

Category

Best Startup

Product/Solution Name

Dendritic Cells Targeting Vaccine Platform

Date of Approval

N/A

Indications

Infectious diseases :

- Covid : 1 bivalent vaccine Gen 1 + 1 multivariant vaccine Gen 2
- HIV : 1 prophylactic vaccine + 1 therapeutic vaccine
- Chlamydia : 1 prophylactic vaccine

Cancers:

- 1 HPV + head and Neck Cancer therapeutic vaccine

Therapeutic Categories

Prophylactic & therapeutic vaccines against viruses, cancers and bacteria

Background information and need for solution/product

In 2011, Prof. Yves Lévy, MD, PhD, Professor of clinical immunology, specialized in immunotherapies, HIV vaccines, immune deficiency diseases and infectious diseases created the Vaccine Research Institute (VRI), Laboratory of Excellence, under the French Investments for the Future (PIA) program and was appointed Executive Director to foster the development of next generation of vaccines targeting the dendritic cells.

This initiative aimed to leverage the groundbreaking discovery by Nobel Prize Prof. Ralph Steinman, to highlight the gateway role played by dendritic cells, - the first point of entry into the immune system and the body's main line of defense, - and to boost research on AIDS/HIV vaccines and (re)emerging infectious diseases.

The COVID-19 pandemic underscored the urgency of implementing new strategies to address future epidemic risks, necessitating the development of innovative vaccines with long-lasting effects and ease of manufacturing. Furthermore, infectious diseases and cancer remain the leading causes of global mortality, representing critical unmet medical needs.

In dec. 2020, building upon the remarkable pre-clinical results in HIV vaccine developed at the VRI, Prof. Yves Lévy and Dr. André-Jacques Auberton Hervé, Honorary Chairman and founder of SOITEC, launched Linkinvax, a biopharma company to develop an innovative protein-based vaccine platform that can accelerate availability of vaccines by leveraging the research conducted at the Vaccine Research Institute (VRI). The platform can adapt to changes and mutations in the target pathogens

and offers disruptive alternatives to conventional technologies and those under development.

Thanks to its breakthrough technology, the platform makes it possible to precisely target dendritic cells using a monoclonal antibody, a protein that is safe and easy to produce. This monoclonal antibody is complemented by proteins corresponding to the antigen of a specific pathogen, to trigger a strong, long-lasting immune response.

Dendritic cells, the keystone of the LinKinVax vaccine platform

LinKinVax DC Targeting platform is “universal”, agile and can address various pathogens, including viruses (HIV, COVID-19), cancers (HPV+ Head & Neck Cancer), and bacteria (Chlamydia). These vaccines benefit from an exclusive worldwide license on over 100 patents from the French National Institute of Health and Medical Research (INSERM), encompassing the platform concept.

The scientific excellence and extensive research background of Linkinvax solidify its position as a serious game changer in vaccine market.

LinKinVax has risen to prominence in France, with Bpifrance granting it €31 Million under a Covid-related PIA PSCP program and Government “Plan Relance”.

Attached Files:

- LinKinVax background solution.pptx

History of the development of the solution/product

Over 250 publications and 11 years of preclinical development have demonstrated the benefits of DC Targeting technology for vaccines, infectious diseases and cancers.

6 assets with different indications :

HIV : TWO VACCINES for THE ‘EVEREST OF VACCINE STRATEGIES’

• Clinical stage: A prophylactic HIV vaccine:

In Feb 2023, LinKinVax presented interim results of the ANRS VRI06 Phase I trial evaluating a preventive HIV vaccine, conducted by the sponsor INSERM-ANRS and the VRI (ANRS and Université Paris-Est Créteil, France). These very promising results show that the vaccine candidate is safe and induces an early, significant and sustained immune response. It is the very first vaccine to target dendritic cells with a novel delivery mode of the HIV envelope protein, potentially critical to future vaccine strategies.

As of today, it is the only HIV vaccine to have shown such performances at this stage of development. Results have been presented at the 30th Conference on Retroviruses and Opportunistic Infections (CROI)

Results of phase I are expected by mid- 2024.

• Pre-clinical stage: A therapeutic HIV vaccine: The vaccine targets HIV sanctuary sites, which persist under antiviral treatment and are difficult to reach with current therapies - this is why, for now, antiviral treatments must be taken for life. When tested on HIV-infected humanized mice, the LinKinVax

vaccine candidate eliminated virus reservoirs. The very promising results obtained in numerous pre-clinical trials will soon lead to the launch of the first human studies.

SARS COV2: Clinical stage

- Since the COVID19 is now expected to settle seasonally, the need to develop new vaccines as the risk of new waves of contamination and hospitalization remains high has been emphasized by the WHO. Recently, The US administration initiated the Project Next Gen to accelerate next generation of coronavirus vaccines that offer longer-lasting protection, that can stand-up to multiple variants.
- LinKinVax objective is to develop a pan-sarbecovirus vaccine for SARS-CoV-2 and its variants, as well as other viruses of the same family, part of them could be conducted in the USA. This accounts for why LinKinVax is currently developing two vaccines against Sars-cov-2, covering several epitopes and variants, qualified for clinical trials (Q3 and Q4 2023) following very satisfactory results in preclinical trials: studies showed that convalescent monkeys vaccinated with a single dose of LinKinVax vaccine six months after a first infection, then re-exposed to the virus later, were protected from infection and eliminated the virus within two days. In the control group, convalescent, unvaccinated and infected monkeys cleared the virus in an average of six days. Furthermore, in vitro studies showed that these vaccines produced cross-reactive antibodies against all variants of SARS-CoV-2.

