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

- Noticias más recientes en la Web sobre vacunas.
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- Patentes más recientes en Patentscope sobre vacunas.

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CUBA

Noticias en la Web

Pfizer reports top-line results from Phase III RSV vaccine trial

Mar 1. Pfizer has reported top-line results from the Phase III RENOIR clinical trial of its respiratory syncytial virus (RSV) vaccine, ABRYSVO, for RSV -linked lower respiratory tract disease (LRTD).

The randomised, placebo-controlled, and double-blinded study evaluated the safety, immunogenicity, and efficacy of a single dose of the vaccine in adults aged 60 and above.

It enrolled subjects following a second RSV season in the Northern and Southern Hemispheres.

According to the findings, the vaccine showed a 77.8% efficacy against RSV-associated LRTD after the second season, a slight decrease from the 88.9% efficacy observed after the first season, indicating durable protection.

Efficacy was consistent for both RSV A and RSV B subtypes, with rates of more than 80% for LRTD with three or more symptoms.

The vaccine's efficacy was demonstrated to be maintained against less severe LRTD, defined by two or more symptoms, from 65.1% after the first season to 55.7% after season two.

Following more than 16.4 months of disease surveillance across both seasons, the vaccine's efficacy against RSV-associated LRTD with three or more symptoms was 81.5%.

Pfizer reported no new adverse events through the second RSV season other than those reported during the first season, indicating ABRYSVO's favourable safety profile.

The company plans to submit these findings to regulatory agencies and vaccine technical committees for review.

Pfizer Vaccine Research and Development senior vice-president and chief scientific officer Annaliesa Anderson said: "We are encouraged by the level of protection that we observed after two full RSV seasons for ABRYSVO.

"This new data indicates that broad and durable protection against both types of RSV that cause disease, RSV A and RSV B, is the potential benefit to having a bivalent vaccine."

The latest development comes after Pfizer's Elrexfio for treating multiple myeloma received conditional market approval from the European Commission (EC), following a Phase II trial in patients who had previously undergone multiple treatments.

Fuente: Clinical Trials Arena. Disponible en https://acortar.link/NaeCQM

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Se presentó frente a las sociedades científicas la vacuna contra el Virus Sincicial Respiratorio

1 mar. Autoridades del Ministerio de Salud de Argentina se reunieron hoy en la sede de la cartera sanitaria nacional con representantes de las sociedades científicas para presentar la estrategia de vacunación contra el Virus Sincicial Respiratorio (VSR) que fue incorporada este año al Calendario Nacional de Vacunación (CNV) para proporcionar protección contra la bronquiolitis durante los primeros seis meses de vida.

Luego de agradecer la presencia de los representantes de las sociedades científicas, el subsecretario de Planificación y Programación Sanitaria, Hernán Seoane, subrayó que "es un honor enorme poder dar buenas noticias en relación a inmunizaciones", a la vez que destacó la decisión del ministro de Salud de la Nación, Mario Russo, de generar "esta inversión en salud pública a sólo dos meses del inicio de nuestra gestión, tomando lo trabajado anteriormente, con un gran espíritu de colaboración entre la cartera sanitaria, la Comisión Nacional de Inmunización (CoNaIn) y las sociedades científicas".

El funcionario añadió que la incorporación de esta vacuna al Calendario Nacional de Vacunación implica contar con la confianza de las embarazadas. "No alcanza solamente con contar con la vacuna. Hasta que no la aplicamos, el proceso no termina. Por eso vamos a necesitar mucho de la colaboración de todos ustedes en cada una de las fases. Ya estamos trabajando con las carteras sanitarias de todas las provincias", señaló.

Seoane remarcó además que nuestro país es pionero en la región con la estrategia de vacunación contra el Virus Sincicial Respiratorio. "Hay un montón de países en América Latina que están mirando esta experiencia argentina. Así que es una doble responsabilidad y tenemos que estar a la altura de esa expectativa", manifestó.

En tanto, la directora de la Dirección de Control de Enfermedades Inmunoprevenibles, Florencia Bruggesser, agradeció a "todas las sociedades científicas y los equipos del ministerio". A la vez, sostuvo que para esta "vacuna tan esperada" es muy importante contar con el acompañamiento de los profesionales obstetras. "Para las embarazadas son como sus médicos de cabecera en ese momento y todo lo que dicen es palabra santa. Por eso creemos que es fundamental su apoyo", agregó.

Por su parte, las sociedades científicas expresaron su apoyo a la incorporación de la vacuna contra el Virus Sincicial Respiratorio al Calendario Nacional de Vacunación y manifestaron su compromiso a fortalecer la aceptación, seguridad y eficacia de esta estrategia de prevención, que aseguraron va a tener un impacto enorme en los chicos, sus familias y los grupos más vulnerables.

La estrategia de vacunación contra el Virus Sincicial Respiratorio fue incorporada al Calendario Nacional de Vacunación con carácter gratuito y obligatorio para personas gestantes con el objetivo de proporcionar, a través del pasaje transplacentario de anticuerpos, protección contra la bronquiolitis durante los primeros seis meses de vida. A tal fin, se aplicará una dosis de esta vacuna a todas las mujeres embarazadas entre las semanas 32 y 36,6 de gestación, antes del inicio y durante la temporada de circulación del VSR.

El Virus Sincicial Respiratorio es la causa principal de infecciones respiratorias agudas bajas en la infancia y en particular en lactantes menores a un año. También provoca aumento de hospitalizaciones, con eventuales complicaciones con requerimientos de cuidados críticos y elevado nivel de consulta ambulatoria en la época invernal.

La incorporación de la vacuna contra el VSR para embarazadas al CNV contribuye al descenso de la

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mortalidad infantil neonatal y postneonatal en nuestro país, al reducir la infección por este virus de niños menores de seis meses de vida. Asimismo, contribuirá a disminuir los altos porcentajes de ocupación en salas de internación general, camas de terapia intensiva pediátrica y neonatal causados por el virus, así como el consiguiente incremento en los costos del sistema de salud.

Participaron del encuentro la Presidenta de la Comisión Nacional de Inmunizaciones y representantes de la Organización Panamericana de la Salud (OPS); Sociedad Argentina de Pediatría (SAP); Sociedad Argentina de Vacunología y Epidemiología (SAVE); Sociedad Argentina de Infectología (SADI); Sociedad Argentina de Infectología Pediátrica (SADIP); Federación Argentina de Sociedades de Ginecología y Obstetricia (FASGO); Sociedad Argentina de Ginecología infanto juvenil (SAGIJ); Federación Argentina de Medicina Familiar y General (FAMFYG); Federación Argentina de Enfermería (FAE).

Por parte del Ministerio de Salud de la Nación también estuvieron presentes el subsecretario de Vigilancia Epidemiológica, Información y Estadísticas de Salud, Federico Pedernera; de la Dirección de Salud Perinatal y Niñez, Sandra Sagradini y María Julia Cuetos; y la coordinadora de Atención Primaria de la Salud (APS), Maia Steinman.

Fuente: Argentina.gob.ar. Disponible en https://acortar.link/LdBVk5

Africa immunization advisory group urges single-dose HPV vaccine adoption to advance vaccination efforts

Mar 1. Cervical cancer poses a significant burden in sub-Saharan Africa, with 120,000 cases annually out of the global total of 690,000, further exacerbated by the HIV epidemic.

In an effort to accelerate progress against cervical cancer, the WHO Africa Regional Immunization Technical Advisory Group (RITAG) during a meeting held 7 – 9 November 2023 has urged countries to adopt a single-dose schedule for the human papillomavirus vaccine (HPV) vaccine in Africa, in line with the World Health Organization's (WHO) recommendations in 2022. Implementation of this recommendation represents a significant step forward in the region's fight against cervical cancer.

Currently, 27 African nations have incorporated the HPV vaccine into their routine immunization programmes, with a primary focus on girls aged 9-14. In November 2023, Togo became the latest country to introduce the human papillomavirus vaccine to protect adolescent girls from the leading cause of cervical cancer, following Nigeria which rolled out the HPV vaccine in October 2023. Overall, HPV vaccine coverage remain low. As of 2022, coverage of first dose in the African Region stands at only 33%, falling short of the global target of 90%. Increasing coverage is essential to reduce the burden of cervical cancer and improve public health outcomes.

However, challenges such as limited vaccine supply have hindered efforts to catch up with older age groups in certain areas.

In response to evolving evidence and challenges, countries like Cameroon and Cabo Verde have demonstrated adaptability by transitioning to a single-dose regimen and expanding vaccination to include boys. Additionally, the endorsement of a single-dose schedule by National Immunization Technical Advisory Groups (NITAGs) in 16 African countries highlights the importance of streamlined and cost-effective strategies.

To accelerate progress, WHO emphasizes a strategic approach that includes political advocacy,

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comprehensive coordination, resource optimization, multisectoral partnerships, and strengthening health systems.

“By integrating HPV vaccination with other health programmes and ensuring equitable access, we can accelerate progress towards protecting people against cervical cancer,” says Dr Matshidiso Moeti, WHO Regional Director for Africa.

RITAG recommends several key actions, including adopting a single-dose schedule, extending vaccination to older age groups and boys where feasible, prioritizing immunocompromised individuals, strengthening advocacy and communication efforts, and promoting peer-to-peer learning for optimal service delivery strategies.

RITAG's endorsement of a single-dose HPV vaccine schedule marks a pivotal moment in Africa's fight against cervical cancer. By implementing these recommendations and adopting a strategic approach, the region can make significant progress in preventing this disease and ensuring a healthier future for its population.

Fuente: Relief web. Disponible en https://acortar.link/TEBM2g

Largest COVID-19 vaccine study to date

Mar 3. The latest, newest and largest study of COVID-19 vaccines was released Friday, Feb. 23, in the international journal ‘Vaccine,” and revealed vaccines that protect against severe illness, death and lingering long COVID symptoms from a coronavirus infection were linked to small increases in neurological, blood and heart-related conditions in the largest global vaccine safety study to date.

