized by CD4+ T- lymphocytes of the overwhelming majority of COVID-19 convalescent individuals.

42.20250041403PHYSIOLOGICAL METRICS AS CANDIDATE PREDICTORS OF ANTIBODY RESPONSE FOLLOWING VACCINATION AGAINST COVID-19

US - 06.02.2025

Clasificación Internacional A61K 39/215Nº de solicitud 18717783Solicitante Ashley E. MASONInventor/a Ashley E. Mason

Methods, systems, and devices are provided for predicting the robustness of an antibody response of a subject to the SARS-COV-2 spike protein receptor binding domain based on measurement of physiological metrics following vaccination. In particular, one or more physiological metrics of the subject selected from dermal temperature deviation, heart rate, respiratory rate, heart rate variability, and deep sleep duration are measured with a wearable device before and after vaccinating the subject, wherein increases in dermal temperature deviation, heart rate, and respiratory rate, and decreases in heart rate variability on the first night after administration of the vaccine to the subject are correlated with greater antibody responses to the SARS-COV-2 spike protein.

43.WO/2025/026209ARF1 INHIBITOR AND USE THEREOF

WO - 06.02.2025

Clasificación Internacional C07D 495/04Nº de solicitud PCT/CN2024/107778Solicitante AOBIO PHARMACEUTICAL CO., LTD.Inventor/a HOU, Steven Xianyu

A compound of formula (I), or a stereoisomer, isotopic variant, pharmaceutically acceptable salt or solvate thereof, wherein R_1, R_2, R_3, R_4, X_1, X_2, X_3, X_4, X_5, X_6, X_7, X_8, X_9, X_{10}, L, ring A, ring B, ring C, and ring D are as described herein. The compound of formula (I), or the stereoisomer, isotopic variant, pharmaceutically acceptable salt or solvate thereof can be used as an Arf1 inhibitor. Further provided are a pharmaceutical composition containing the compound of formula (I), or the stereoisomer, isotopic variant, pharmaceutically acceptable salt or solvate thereof, and a use in the treatment or prevention of a disease, such as cancer or tumor, associated with Arf1 pathway activity in a subject. Further provided is a use of the compound of formula (I), or the stereoisomer, isotopic variant, pharmaceutically acceptable salt or solvate thereof in the preparation of a therapeutic vaccine for retarding tumor development.

44.WO/2025/030154PHARMACEUTICAL COMPOSITIONS FOR DELIVERY OF HERPES SIMPLEX VIRUS GLYCOPROTEIN B ANTIGENS AND RELATED METHODS

WO - 06.02.2025

Clasificación Internacional A61K 39/12Nº de solicitud PCT/US2024/040844Solicitante THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIAInventor/a FRIEDMAN, Harvey

The present disclosure provides pharmaceutical compositions for delivery of HSV antigens (e.g., an HSV vaccine) and related technologies (e.g., components thereof and/or methods relating thereto).

45.4499805ANTIGENLIEFERNDE SALMONELLA ZUR VERWENDUNG ALS TUMOR-HOMING-BAKE ZUM REFOKUSSIEREN VON BEREITS BESTEHENDEN, IMPFSTOFFERZEUGTEN T-ZELLEN ZUR BEKÄMPFUNG VON KREBS

EP - 05.02.2025

Clasificación Internacional C12N 1/06Nº de solicitud 23720019Solicitante UNIV MASSACHUSETTSInventor/a FORBES NEIL S

To make an immunotherapy that is effective for a larger group of cancer patients, *Salmonella* have been genetically engineered to deliver proteins from prior vaccines into the cytoplasm of tumor cells.

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