CANCER : Clinical stage

LinKinVax and Gustave Roussy are entering a collaboration on a Phase I/IIa clinical trial to develop CD40HVac new and effective therapeutic vaccine against HPV-associated malignancies to better address the needs of patients. The interest for a therapeutic vaccine against some HPV cancers was highlighted during the ASCO congress 2023.

The aim of LinKinVax vaccine is to eliminate the virus, which may persist in certain residual tumor cells, and thus prevent recurrence. In mice grafted with HPV-infected tumor cells, the vaccine was shown to foster the elimination of cancer cells.

- The clinical trial (start July 23) will aim to assess the safety, immunogenicity, and recommended dose of the vaccine candidate, as well as explore progression-free survival and overall survival.

CHLAMYDIA :

- A vaccine against Chlamydia, responsible for common sexually transmitted infections that cause few symptoms and sometimes go unnoticed for which a promising first battery of in vitro tests has been carried out. This vaccine would be used particularly in adolescents to protect them from this STD. It could also help prevent trachoma in developing countries.

In addition, five other vaccines are currently under pre-clinical development and promise sustainable growth (Ebola, Nipah, HBV, TB, Anti-langerin, ...).

Attached Files:

- LinkinVax clinical evidence.pptx

Why this solution/product is innovative, the broad implications for future research, and/or how it will improve the human condition

Linkinvax DC Targeting platform is a real break-through in today's vaccine offering and medical needs. Agile, faster, safer and more effective, its innovative technology will save years of vaccine development wandering - years that we can unfortunately no longer afford to lose at a time when epidemic risks are becoming ever greater, and with the rapid mutation of different pathogens. Where today, the R&D and marketing of a vaccine takes, on average, 10 to 20 years, Linkinvax's approach ensures safety and efficacy in a short space of time, and at a reduced cost.

Linkinvax's vaccine solutions pave the way for the development of a wide range of new generation of vaccines, both preventive and therapeutic.

In a nutshell, LinKinVax is :

- A "universal" DC Targeting platform with numerous possibilities

Because it can address a wide range of pathogens, the platform offers solutions in several therapeutic fields (cancer, immune diseases, viruses, etc.), and can be combined with other therapeutic strategies.

- An Innovative technology

LinKinVax DC Targeting platform is built around a humanized monoclonal antibody, which is fused with regions of pathogens of interest, targeting the CD40 molecule expressed by dendritic cells, DC, which play a key role in stimulating the immune system. The pre-clinical and ongoing clinical results obtained demonstrate the benefits of this strategy owing to the small quantity of antigens required to activate the immune system, with or without an adjuvant, and its ability to trigger a lasting cellular and humoral and immune response. The platform also benefits from the experience and safety profile of the protein-based vaccines that have been widely used for over 30 years now.

- Convenient product form

Products can be supplied in liquid form, like a conventional vaccine, or in freeze-dried form. The latter promises incomparable advantages beyond effective immunization: a single-injection regimen, no cold chain constraints for storage, transport and distribution, and low cost. This user-friendly packaging makes the product eligible for the shelf strategy and a good candidate for LMIC markets.

Attached Files:

- LinkinVax clinical evidence.pptx

Please provide appropriate references (ie Pubmed links)

1. Nature Communications – SARS-CoV-2

Marlin, Romain, Veronique Godot, Sylvain Cardinaud, Mathilde Galhaut, Severin Coleon, Sandra Zurawski, Nathalie Dereuddre-Bosquet, et al. « Targeting SARS-CoV-2 Receptor-Binding Domain to Cells Expressing CD40 Improves Protection to Infection in Convalescent Macaques ». Nature Communications 12, no 1 (1 septembre 2021): 5215. <https://doi.org/10.1038/s41467-021-25382-0>.

2. EbioMedicine – Pan-Sarbecovirus

Coléon, Séverin, Aurélie Wiedemann, Mathieu Surénaud, Christine Lacabartz, Sophie Hue, Mélanie Prague, Minerva Cervantes-Gonzalez, et al. « Design, Immunogenicity, and Efficacy of a Pan-Sarbecovirus Dendritic-Cell Targeting Vaccine ». EBioMedicine 80 (juin 2022): 104062. <https://doi.org/10.1016/j.ebiom.2022.104062>.

3. Cancer Immunology Research- HPC Cancer

Yin, Wenjie, Dorothée Duluc, HyeMee Joo, Yaming Xue, Chao Gu, Zhiqing Wang, Lei Wang, et al. « Therapeutic HPV Cancer Vaccine Targeted to CD40 Elicits Effective CD8+ T-Cell Immunity ». Cancer Immunology Research 4, no 10 (1 octobre 2016): 823 34. <https://doi.org/10.1158/2326-6066.CIR-16-0128>.

4. Clinical investigation – HIV

Cheng, Liang, Qi Wang, Guangming Li, Riddhima Banga, Jianping Ma, Haisheng Yu, Fumihiko Yasui, et al. « TLR3 Agonist and CD40-Targeting Vaccination Induces Immune Responses and Reduces HIV-1 Reservoirs ». Journal of Clinical Investigation 128, no 10 (27 août 2018): 4387 96. <https://doi.org/10.1172/JCI99005>.

5. CROI – Abstract interim results HIV clinical trials

Document uploaded “CROI 2023.pptx”

Attached Files:

- CROI 2023.pptx