The Guardian, an independent online news source states, “Findings published in journal “Vaccine” compared the rates of 13 brain, blood and heart conditions in people after they received the Pfizer, Moderna or AstraZeneca vaccine. Two new but exceptionally rare COVID-19 vaccine side effects - a neurological disorder and inflammation of the spinal cord - have been detected by researchers in this study.”

More than 99 million people from Australia, Argentina, Canada, Denmark, Finland, France, New Zealand and Scotland were in the study that also confirmed how rare known vaccine complications are, with researchers also confirming the benefits from vaccines still vastly outweigh the risks.

The links between the Pfizer and Moderna vaccines confirmed the rare side-effects of myocarditis (inflammation of the heart muscle) and pericarditis (swelling of the thin sac covering the heart). The study also confirmed Guillain-Barré syndrome (where the immune system attacks the nerves) and cerebral venous sinus thrombosis (a type of blood clot in the brain) are rare side effects linked to the AstraZeneca vaccine. A new rare side-effect, acute disseminated encephalomyelitis (an inflammation and swelling in the brain and spinal cord) was also identified in the data analysis as being linked to the AstraZeneca vaccine.

The most successful vaccine for COVID-19, based on the comparison between people who got COVID-19 in the placebo group, the Moderna COVID-19 vaccine was 98% effective at preventing serous COVID-19 illness. New data from CDC (Center of Disease Control) show that the updated COVID-19 vaccines were more effective against COVID-19 during September 2023 through January 2024, including against variants from the XBB lineage, which is included in the updated vaccine and JN.1, a new variant that has become dominant in recent weeks.

Professor Jim Buttery, co-director of the “Global Vaccine Data Network,” said the findings prompted researchers to independently confirm the side-effect by completing a second separate study including

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6.8 million Australians who received the AstraZeneca. The results confirmed acute disseminated encephalomyelitis but the data also allowed them to detect a second new rate side-effect, transverse myelitis or spinal cord inflammation.

Buttery, who is also a senior research analyst with the Murdoch Children's Research Institute in Australia said, "For rare side effects, we don't learn about them until the vaccine has been used in millions of people … No clinical trial can ever have the size to answer these questions and so we only find out after a vaccine has been introduced."

The risk of myocarditis is even higher with natural COVID-19 infection than it is following vaccination, according to Buttery. He added, both conditions are serious but patients usually recover from them.

It is noted by vaccine expert Professor Julie Leask at the University of Sydney, a COVID infection increases the risk of some of these rare conditions much more than a vaccine does. Vaccines protect against severe illness, death and lingering long COVID symptoms from a coronavirus infection.

The CDC data show that vaccination offered significant protection. "People who received the updated COVID -19 vaccine were 54% less likely to get COVID-19 during the four-month period from mid-September 2023 to January 2024 (the highest season for the virus).

"The COVID-19 will continue to evolve, as for viruses to survive, they must continually make copies of themselves and infect new cells. Like other viruses, SARS-CoV2, the virus that causes COVID-19, will continue to evolve because it makes errors, or mutations, when it is creating copies. Some mutations help the virus survive better or spread more easily, leading to different variants over time. During the analysis period, many different variants were infecting people."

CDC also stated most people who are vaccinated and those who had COVID-19 will have some protection from future severe COVID-19. Although the amount and duration of protection from vaccination or infection can vary from person to person. CDC continues to recommend everyone 6 months or older get an updated COVID-19 vaccine. Vaccination remains the best protection against COVID-19-related hospitalization and death. Vaccination also reduces your chance of suffering the effects of Long COVID, which can develop during or following acute infection and last for an extended duration.

Vaccination is especially important for people at higher risk of severe illness from respiratory diseases, including young children, older adults, people with underlying medical conditions and pregnant people. People who are moderately or severely immunocompromised may receive one or more additional doses of an updated COVID-19 vaccine. Last October adventhealth.com stated, "Experts recommend boosters or updated doses of the COVID-19 should follow three to four months after your last COVID shot since the vaccines are most effective in the first few months following your shot."

Fuente: News Mirror. Disponible en https://acortar.link/OZIy6X

CDC recommends another COVID-19 vaccine dose for older adults

Mar 3. The Centers for Disease Control and Prevention is now recommending adults 65 and older get an additional dose of this season's COVID-19 vaccination.

"(The recommendation announced on Feb. 28) allows older adults to receive an additional dose of this season's COVID-19 vaccine to provide added protection," said Dr. Mandy Cohen, CDC director.

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"Most COVID-19 deaths and hospitalizations last year were among people 65 years and older. An additional vaccine dose can provide added protection that may have decreased over time for those at highest risk."

Those who are immunocompromised were already eligible for an additional dose, the CDC said.

According to the CDC, adults 65 years and older are disproportionately impacted by COVID-19, with more than half of the nation's COVID-19 hospitalizations during October to December 2023 occurring in this age group.

The CDC recommends everyone 6 months and older get this season's vaccine. To find COVID-19 or flu vaccines, visit vaccines.gov or call the Jefferson County Health Department at 636-797-4631.

The Missouri Department of Health and Senior Services said a flu vaccination still can provide benefit this respiratory season, which began Oct. 1 and ends in May. Like the COVID-19 vaccine, the flu shot, can protect people from serious illness.

Everyone 6 months and older is eligible to get a flu vaccine. It takes two weeks after vaccination for antibodies to develop in the body and provide protection against the viruses, DHSS said.

The department also recommends an RSV vaccine for adults 60 and older to protect them from severe RSV illness. It is given as a single dose and can be prescribed by a health care provider. Options also are available for young children and pregnant women. People should talk to their health care provider to determine if the RSV vaccine is right for them.

According to DHSS, there are also various programs for those without health insurance to receive vaccinations or testing.

The CDC's Bridge Access Program provides COVID-19 vaccinations at no cost to adults. The Vaccines for Children Program, funded by the CDC, provides free vaccines to children who qualify and is designed to help protect children against vaccine-preventable diseases.

Home Test to Treat, a new nationwide program, provides access to free testing, telehealth visits, and treatment for COVID-19 and flu. Free telehealth visits and treatment are available for anyone who tests positive for either condition, regardless of insurance status.

Anyone who is uninsured or enrolled in Medicaid, Medicare, VA Healthcare or Indian Health Services also may receive free at-home COVID-19 and/or flu tests, even if they are not currently positive. Call 1-800-682-2829 or visit test2treat.org to learn how to enroll.

Fuente: My Leader Paper. Disponible en https://acortar.link/Oh0672

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VAX-24 Vaccine Proceeds in Infant Phase 2 Study for Preventing Invasive Pneumococcal Disease

Mar 4. Vaxcyte, Inc. today announced it has completed enrollment for its Infant Phase 2 clinical study evaluating VAX-24, a 24-valent pneumococcal conjugate vaccine (PCV) engineered to prevent invasive pneumococcal disease (IPD).

The primary three-dose immunization series is expected to produce topline safety, tolerability, and immunogenicity data by the end of the first quarter of 2025. And the booster dose results will be announced by the end of 2025.

These results will be crucial in demonstrating the effectiveness of VAX-24 and its potential to protect humankind from bacterial diseases.

"Despite the effectiveness of current vaccines, IPD, which includes meningitis and bacteremia, remains persistent in the first years of life and is a leading cause of invasive disease in children two years of age and under," said Jim Wassil, Executive Vice President and Chief Operating Officer of Vaxcyte, in a press release on March 4, 2024.

Vaxcyte's carrier-sparing PCV franchise candidates include VAX-24 and VAX-31, the Company's next-generation 31-valent PCV currently being evaluated in a Phase 1/2 study, are being studied to prevent IPD.

Fuente: precisionvaccinations. Disponible en https://acortar.link/KrB39c

Europa da luz verde a la vacuna que debería frenar la próxima pandemia

5 mar. Europa ha comenzado a prepararse ante una hipotética pandemia cuyo protagonista sea el virus de la influenza aviar. Después del impacto de la COVID-19 en los últimos años, la Agencia Europea del Medicamento (EMA) ha dado luz verde a la vacuna contra la gripe aviar.

De hecho, son dos vacunas de preparación contra este patógeno, que es el subtipo H5N1 del virus de la gripe A. La primera fórmula, está basada en un virus que ha circulado entre pavos en el año 2005. El nombre de la primera dosis es Celldemic (vacuna contra la gripe zoonótica). Estará destinada a la inmunización durante los brotes de gripe procedente de animales.

Formada por dos proteínas de la superficie del virus, la hemaglutinina y la neuraminidasa,

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provocan la respuesta del sistema inmunitario inoculada la dosis. Por otro lado, se encuentra la segunda fórmula, de preparación para una pandemia. Se trata de Incellipan (vacuna contra la gripe pandémica). A diferencia de la primera, se empleará si se declara oficialmente la pandemia por gripe aviar. Esta contiene antígenos de superficie de hemaglutinina y neuraminidasa purificados a partir de virus inactivos.

Dosis, intervalo entre cada vacuna y efectos secundarios

El desarrollo de ambas dosis contra el virus H5N1, causante de la gripe aviar, corre a cargo de la farmacéutica CSL Seqirus, uno de los mayores productores de vacunas a nivel mundial. Ambas están disponibles en suspensiones inyectables de 7,5 microgramos por dosis de 0,5 ml.

Las dos dosis de la vacuna Incellipan, en caso de pandemia por gripe aviar, se administrarán con un intervalo de tiempo de tres semanas. Están indicadas tanto para adultos, como para los niños mayores de seis meses. Tanto en menores, como en adultos, la vacuna proporcionará la respuesta inmunitaria tres semanas después de la administración de dos dosis.

Sobre los efectos secundarios, en el caso de los adultos, según especifica la EMA, los más frecuentes son el dolor en el lugar de la inyección, fatiga, dolor de cabeza, malestar general, mialgias y artralgias. Por su parte, en los menores entre seis y 18 años, puede causar dolor en el lugar de la inyección, mialgia, fatiga, malestar general, dolor de cabeza, pérdida de apetito, náuseas y artralgia. Mientras, en niños entre cero y seis años, los más comunes son sensibilidad en el lugar de la inyección, irritabilidad, somnolencia, cambios en los hábitos alimentarios y fiebre.

Fuente: As. Disponible en https://acortar.link/7LcMQC

How close is Cuba to having a dengue vaccine?

Mar 6. On February 17, El País reported that Brazil is experiencing the worst dengue epidemic in the last 90 years, with more than half a million patients and almost a hundred deaths from this disease. To face the crisis, health authorities decided to incorporate a vaccine into the dengue combat scheme.

The above makes Brazil the first country on the continent to use this health tool to combat the disease. The immunizer, purchased from the Japanese laboratory Takeda, began to be used in a clinical trial involving 20,000 people between 18 and 40 years old, who will receive two doses with an interval of three months between each one and will be followed for two years; well, although the drug has proven to be safe, it is not known for sure how it behaves in large population groups.

With this, the vaccine, which has already been marketed in the Brazilian private network since 2023, is now extended to the public health system.

The idea is to administer the six million doses acquired, prioritizing children over 10 years of age1 in the 541 cities with the highest incidence of cases. However, this is little for a country of 210 million inhabitants exposed to the disease.

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A disease that spreads on a global scale

According to the WHO, in recent decades the number of reported cases of dengue has multiplied by 10, going from 500,000 to more than 5 million a year. The number of patients is probably between ten and twenty times greater.

During 2020 and 2022, a decrease in the number of reported cases was observed. However, last year we witnessed a peak that approached historical highs, with outbreaks in areas where it is not common. For example, in 2023, 43 cases were reported in France, 82 in Italy, and 3 in Spain, totaling 128 cases. So far this year, 312 cases have been diagnosed in the United States.

Although the state with the highest incidence is Florida, patients have also been reported far north of the subtropical belt in states such as Michigan, Illinois, New York, Montana, or Pennsylvania, close to Canada.

According to the UN agency, the Americas region, with 4.1 million cases, led the world in terms of reporting the disease, accounting for nearly 80% of the total cases. In the region, an incidence of 416 cases per 100,000 inhabitants was also observed, more than 6,000 serious cases and 2,049 deaths, for a fatality rate of 0.05 per thousand patients. Additionally, 45% of the reported cases were confirmed by laboratory studies.

Even though Cuba is not among the countries that reported the most cases nor those that reported the greatest number of serious illnesses or deaths to the international organization, on the island dengue is a recurring problem that the health authorities and, of course, the population have to confront. In fact, the incidence of the virus has sometimes been above 100 cases per 100,000 inhabitants.

Having a vaccine that prevents this disease is an old desire of Cuban scientists. Is this being worked on? How much progress has been made? How close is the country to having a dengue vaccine?

On the trail of the Cuban vaccine

Few diseases had as great an impact on Cuban public health during the second half of the 20th century as dengue. According to an article by Dr. Gustavo Kourí, one of the world authorities on this disease, the Dengue Type 2 epidemic that devastated the country from the end of May to October 1981 left a total of more than 344,000 patients, with weeks of close to 10,000 cases. Of that total, about 9,000 suffered a severe form of the disease.

According to the prominent virologist, 158 deaths were recorded, with a fatality rate of 0.46 per thousand patients, 101 of which were children. The ages where the highest number of deaths were concentrated were between 4 and 6 years old, which made this epidemic especially painful.

Since then, Cuban scientists such as Dr. Kourí and his wife, Dr. Mary Guzmán, together with a group of prominent researchers, have contributed to elucidating different characteristics of the virus and the pathogenesis of the disease it causes.

Their contributions have earned them important international awards, such as the 2022 L'Oreal for Dr. Guzmán, which she shared, among others, with last year's Nobel Prize winner in Medicine and Physiology, Dr. Katalin Karikó, to whom we dedicate an article.

According to an article in Swissinfo, since 1992 Cuban scientists have been searching for a dengue vaccine. For more than two decades, different compounds have been tested that could lead to formulations capable of becoming a vaccine.

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In 2006, a protein called Domain III caught the interest of the group of Cuban researchers from the Center for Genetic Engineering and Biotechnology (CIGB) and the Pedro Kourí Institute (IPK) who are working together in search of the immunizer. The compound's ability to generate immunity against dengue in primates was encouraging. New results on this line of research were published in 2008 and 2009.

In this way, the concept of a quadrivalent vaccine candidate was built, that is, capable of protecting against the four serotypes of the dengue virus, one of the golden goals for any vaccine that aims to be effective against the disease and something already achieved by the Takeda laboratory, mentioned at the beginning of the article.

In 2014, a study was published according to which a formulation based on the combination of different proteins present in areas of the virus structure, including Domain III, had the capacity to generate an immunological (defensive) response of the organism against the pathogen, making it viable as a vaccine candidate.

The formula, called TetraDIIIC, was tested in 2015 in mice and non-human primates, obtaining encouraging results. In the following years, experiments were carried out to determine which doses allowed the best immunological response to be obtained in laboratory animals and the results were published in 2017, through several articles.

In 2019, a work in which the strategy of combining the vaccine candidate, TetraDIIIC, to which we have been referring, with another tetravalent candidate of attenuated viruses, known as TV005, developed by the U.S. National Institute of Allergy and Infectious Diseases.2 In this case, instead of the protein-based compound, a formulation containing weakened viruses of the four serotypes of dengue was used.

A new strategy?

In September 2022, national media briefly reported on the presentation by Dr.S. Gerardo Guillén Nieto — member of the team of researchers in charge of the development of the vaccine since the first published works and director of Biomedical Research at the CIGB — on "the Cuban strategy for the dengue vaccine" before the highest authorities of the country.

In March 2023, the CIGB reported through the X social media that the Cuban strategy to obtain a vaccine against this disease is based on recombinant proteins, but on this occasion, they were referring to the use of different structures than the one they were following with TetraDIIIC. According to the institution's publication, it is "a very secure technological platform. We have a tetravalent candidate, based on proteins from the four dengue viruses, that we are evaluating at this moment."

A month later, the aforementioned scientific institution announced that the vaccine candidate against dengue is currently in the "research-development stage." According to the publication, the researchers "are beginning preclinical studies, where they are testing 2 different formulations, intending to determine which one will be taken to clinical studies," that is, which one will be tested in humans.

On that same date, in an interview given to EFE and reproduced by Swissinfo, the CIGB research director explained that "instead of using the protein found in the virus membrane," Cuban researchers "are experimenting with its non-structural proteins (which encode the genes of the virus)."

According to Guillén Nieto, what they are pursuing is to create a vaccine capable of strengthening the cell-mediated response in the person who receives it and not that of their antibodies. What does this mean?

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The body's immune response is made up of two fundamental branches: the humoral response and the cellular response. A humoral response is understood as the body's way of dealing with toxins and infections through antibodies, which are proteins specifically designed against different antigens and transported by the blood, something like the infantry of the immune system.

They have the function of preventing the infection from entering the cells and multiplying. It is important to remember that viruses need the cellular apparatus to replicate.

Cellular immunity is focused on eliminating different enemies through the direct action of the cells of the immune system, such as T lymphocytes, which would be the motorized artillery and aviation of our defensive system. These cells have the ability to identify and eliminate infected cells, without attacking healthy ones or causing very little damage. It is a second line of defense against antibody-mediated immunity, which it completes and complements.

Does this new bet in the development of the Cuban vaccine mean abandoning years of research and starting a new path to obtain an efficient immunizer? What is this about? The answer is not clear. Based on more recent announcements, the Cuban team decided to put aside the line of research on the TetraDIIIC vaccine candidate.

In fact, since 2019, after intense activity in previous years with dozens of scientific articles on this line, the number of publications with the domain "Cuba dengue vaccine" on the Pubmed site decreased drastically, finding only 6 between 2020 and 2023. On the other hand, since that year, publications with the TetraDIIIC domain have not been collected on the same specialized site.

This may have to do with the safety profile of the Cuban candidate and may be related to what happened with Dengvaxia, the first approved dengue vaccine in the world, to which the CIGB research director refers in the Swissinfo publication.

Dengvaxia is an immunizer developed by a French pharmaceutical company based in the United States, Sanofi Pasteur. In 2017, after having vaccinated more than 733,000 minors in the Philippines, its administration was prohibited in that country, after the death of children with severe forms of the disease was recorded. Based on that, the FDA, the U.S. regulatory agency, ordered the suspension of all "sale, marketing, and marketing operations" of the product and "initiating an information campaign about the risks," according to an article in El Mundo, generating a great deal of scandal with multiple implications.

Why was this vaccine unsafe? Everything seems to indicate that it is due to a phenomenon known as antibody-dependent amplification (ADA), which is characteristic of this disease. When a person is infected by a virus of one of the four dengue serotypes, say 1, the infection is usually asymptomatic or very mild.

However, if a person becomes infected in the future with a virus of any of the other serotypes, then there is a possibility that instead of a banal infection, a severe form of the disease will appear, which can lead to death. This happens because antibodies, that first line of defense, instead of protecting the body against infection, induce an exaggerated response.

Returning to Dr. Guillén Nieto's interview, "Cuba seeks to make the vaccine in a different way" and, according to the expert, "it is the only country that is trying to do it this way," experimenting with non-structural proteins, that is, they are not part of the virus envelope, but are encoded by its genes.

So that it is understood, the virus is known as a "virion" when it has not infected the cell. The virion is DNA or

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RNA (genetic information) that encodes the proteins responsible for the activity of the virus, covered by different molecules that make up a structure called capsid. These molecules are known as capsomers and are responsible for protecting the viral core.

Non-structural proteins are contained in the genetic information carried by the virus and have different functions. Viruses need the cell's assembly machinery to reproduce or replicate.

This would avoid ADA or immunoamplification, as the phenomenon is also known, generating an important cellular response that would prevent severe forms of dengue. According to the CIGB research director, what is sought is that the "cellular response is sufficient to protect (from the four serotypes). We are going to have a safety guarantee, but it remains to be demonstrated whether we are going to be sufficiently effective to protect against the disease."

In the near future, there will surely be more information on this topic. At the moment, there is a precedent for a 2014 publication in which antigenicity (the ability to produce an immune response in the body) and immunogenicity were studied, which is related to the immunological memory of the recombinant non-structural protein 3 (NS3) of dengue.

Be that as it may, it is a fact that Cuban scientists have worked for decades to obtain a vaccine against the four serotypes of the dengue virus. The path has been complex, not only for the island's researchers but for all those who have tried to find the precious formulation.

As we saw, there are only two approved vaccines in the world: Dengvaxia, from a French laboratory, whose safety problems have considerably limited its marketing, and Qdenga, as the Japanese vaccine is also known, whose cost per dose, according to an Argentine newspaper, is 52 dollars. Qdenga manufacturers cannot meet the demand of a country like Brazil,3 much less that of nearly 50% of the world's population exposed to the virus.

In this way, the strategy of having a nationally produced compound in Cuba would be extraordinary from many points of view. Firstly, the country would greatly reduce the costs of immunizing its population. On the other hand, it would enter a market of billions of people in the world who are exposed to dengue throughout the tropical and subtropical belt, which would bring obvious economic benefits.

However, the achievement of a Cuban antigen against dengue will take time. To give you an idea, only phase III studies last between 3 and 5 years in the case of vaccine candidates against this disease and are the last step in the long process of research and development of an immunizer, which in the conditions in Cuba, according to CIGB authorities, are made more complex by U.S. regulations.

But the longest path begins with the first step, no matter how many times it is necessary to take it.

Fuente: On Cuba News. Disponible en https://acortar.link/fjtez0

SK bioscience Breaks Ground on Manufacturing Facility Expansion for Extending Product Pipeline

Mar 7. SK bioscience, a global innovative vaccine and biotech company committed to promoting human health from prevention to cure, announced today that the company broke ground on a major expansion of its vaccine manufacturing plant, L HOUSE, located in Andong, Gyeongsangbuk-do, South. The groundbreaking ceremony was attended by Cheol-woo Lee, Governor Gyeongsangbuk-do, GiChang Kwon, Mayor Andong

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City, Pascal Robin, General Manager and Representative Director of Vaccines at Sanofi Korea, and Jaeyong Ahn, CEO of SK bioscience, on March 6, 2024.

This expansion aims to strengthen its manufacturing capabilities for global supply by adding two floors to the existing vaccine manufacturing department in L HOUSE, which will create approximately 4,200㎡ of new space.

The new, expanded space will serve as a production base for the next-generation pneumococcal conjugate vaccine candidate 'GBP410' (also known as SP0202), jointly developed by SK bioscience and Sanofi, who are co-investing in the expansion.

GBP410 includes 21 serotypes to offer enhanced coverage of pneumococcal disease. Currently, domestically licensed pneumococcal protein conjugate vaccine includes up to 15 serotypes. However, the burden of disease associated with these serotypes has diminished, while the burden of disease associated with those excluded from the vaccine has risen. Hence, there is a strong demand for a vaccine like GBP410 which encompasses a broader range of serotypes.

Diseases caused by Streptococcus pneumoniae (the pneumococcus) are a major public health problem worldwide. The World Health Organization (WHO) estimates that about a million children succumb to this disease annually, with more than 300,000 being under 5 years of age.

The Protein conjugation methods applied to GBP410 combines specific proteins with the polysaccharide capsule of Streptococcus pneumoniae, which causes pneumococcal diseases. The protein conjugation method, which enhances immunogenicity by triggering a T-cell immune response, is said to be the most effective pneumococcal vaccine ever developed.

In June 2023, SK bioscience and Sanofi announced positive results from its Phase II clinical trials evaluating the safety and immunogenicity of 'GBP410' in infants, raising optimism for the development of a vaccine with blockbuster potential.

The Phase II study, which enrolled 140 toddlers aged 12 to 15 months and 712 infants aged 42 to 89 days, demonstrated comparable immunogenicity of GBP410 compared to the control vaccine, following the primary vaccination at 2, 4, and 6 months of age as well as the booster vaccination for ages of 12 to 15 months. This study was conducted in the United States, Canada, and Honduras and it commenced in May 2020.

In particular, GBP410 is expected to offer a 5 to 7 percent wider preventive range than the 20-valent vaccine currently developed globally for invasive pneumococcal disease (IPD) across all ages if GBP410 is successfully commercialized.

The data also showed a well-tolerated safety profile, with comparable reactogenicity profile to the control vaccine and no vaccine-related serious adverse events. Furthermore, GBP410 did not interfere with the immunogenicity and safety profile of the co-administered recommended pediatric vaccines, such as tetanus,

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diphtheria, pertussis, polio, and Haemophilus influenzae type b vaccines.

The companies are currently preparing for a global Phase III clinical trial with an expected regulatory submission in 2027.

In addition to facility expansion, SK bioscience plans to quickly obtain cGMP (Current Good Manufacturing Practice) certification for the new facility, which is the standard for pharmaceutical manufacturing and quality management in the United States, to enhance global competitiveness. L HOUSE has already obtained EU-GMP certification from the European Medicines Agency (EMA) in 2021, making it the first domestic vaccinemanufacturing facility to do so.

SK bioscience and Sanofi plan to utilize the expanded manufacturing facility to accelerate the successful introduction of GBP410 into the global market, including United States, Europe, and South Korea. The combination of SK bioscience's and Sanofi's expertise is expected to create synergies and drive rapid market share expansion worldwide.

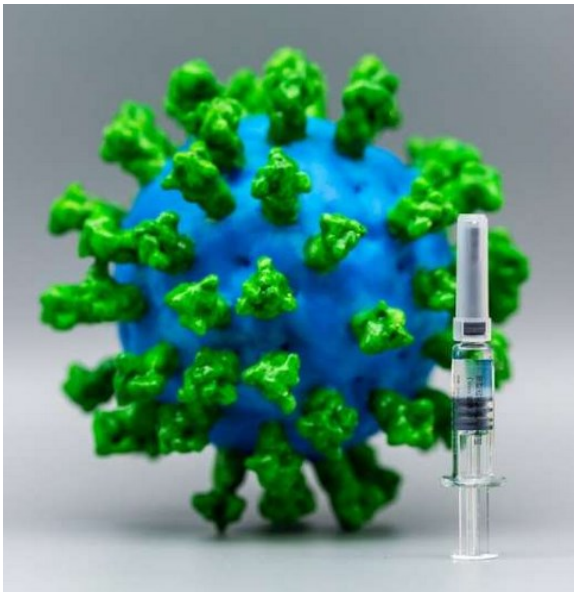
According to Evaluate Pharma, the pneumococcal vaccine market is the largest segment in the global vaccine market and is forecasted to grow from $8.47 billion in 2023 to $10.3 billion by 2028.

Jaeyong Ahn, CEO of SK bioscience, said, "L HOUSE, which demonstrates global competitiveness in manufacturing capabilities, will firmly establish itself as a global vaccine hub through this expansion. We will make every effort to achieve successful development and supply of a vaccine with blockbuster potential."

Meanwhile, SK bioscience continues to push ahead to ensure global competitiveness across all aspects, spanning from vaccine design to production by establishing the cGMP-level manufacturing facility at the R&PD Center in Songdo. This facility will play a pivotal role in collaborations with global partners, as it will be constructed as a Pilot Plant for conducting small-scale tests before the introduction of a new process or product.

Fuente: Business Korea. Disponible en https://acortar.link/wx2WTx

Investing in a universal COVID-19 vaccine would be worth it



Mar 7. Four years into the COVID-19 pandemic, the disease is still responsible for more than 3,000 U.S. deaths a month, according to the Centers for Disease Control and Prevention.

To date, the public health strategy has been that once a wave of deaths occurs due to a COVID-19 variant, a new vaccine is developed to suit its prevalence. But over time, the variant subsides, and a new variant emerges.

And interest in boosters has also waned, as only 17% of the U.S. population has received the updated bivalent COVID-19 booster dose, as compared to the uptake rate of over 50% population for the first U.S. approved booster in 2021. Investing in a universal COVID-19 vaccine would be much more beneficial than the current approach of relying on variant-specific boosters, according to new Dartmouth-led research.

The study examines the potential effectiveness of a universal COVID-19 vaccine in relation to COVID-19 deaths that the country has been experiencing since the onset of the pandemic (known as "background

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mortality rates") and those from new variant waves.

The findings are reported as part of the National Bureau of Economic Research Working Paper series.

"Although it may sound fanciful, the possibility of developing a universal COVID-19 vaccine is real," says senior author Christopher Snyder, the Joel Z. and Susan Hyatt Professor of Economics. "Scientific advances have suggested ways to attack the virus that are generalizable enough to cover any one of the pathogens within the family."

"The key value of a universal COVID-19 vaccine is that it could anticipate future variants rather than always lagging. It would be more effective and could require fewer boosters," says Snyder. "If it puts us in a 'one and done' situation, that might actually help with vaccine hesitancy."

"So, this type of vaccine could be a win in that regard and help renew people's confidence in vaccines," says Snyder.

The researchers set out to determine if a universal COVID-19 vaccine is worth the investment.

They applied some of the same techniques that their team used in an earlier study on the pandemic that estimated the value of adding more capacity to produce existing COVID-19 vaccines.

While a COVID-19 vaccine helps mitigate risks of getting sick, missing school and work, and economic losses, the study focused on mitigating deaths, in this case mortality harm from COVID-19.

To compute the extra benefits that could be obtained from developing a universal COVID-19 vaccine relative to the status quo of relying on variant-specific boosters, the team ran a series of projections. They played out possible scenarios that simulated when future variants of concern would emerge, waves of deaths to follow, and whether a successful booster or a generalized vaccine is available in advance before the wave hits, or the pandemic ends, while also assuming that the background death rates continue until a new variant emerges.

The model also simulated the vaccine's uptake rate. The researchers tried to be somewhat conservative by assuming that the uptake rate for the two different types of COVID-19 vaccines would resemble that of the bivalent booster.

To run the projections, a timeframe of 250 days, or roughly nine months, to develop a variant-specific booster was applied, which is consistent with prior data on how long it takes to identify and sequence a variant and create a vaccine specific to it.

Using Federal Emergency Management Administration data that was adjusted for inflation, the researchers calculated that the estimated value of a human life is $13.5 million.

By averaging the value of the universal COVID-19 vaccine across simulations, the social value of the avoided COVID-19 mortality rate was found to be $1.5 trillion to $2.6 trillion more than variant-specific boosters.

"Even when the mortality wave was zeroed out in the simulation and the background mortality rate was not completely defeated, our results showed that there is still a $1.5 trillion benefit from a universal COVID-19 vaccine," says Snyder. "When a future wave is assumed, the value jumps to $2.6 trillion saved."

According to the team, one possible way to spur the development of a generalized COVID-19 vaccine is for the federal government to implement an "advance market commitment" policy in which federal public health

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officials pledge to purchase a vaccine at a predetermined price if it meets a certain technical product profile. This type of financing is also known as "pull funding." The vaccine would be bought in quantity by the government, so that it could be rolled out across the country.

"What makes these contracts interesting and maybe unusual is that the government essentially posts a call in which anyone can respond," says Snyder. "It's kind of like a prize where anyone can be the inventor of the technology or solver of the problem."

"But in this case, the government is saying, 'we will stand ready to purchase the vaccine from you,'" says Snyder, who is a faculty director of the University of Chicago's Market Shaping Accelerator.

Fuente: Medical Xpress. Disponible en https://acortar.link/mmysSS

Vaccine Alliance outlines path to improve HPV vaccine market

Mar 8. More adolescent girls across the world will be able to access the human papillomavirus (HPV) vaccine, thanks to proactive efforts from the Vaccine Alliance and manufacturers, which have led to increasing supply. According to projections outlined in a new insight paper published by Gavi, the Vaccine Alliance, overall HPV vaccine supply is expected to increase, and demand could be met in 2025. However, careful planning will be needed in 2024. Developed in consultation with a range of key Alliance partners, the Gavi market shaping roadmap for HPV vaccines also showcases how partners, manufacturers and countries must work together to secure a sustainable pipeline of supply over the next decade.

“Lower-income countries have missed out on HPV vaccines for far too long. To ensure we reach our goal of protecting 86 million girls by 2025, it’s vital that our current supply of doses is managed carefully, and we have donor and manufacturer support to go further and protect more girls.” said Aurélia Nguyen, Chief Programme Officer at Gavi. “With an increase in the number of suppliers and the WHO SAGE one-dose recommendation, Gavi is urgently acting on these opportunities, collaborating with partners and countries to scale up access, while equally driving efforts to ensure there is a sustainable supply of HPV vaccines – now, and in the future.”

For over a decade, Gavi has been working to address historical supply challenges while supporting countries to protect 16.3 million adolescent girls with the HPV vaccine. However, these challenges, combined with barriers to accessing the HPV vaccine and the COVID-19 pandemic, led to a concerning drop in coverage of the HPV vaccine across lower-income countries. Coverage in 2022 surpassed pre-pandemic levels at 21% for one dose, but it is still well below ideal levels; and the majority of the world’s unprotected girls are in lower-income Gavi implementing countries.

With over 348,000 deaths in 2022, cervical cancer continues to kill women across the world and disproportionately impact the most vulnerable communities: 90% of these deaths occurred in low- and middle-

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income countries. Yet the HPV vaccine is 90% effective at preventing the disease. With an increased number of suppliers and vaccines available, establishing a secure and sustainable pipeline of supply will be critical to ensure communities everywhere have access and adolescent girls are protected, regardless of where they live.

To achieve its vision of a healthy vaccine market, Gavi has highlighted four key market objectives, each of which is underpinned by target outcomes: supply meets demand to support HPV vaccine programme implementation; predictability of medium- to long-term demand is enhanced to facilitate secure supply of affordable vaccines; diversity of products suitable for different country contexts is achieved with healthy competition between suppliers; and future innovations for potentially new HPV vaccines are accommodated – such as vaccine microarray patches (MAPs) that are applied to the skin to painlessly deliver a vaccine.

Addressing vaccine market failures has been key to Gavi's success in expanding childhood immunisation. Over the past 24 years, Gavi has helped create sustainable vaccine markets through a deliberate market shaping approach which aims to foster a sustainable and competitive supplier base, healthy demand and an environment that encourages innovation. In 2022, Gavi revitalised its HPV vaccine programme, dedicating additional targeted resources with the goal of reaching 86 million adolescent girls by 2025 and averting 1.4 million deaths. In 2023, Gavi helped enhance access to the HPV vaccine in Nigeria, Bangladesh and Indonesia among others -– reaching over 8 million girls in these three countries alone.

Fuente: GAVI. Disponible en https://acortar.link/hwXd1u

Serum Institute of India looks beyond COVID with new vaccines for malaria, dengue

Mar 10. The CEO of the world's biggest vaccine maker, Serum Institute of India, said the company has bolstered its manufacturing ahead of launches over the next few years of shots against diseases like malaria and dengue by repurposing facilities used to make COVID-19 immunizations.

With COVID manufacturing scaled back as demand ebbs, the company is using those facilities to instead manufacture its newer shots, which it estimates will boost total production by two and a half billion doses, CEO Adar Poonawalla said in an interview.

Serum produces AstraZeneca's (AZN.L), COVID-19 vaccine under the brand name Covishield in India, and also makes Novavax's (NVAX.O), protein-based COVID shots.

It invested $2 billion during the peak of the global health crisis to boost production.

The company currently sells about 1.5 billion total vaccine doses every year, and estimates a total production capacity of as much as 4 billion doses.

"And this is also important because if there is a pandemic again in the future, we can vaccinate the whole of India in a matter of three months, three to four months," Poonawalla said.

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The company is in talks with other countries and governments to utilize those facilities in the event of future outbreaks, he said, but did not provide further details on the discussions.

Poonawalla said Serum has capacity to manufacture 100 million doses of its malaria vaccine, and could scale up further depending on demand. It has already produced 25 million doses ahead of a launch in the coming months.

The ancient mosquito-borne disease still kills more than half a million people, mainly young children in sub-Saharan Africa, every year.

Poonawalla said Serum would focus on exporting its vaccines, such as the malaria shot, to other countries, rather than sign technology transfer deals.

Serum is also testing a single-dose vaccine for dengue, another mosquito-borne, painful and sometimes fatal disease, which it developed building on research done by the U.S. National Institutes of Health.

That vaccine is in early- to mid-stage trials in India and the company expects to complete late-stage trials in the next three years, the CEO said.

Japan's Takeda Pharmaceutical, also makes a dengue shot, which is available in countries like Indonesia and Thailand, as well as Argentina and Brazil, which is currently dealing with a major outbreak and not enough vaccine.

Other companies such as Indian Immunologicals are also developing vaccines against the disease.

Fuente: REUTERS. Disponible en https://acortar.link/AuPVhf

OPS por eliminar el cáncer cervicouterino en América Latina

10 mar. El cáncer cervicouterino podría ser el primero del mundo en ser eliminado, dijo hoy Jarbas Barbosa, director de la Organización Panamericana de la Salud (OPS).

En un artículo de opinión publicado por El Diario El Salvador, el directivo precisó que gracias a las estrategias para ampliar la vacunación contra el virus del papiloma humano (VPH), combinadas con pruebas de detección de VPH innovadoras y tratamiento precoz, el cáncer cervicouterino podría ser el primero del mundo en ser eliminado.

Agregó que la OPS se reunirá con Gobiernos, donantes y la sociedad civil en Cartagena, Colombia, para celebrar el Foro Mundial para la Eliminación del Cáncer Cervicouterino, una oportunidad para que las Américas, una vez más, asuman el liderazgo en la aceleración del progreso hacia la eliminación de la enfermedad.

El este tipo de cáncer, provocado por la infección persistente con cepas de alto riesgo del VPH, es una de las principales causas de muerte relacionada con el cáncer en las mujeres de América Latina y el Caribe, con más de 63 mil casos diagnosticados cada año y 33 mil vidas perdidas, indicó.

Además, agregó, es una enfermedad que afecta de forma desproporcionada a mujeres en situación de pobreza y vulnerabilidad, y la gran mayoría de las muertes se produce en países de ingresos bajos y medios.

En lo que respecta a la inoculación, las Américas van por delante de otras regiones de la Organización Mundial de la Salud, ya que 48 de sus 51 países y territorios incorporaron la vacuna contra el VPH en sus calendarios nacionales.

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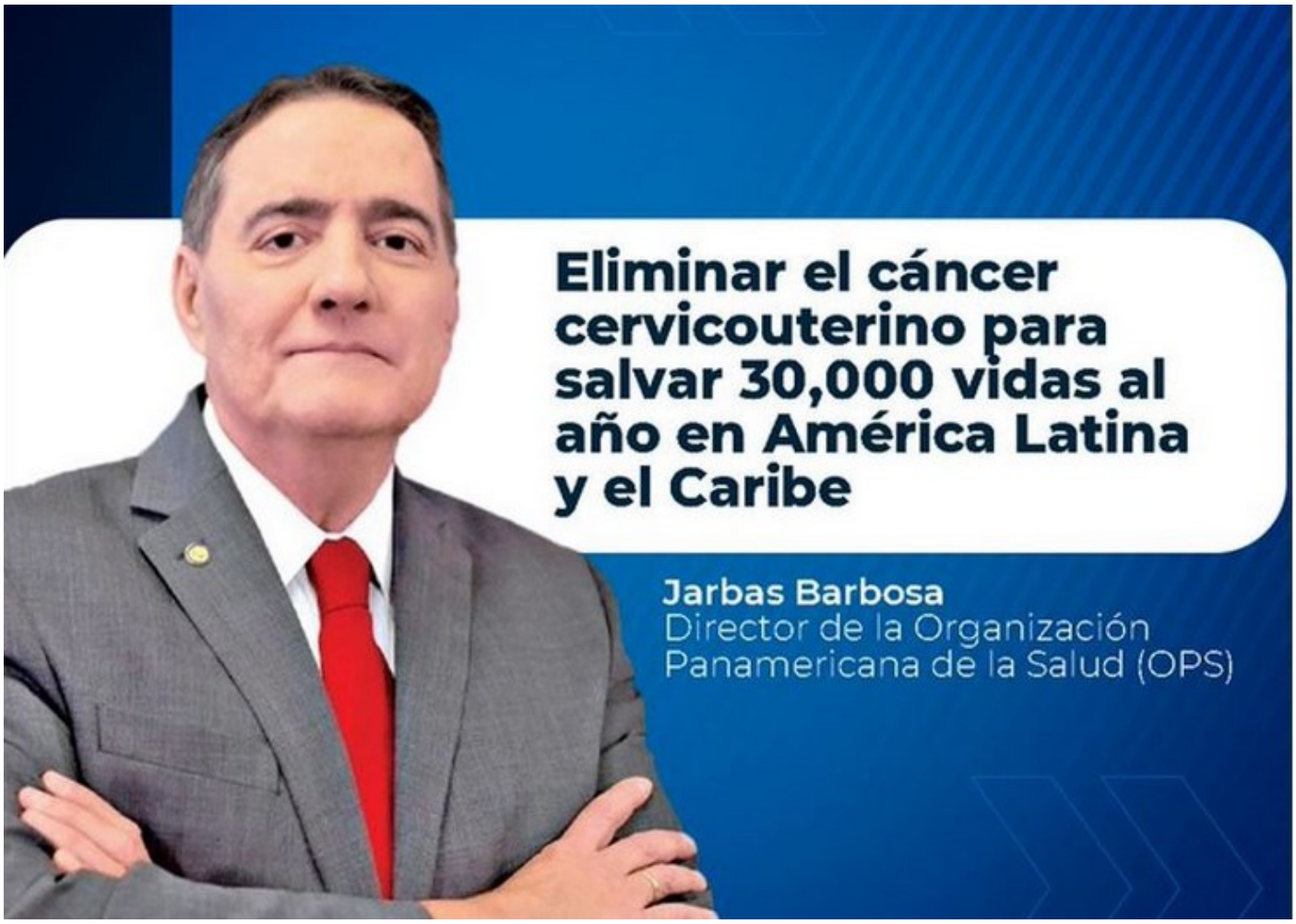
Las dudas sobre la inyección, dijo, también siguen apuntalando las bajas tasas de vacunación. Para abordar estos desafíos, puntualizó, la OPS recomienda la aplicación de dosis única para facilitar la cobertura, en particular entre los grupos de riesgo, y optimizar el uso de los escasos recursos.

América es durante mucho tiempo un líder mundial en la eliminación de enfermedades infecciosas. Con compromiso y esfuerzo también podemos eliminar exitosamente el cáncer cervicouterino, puntualizó Barbosa.



Fuente: Prensa Latina. Disponible en https://acortar.link/ypvjQw

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Patentes registradas en Patentscope

Estrategia de búqueda: *Vaccine in the title or abstract AND 20240301:20240310 as the publication date 31 records*

1.WO/2024/050498VESICULAR STOMATITIS VIRUS MARBURG VIRUS VACCINE
WO - 07.03.2024
Clasificación Internacional A61K 39/12 Nº de solicitud PCT/US2023/073272 Solicitante INTERNATIONAL AIDS VACCINE INITIATIVE, INC. Inventor/a PARKS, Christopher, L.
The present invention relates to a vesicular stomatitis virus vaccine vector encoding a MARV glycoprotein (rVSVΔG-MARV-GP). Vaccination with as little as 200 plaque-forming units was 100% efficacious against MARV lethality and prevented development of viremia. rVSVΔG-MARV-GP vaccination induced MARV GP-specific serum IgG, and virus-neutralizing activity in serum was detectable in animals vaccinated with the highest doses.

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2.20240075165CORONAVIRUS VACCINE
US - 07.03.2024
Clasificación Internacional A61K 48/00 Nº de solicitud 17988742 Solicitante BioNTech SE Inventor/a Ugur Sahin
This disclosure relates to the field of RNA to prevent or treat coronavirus infection. In particular, the present disclosure relates to methods and agents for vaccination against coronavirus infection and inducing effective coronavirus antigen-specific immune responses such as antibody and/or T cell responses. Specifically, in one embodiment, the present disclosure relates to methods comprising administering to a subject RNA encoding a peptide or protein comprising an epitope of SARS-CoV-2 spike protein (S protein) for inducing an immune response against coronavirus S protein, in particular S protein of SARS-CoV-2, in the subject, i.e., vaccine RNA encoding vaccine antigen.

3.20240075115BREAST CANCER VACCINE
US - 07.03.2024
Clasificación Internacional A61K 39/00 Nº de solicitud 18063999 Solicitante The Cleveland Clinic Foundation Inventor/a Vincent K. Tuohy
Compositions and methods for immunization against human breast cancer are disclosed. A breast cancer vaccine comprises an immunogenic polypeptide comprising human α-lactalbumin.

4.20240075127VACCINE COMPOSITIONS
US - 07.03.2024
Clasificación Internacional A61K 39/215 Nº de solicitud 18272115 Solicitante Oxford University Innovation Limited Inventor/a Robert CARLISLE
The invention describes vaccine compositions containing particles having a polypeptide shell and a water-immiscible core. The polypeptide shell may comprise one or more pathogenic antigen proteins and/or one or more adjuvant polypeptides. Administration of the composition generates an immune response to the polypeptide contained in the shell. Adjuvant may be comprised in the water-immiscible core of the particle. The particles are therefore useful in methods of vaccination.

5.20240075124STABLE FORMULATION OF HUMAN PAPILLOMAVIRUS VIRUS-LIKE PARTICLE VACCINE
US - 07.03.2024
Clasificación Internacional A61K 39/12 Nº de solicitud 18261199 Solicitante SINOCELLTECH LTD Inventor/a Yan LIU
Provided is a stable formulation of a human papillomavirus virus-like particle vaccine. The stable formulation is composed of a human papillomavirus virus-like particle, a buffer solution, an osmotic pressure regulator, a surfactant and an aluminum adjuvant, wherein the components of the vaccine comprise HPV virus-like particles assembled by L1 proteins of HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58, and one or more HPV virus-like particles assembled by L1 proteins of other pathogenic HPV types. The formulation can enhance the stability of the vaccine and prolong the validity period of the vaccine in an aqueous formulation.

6.WO/2024/048570HEPATITIS B VACCINE COMPOSITION FOR NASAL ADMINISTRATION AND NASAL ADMINISTRATION SYSTEM THEREOF
WO - 07.03.2024
Clasificación Internacional A61K 39/29 Nº de solicitud PCT/JP2023/031188 Solicitante NATIONAL UNIVERSITY CORPORATION EHIME UNIVERSITY Inventor/a HIASA, Yoichi
The present invention addresses the problem of providing a vaccine composition for nasal administration that is usable for preventing and treating hepatitis B, and a nasal administration system of the vaccine. Provided is a hepatitis B vaccine composition that comprises: (i) virus-like particles containing hepatitis B

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surface L antigen proteins (HBs-L antigen proteins) of two or more genotypes selected from the group consisting of types A, B, C and D, and a hepatitis B nucleocapsid antigen (HBc antigen) protein; and (ii) a base material containing a carboxyvinyl polymer having been treated by externally applying a shear force. Also provided is a nasal administration system of the hepatitis B vaccine, said system comprising the composition filled into a sprayable device equipped with a nasal spray nozzle.

7.WO/2024/050486PEPTIDE-LOADED ANTIGEN PRESENTING CELL-DERIVED EXTRACELLULAR BLEBS AS A MOLECULARLY TARGETED VACCINE
WO - 07.03.2024
Clasificación Internacional A61K 39/02 Nº de solicitud PCT/US2023/073255 Solicitante THE REGENTS OF THE UNIVERSITY OF CALIFORNIA Inventor/a KWON, Young Jik
The disclosure provides for vaccine preparations compnsing isolated or purified extracellular blebs that display engineered MHC I and MHC II peptides that target specific antigen(s) or a specific epitope(s) from a pathogen, and uses thereof, including for vaccination against the pathogen and disease.

8.20240075265METHOD AND APPARATUS FOR EPIDERMAL DELIVERY OF POWDERED MEDICAMENTS
US - 07.03.2024
Clasificación Internacional A61M 37/00 Nº de solicitud 18243404 Solicitante Particle Vaccine Canada Ltd. Inventor/a Christopher Rodriguez
Apparatus for transdermal delivery of a powdered agent to a patient, the apparatus comprising a fluid source comprising a fluid; a nozzle extending distally from the fluid source, the nozzle comprising a proximal end, a distal end and a lumen extending from the proximal end to the distal end; a blister containing a powdered agent disposed within the lumen of the nozzle; and an actuation element for releasing the fluid from the fluid source, wherein the actuation element causes the released fluid to be propelled through the blister with sufficient pressure to entrain the powdered agent into the released fluid and move the entrained powdered agent through the lumen of the nozzle and out the distal end of the nozzle.

9.WO/2024/048430VACCINE PREPARATION AND PRODUCTION METHOD THEREOF, AND METHOD FOR PREVENTING FISH BACTERIAL INFECTION
WO - 07.03.2024
Clasificación Internacional A61K 39/02 Nº de solicitud PCT/JP2023/030635 Solicitante SHIGA PREFECTURE Inventor/a KINTSUJI, Hiroaki
The present invention provides a vaccine preparation for immersion or injection which is to be used for preventing a fish bacterial infection and which contains, as an active ingredient, at least one selected from the group consisting of a biofilm (BF) derived from the bacterium causing the fish bacterial infection, a component produced in the course of the formation, maturation and disintegration of the BF, and bacterial cells.

10.20240075126SARS-CoV-2 mRNA Vaccine and Preparation Method and Use Thereof
US - 07.03.2024
Clasificación Internacional A61K 39/215 Nº de solicitud 18260497 Solicitante Shenzhen Rhegen Biotechnology Co., Ltd. Inventor/a Yong HU
Provided is a SARS-CoV-2 mRNA vaccine, and the preparation method and use thereof. The present invention provides an mRNA molecule capable of encoding a target polypeptide, wherein the target polypeptide comprises an NTD-RBD natural domain in the Spike (S) protein of SARS-CoV-2, and wherein the NTD-RBD natural domain comprises an NTD fragment and an RBD fragment, the NTD fragment and the RBD fragment being linked together via a natural amino acid sequence derived from the S protein as a linker. The present invention provides an mRNA encoding a NTD-RBD natural domain in the Spike

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protein of SARS-CoV-2, which achieves an immune effect against SARS-CoV-2 mutant strains and is widely applicable.

11.4331602LEBENDES ABGESCHWÄCHTES SARS-COV-2 UND DARAUS HERGESTELLTER IMPFSTOFF
EP - 06.03.2024
Clasificación Internacional A61K 39/12 Nº de solicitud 22193939 Solicitante UNIV BERLIN FREIE Inventor/a TRIMPERT JAKOB
The invention relates to a polynucleotide encoding a) severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein; and/or b) at least one non-structural SARS-CoV-2 protein selected from the group consisting of non-structural protein 7, non-structural protein 8, non-structural protein 9, non-structural protein 10, non-structural protein 11, non-structural protein 12, an endoribonuclease, and a 2'-O-methyltransferase, wherein the polynucleotide comprises or consists of at least one sequence part comprising codon-pair deoptimizations in comparison to the SARS-CoV-2 genome, and wherein the polynucleotide further comprises a furin cleavage site modification resulting in a loss of a furin cleavage site being naturally present in the SARS-CoV-2 genome. The invention further relates to a live attenuated SARS-CoV-2 comprising this polynucleotide, to a vaccine comprising this live attenuated SARS-CoV-2, as well as to associated methods.

12.4331616ANTIKÖRPER-WIRKSTOFF-KONJUGAT, HERSTELLUNGSVERFAHREN DAFÜR UND ANWENDUNG DAVON
EP - 06.03.2024
Clasificación Internacional A61K 47/68 Nº de solicitud 22806846 Solicitante UNIV TSINGHUA Inventor/a LIAO XUEBIN
Disclosed are an antibody drug conjugate, a preparation method therefor and an application thereof, which are in particular, a conjugate of an anti-PD-L1 antibody and a TLR7 and/or TLR8 agonist, a pharmaceutical composition thereof, a preparation method therefor and an application thereof. In the present invention, a modified anti-PD-L1 antibody having mutated cysteine is obtained by means of gene editing, basically retains the structure of the original antibody, and may be used for the construction of antibody drug conjugates. By means of anti-tumor experiments, it has been discovered that the obtained antibody drug conjugate has good activity, such as strong anti-tumor activity, which may significantly improve the survival rate of tumor-bearing animals, and significantly reduce toxicity. Moreover, the antibody drug conjugate is less burdensome on the bodies of test animals, which greatly reduces the minimum effective dose of small molecular drugs when used alone, expands the therapeutic window thereof, is expected to be used in the development of therapeutic drugs for various diseases (such as tumors, viral diseases such as hepatitis B, etc.), and has good application prospects and value.

13.20240076320DOWNSTREAM PROCESS FOR PURIFICATION OF VIRAL PROTEINS WITH HYDROPHOBIC MEMBRANE DOMAIN FOR USE IN VACCINE COMPOSITIONS
US - 07.03.2024
Clasificación Internacional C07K 14/005 Nº de solicitud 18458789 Solicitante Novavax, Inc. Inventor/a Timothy Hahn
The present invention is directed to methods of purifying viral proteins for use in vaccine compositions. The method includes a capture step and a polish step. The capture step includes passing a solution containing a protein over a hydrophobic interaction chromatography column and eluting a crude protein eluate from the column. The polish step includes passing the crude protein eluate over a ligand affinity chromatography column and recovering a first flow through intermediate, passing the first flow through intermediate over an anion exchange chromatography column and recovering a second flow through intermediate, and passing the second flow through intermediate over another ligand affinity

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chromatography column and recovering a purified protein eluate. The present invention also provides a purified protein having a hydrophobic membrane domain that is produced by a baculovirus expression system in cultured insect cells, wherein the purified protein has a purity of greater than 85%.

14.WO/2024/050015DOWNSTREAM PROCESS FOR PURIFICATION OF VIRAL PROTEINS WITH HYDROPHOBIC MEMBRANE DOMAIN FOR USE IN VACCINE COMPOSITIONS
WO - 07.03.2024
Clasificación Internacional A61K 39/145 Nº de solicitud PCT/US2023/031715 Solicitante NOVAVAX, INC. Inventor/a HAHN, Timothy
The present invention is directed to methods of purifying viral proteins for use in vaccine compositions. The method includes a capture step and a polish step. The capture step includes passing a solution containing a protein over a hydrophobic interaction chromatography column and eluting a crude protein eluate from the column. The polish step includes passing the crude protein eluate over a ligand affinity chromatography column and recovering a first flow through intermediate, passing the first flow through intermediate over an anion exchange chromatography column and recovering a second flow through intermediate, and passing the second flow through intermediate over another ligand affinity chromatography column and recovering a purified protein eluate. The present invention also provides a purified protein having a hydrophobic membrane domain that is produced by a baculovirus expression system in cultured insect cells, wherein the purified protein has a purity of greater than 85%.

15.20240075121CIRCUMSPOROZOITE PROTEINS WITH INCREASED EXPRESSION IN MAMMALIAN CELLS
US - 07.03.2024
Clasificación Internacional A61K 39/015 Nº de solicitud 18481729 Solicitante Fred Hutchinson Cancer Center Inventor/a Marie Pancera
Mutated and/or truncated malarial circumsporozoite proteins (CSP) and associated nucleic acids that are more stable and highly expressed in mammalian cells are described. The mutated and/or truncated CSP and associated nucleic acids can be expressed to produce malaria vaccine antigens.

16.WO/2024/050549PREFUSION-STABILIZED CMV GB PROTEINS
WO - 07.03.2024
Clasificación Internacional C07K 14/045 Nº de solicitud PCT/US2023/073369 Solicitante BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM Inventor/a MCLELLAN, Jason
Provided herein are engineered hCMV gB polypeptides. In some aspects, the engineered gB polypeptides exhibit enhanced conformational stability and/or antigenicity. Methods are also provided for use of the engineered gB polypeptides as diagnostics, in screening platforms, and/or in vaccine compositions.

17.20240075129Anti COVID-19 Therapies targeting nucleocapsid and spike proteins
US - 07.03.2024
Clasificación Internacional A61K 39/215 Nº de solicitud 18488629 Solicitante ImmunityBio, Inc. Inventor/a Patrick Soon-Shiong
Disclosed herein are methods for inducing immunity against a virus such as a coronavirus in the mucosal tissue of a patient, include administering a vaccine composition to the patient by oral administration (e.g., nasal injection, nasal inhalation, oral inhalation, and/or oral ingestion). Also disclosed are compositions for assaying the presence of anti-viral antibodies induced by the administered vaccine or the presence of viral proteins in a saliva sample include a stabilizing solution and may also include the use of aragonite particle beads. Compositions and methods are presented for prevention and/or treatment of a coronavirus disease wherein the composition comprises comprises a recombinant entity. The recombinant entity is bivalent, comprising a nucleic acid encoding a coronavirus 2 nucleocapsid protein CoV2 nucleocapsid

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protein fused to an endosomal targeting sequence, and a nucleic acid encoding a CoV2 spike protein sequence optimized for cell surface expression.

18.20240076632RECOMBINANT INFLUENZA VIRUSES WITH STABILIZED HA FOR REPLICATION IN EGGS
US - 07.03.2024
Clasificación Internacional C12N 7/00 Nº de solicitud 18461321 Solicitante The University of Tokyo Inventor/a Yoshihiro Kawaoka
Modified influenza virus neuraminidases are described herein that improve viral replication, thus improving the yield of vaccine viruses. Expression of such modified neuraminidases by influenza virus may also stabilize co-expressed hemagglutinins so that the hemagglutinins do not undergo mutation or decrease the need for HA binding to cells.

19.WO/2024/050380DETECTION OF A GENETIC FUSION OR DELETION THAT RESULTS IN EXPRESSION OF A NEOANTIGEN
WO - 07.03.2024
Clasificación Internacional A61K 39/00 Nº de solicitud PCT/US2023/073113 Solicitante FLAGSHIP PIONEERING INNOVATIONS VI, LLC Inventor/a SHUBER, Anthony P.
The invention provides methods of detecting a sequence modification (e.g., a genetic fusion or deletion) associated with cancer development that results in expression of a neoantigen. The neoepitope serves as the basis for manufacture of a vaccine, which is administered to a subject to induce an immune response against those cells producing the neoantigen.

20.3986866IONISERBARE LIPIDER TIL NUKLEINSYRELEVERING
DK - 04.03.2024
Clasificación Internacional A61K 39/00 Nº de solicitud 20826513 Solicitante Precision Nanosystems ULC Inventor/a JAIN, Nikita
The present document describes compounds, or pharmaceutically acceptable salt thereof, of a core formula (I) where R_1 features an amine group, particularly useful in the formulation of lipid particles including nucleic acid therapeutic agents, or proteins, or both, and for delivery of nucleic acid and protein therapeutics to cells *in vivo* or *ex vivo*, including anticancer and vaccine applications.

21.WO/2024/049153MICELLE COMPRISING AMPHIPHILIC PEPTIDE, AND ANTIGEN CARRIER NANOPARTICLE USING SAME
WO - 07.03.2024
Clasificación Internacional C07K 19/00 Nº de solicitud PCT/KR2023/012758 Solicitante RTAB CO., LTD. Inventor/a RHIM, Taiyoun
The present invention relates to a nanoparticle and a preparation method therefor, the nanoparticle comprising an amphiphilic peptide, which forms a micelle structure through self-assembly, and a target peptide (preferably, a water-soluble antigen peptide), which electrically binds to the surface of the amphiphilic peptide. The target peptide electrically binds to the surface of the amphiphilic peptide micelle structure and becomes particulated, and thus can be effectively presented to an antigen-presenting cell, and the weight ratio of the amphiphilic peptide and the target peptide is controlled so that the size of nanoparticles is controlled and endocytosis thereof is carried out, and thus immunity by means of cytotoxic T cells can be induced. Nanoparticles of the present invention exhibit use only an epitope of a more accurate region so as to be effective as a vaccine, and thus have minimal side effects. Therefore, the present invention exhibits excellent antigen-specific antibody and cell immunotherapy effects, and thus can be used in various fields such as vaccine production.

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22.4329931VERFAHREN UND ZUSAMMENSETZUNGEN ZUR MASSENKONJUGIERBAREN POLYMER- UND PROTEINSYNTHESE
EP - 06.03.2024
Clasificación Internacional B01J 16/00 Nº de solicitud 22796997 Solicitante LIGANDAL INC Inventor/a WATSON ANDRE
Methods and compositions for manufacturing large-scale quantities of conjugatable peptides/peptoids/polymers/nucleic acids and conjugatable proteins, as well as hybrid materials consisting of synthetic and unnatural amino acids, glycopeptides, proteoglycans, and other molecular modifications are disclosed, for a variety of purposes including rapid antidote and vaccine applications in biodefense, therapeutics, diagnostics, theranostics, thin films, multilayered assemblies, biofilms, sensors, drug delivery vehicles, gene delivery vehicles, gene editing vehicles, staged release compounds, and the like.

23.4329799MESSENGER-RNA-THERAPEUTIKA UND ZUSAMMENSETZUNGEN
EP - 06.03.2024
Clasificación Internacional A61K 39/215 Nº de solicitud 22796918 Solicitante GREENLIGHT BIOSCIENCES INC Inventor/a ABSHIRE JAMES ROBBINS
In the various aspects and embodiments, this disclosure provides messenger RNA (mRNA) constructs for therapeutic delivery, as well as methods for making such mRNA constructs and pharmaceutical compositions comprising the same (including mRNA vaccine compositions). In still other aspects, the invention provides methods for treating patients by expression of therapeutic proteins, including for preventing or reducing probability of infection by, or illness involving, a virus. Exemplary viruses include coronaviruses (such as SARS-CoV-2 and variants therefore) and influenza viruses, among others.

24.WO/2024/049990NANOPARTICLE-DERIVED VACCINES AGAINST POXVIRUSES, AND METHODS FOR MAKING AND USING THE SAME
WO - 07.03.2024
Clasificación Internacional A61K 39/385 Nº de solicitud PCT/US2023/031683 Solicitante THE UNITED STATES OF AMERICA AS REPRESENTED BY THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES Inventor/a MOSS, Bernard
The present disclosure relates generally to vaccines against orthopoxviruses, and methods for making and using such vaccines. In particular, in some embodiments, the present disclosure relates to nanoparticle-derived vaccines, and compositions based thereon, that elicit an immune response against an orthopoxvirus. The present disclosure further relates to the use of vaccines and vaccine compositions for preventing; decreasing the severity, morbidity and/or mortality of; shortening the duration of; and/or reducing the symptoms of, a poxvirus infection, such as, for example, an orthopoxvirus infection.

25.WO/2024/047091VETERINARY COMPOSITIONS OF MODIFIED VIRUS-LIKE PARTICLES OF CMV AND NGF ANTIGENS
WO - 07.03.2024
Clasificación Internacional A61K 39/12 Nº de solicitud PCT/EP2023/073758 Solicitante SAIBA ANIMAL HEALTH AG Inventor/a ZELTINS, Andris
The present invention relates to compositions comprising modified virus-like particles (VLPs) of Cucumber Mosaic Virus (CMV), and in particular to modified VLPs of CMV comprising chimeric CMV polypeptides which comprises a stretch of consecutive negative amino acids selected from aspartic acid or glutamic acid to which nerve growth factor (NGF) antigens are linked as well as pharmaceutical compositions thereof, which compositions preferably serve as vaccine platform for generating immune responses, in particular antibody responses, against said NGF antigens linked to the modified CMV VLPs.

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26.20240076349NOVEL PEPTIDES AND COMBINATION OF PEPTIDES FOR USE IN IMMUNOTHERAPY AGAINST OVARIAN CANCER AND OTHER CANCERS
US - 07.03.2024
Clasificación Internacional C07K 14/74 Nº de solicitud 18192752 Solicitante Immatics Biotechnologies GmbH Inventor/a Heiko SCHUSTER
The present invention relates to peptides, proteins, nucleic acids and cells for use in immunotherapeutic methods. In particular, the present invention relates to the immunotherapy of cancer. The present invention furthermore relates to tumor-associated T-cell peptide epitopes, alone or in combination with other tumor-associated peptides that can for example serve as active pharmaceutical ingredients of vaccine compositions that stimulate anti-tumor immune responses, or to stimulate T cells ex vivo and transfer into patients. Peptides bound to molecules of the major histocompatibility complex (MHC), or peptides as such, can also be targets of antibodies, soluble T-cell receptors, and other binding molecules.

27.4329814THERMISCH STABILE IMPFSTOFFFORMULIERUNGEN MIT SCHALEN AUS METALLORGANISCHEM GERÜST (MOF)
EP - 06.03.2024
Clasificación Internacional A61K 47/34 Nº de solicitud 22794101 Solicitante COMMW SCIENT IND RES ORG Inventor/a SINGH RUHANI
The present application relates to metal-organic framework (MOF) encapsulation or viral vaccines and vectors. The present application discloses methods for stabilizing viral vaccines and vectors and provides MOF encapsulated viral vaccines and vectors with improved stability.

28.WO/2024/047090MODIFIED VIRUS-LIKE PARTICLES OF CMV
WO - 07.03.2024
Clasificación Internacional A61K 39/12 Nº de solicitud PCT/EP2023/073756 Solicitante SAIBA ANIMAL HEALTH AG Inventor/a ZELTINS, Andris
The present invention relates to a modified virus-like particle (VLP) of cucumber mosaic virus (CMV) comprising at least one chimeric CMV polypeptide, wherein said at least one chimeric CMV polypeptide comprises, preferably consists of (i) a CMV polypeptide, wherein said CMV polypeptide comprises a coat protein of CMV or an amino acid sequence having a sequence identity of at least 75% with SEQ ID NO:48; and (ii) a polypeptide comprising, preferably consisting of, a stretch of consecutive negative amino acids, wherein said negative amino acids are independently selected from aspartic acid or glutamic acid, wherein said polypeptide is inserted between any amino acid residue of said CMV polypeptide corresponding to any amino acid residue between position 75 and position 85 of SEQ ID NO:48, as well as to compositions and pharmaceutical compositions comprising such modified VLPs to which antigens are linked, which compositions preferably serve as vaccine platform for generating immune responses, in particular antibody responses, against said antigens linked to the modified CMV VLPs.

29.WO/2024/050488HIV VACCINE IMMUNOGENS FOR THE INDUCTION OF V3-GLYCAN TARGETING ANTIBODIES
WO - 07.03.2024
Clasificación Internacional C07K 14/16 Nº de solicitud PCT/US2023/073257 Solicitante DUKE UNIVERSITY Inventor/a HENDERSON, Rory
The invention is directed to modified HIV-1 envelopes, compositions comprising these modified envelopes, nucleic acids encoding these modified envelopes, compositions comprising these nucleic acids, and methods of using these modified HIV-1 envelopes and/or these nucleic acids to induce immune responses.

30.WO/2024/046312RECOMBINANT PROTEIN AND THE USE THEREOF IN PREPARATION OF RESPIRATORY SYNCYTIAL VIRUS VACCINE

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WO - 07.03.2024
Clasificación Internacional C07K 14/135 Nº de solicitud PCT/CN2023/115508 Solicitante GUANGZHOU YUANBO MEDICAL TECHNOLOGY CO., LTD. Inventor/a WANG, Yi
The present invention belongs to the technical field of biology, and particularly relates to a recombinant protein and the use thereof. The recombinant protein contains: an SH protein (SH) of the respiratory syncytial virus and a G protein (G(CX3C)) of the respiratory syncytial virus containing a CX3C motif. The recombinant protein improves the immunogenicity of the low-molecular-weight antigen SH and the G(CX3C) protein, thereby having good immunogenicity and a high neutralizing antibody titer. In addition, the recombinant protein has a good protection effect on two immune sites and can therefore be used for preparing products, such as vaccines, respiratory syncytial virus antibodies, anti-respiratory syncytial virus serums and diagnostic antigens.

31.WO/2024/047048CANCER VACCINE COMPRISING EXOSOMES OBTAINED OR DERIVED FROM ACTIVATED AND MATURE HUMAN B-LYMPHOCYTES
WO - 07.03.2024
Clasificación Internacional A61K 39/00 Nº de solicitud PCT/EP2023/073684 Solicitante TERASOM S.R.O. Inventor/a PANKOVA, Daniela
The present invention relates to compositions comprising one or more populations of activated exosomes, which are suitable for use as cancer vaccines. The activated exosomes in a first population each display CD19 and one or more further surface molecules which are characteristic of mature or activated B-lymphocytes, and each comprise or display one or more tumour antigens selected from MAGEA4, GAGE2D and 5T4. Also provided are methods for the prevention or treatment of cancer using such compositions, and processes for the production of such compositions.

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