

Osivax Receives Over USD 1.5M Grant from NIAID to Advance Development of Broad-Spectrum Influenza Vaccine Candidate, OVX836

- Grant to support preclinical evaluation of OVX836 in providing protection against pandemic influenza strains
- OVX836 has already been evaluated in several Phase 2 clinical trials against seasonal influenza with initial signals of broad-spectrum protection

Lyon, France – December 5, 2023 – <u>Osivax</u>, a biopharmaceutical company developing vaccines to provide broad-spectrum protection against highly mutating infectious viruses, today announced that it has received a grant of over USD 1.5M from the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH). The grant (project number 1R01AI177376) will support preclinical studies evaluating the breadth of protection and immune response induced by the company's lead, broad-spectrum influenza vaccine candidate, OVX836 against pandemic influenza strains.

The preclinical studies are planned to be conducted at the Infectious Diseases Models for Innovative Therapies (IDMIT) department at the French Alternative Energies and Atomic Energy Commission (CEA) site in Fontenay-aux-Roses, France. The IDMIT is highly specialized in human infectious diseases and has the facilities needed for testing the immunogenicity and efficacy of OVX836 as a vaccine against pandemic influenza strains in preclinical models.

OVX836 will be evaluated against two pandemic influenza A-strains: the once pandemic but now seasonal, pH1N1, and the highly pathogenic variant with pandemic potential, H5N1, in preclinical models.

"Testing OVX836 in preclinical models is essential to assess the breadth of protection against strains with pandemic potential," commented **Florence Nicolas, Co-Founder of Osivax and Principal Investigator**. "Importantly, these new preclinical studies will allow us to identify potential correlates of protection to be further evaluated in human clinical studies."

"Working together with Osivax on the evaluation of OVX836 against pandemic strains is an important step toward preparing for future influenza outbreaks that pose a significant risk to public health," commented **Roger Le Grand, Director** of IDMIT and Principal Investigator.

"Receiving this grant from the NIAID will support our progress in developing OVX836 to provide broad-spectrum protection against influenza, which remains a perennial pandemic threat," commented **Alexandre Le Vert, Co-Founder and CEO of Osivax**. "We believe that by generating these additional data against pandemic influenza strains, we will be able to bolster the positive results generated



by OVX836 against seasonal strains, placing us on a strategic path toward future regulatory approval."

OVX836 has shown promising safety, immunogenicity, and efficacy data across preclinical and clinical trials (Phase 1 and 2a). It is being evaluated in additional ongoing clinical trials: two co-administration studies conducted in Australia (OVX836-004 and OVX836-006) with OVX836 and quadrivalent inactivated influenza virus (QIV) vaccines. Osivax also recently published the results of a Phase 2a dose-optimization study (OVX836-003) in *The Lancet Infectious Diseases* showing efficacy in humans against seasonal strains.

About OVX836

OVX836 is a first-in-class influenza vaccine candidate that targets the nucleoprotein (NP), a highly conserved internal antigen. Unlike surface antigens, the NP is much less likely to mutate, providing a broader and more universal immune response. Osivax' oligoDOM[®] technology enables the design and production of a recombinant version of the NP which self-assembles into a nanoparticle, thus triggering powerful T- and B-cell immune responses. OVX836 has been tested in 5 clinical trials with 1200 participants so far, and has shown promising safety, immunogenicity, and efficacy read-outs.

About Osivax

Osivax is a clinical-stage biopharmaceutical company leveraging its novel, selfnanoparticle platform technology, oligoDOM[®], to develop assembling transformative, first-in-class pan-respiratory virus vaccines generating superior Tcell responses in addition to strong and sustained B-cell responses. The company is establishing proof of concept with its broad-spectrum, "universal" influenza candidate, OVX836, which is currently in Phase 2 clinical trials with over 1200 subjects tested and encouraging efficacy proof of concept data. Osivax' ambition is to develop a pan-respiratory virus vaccine to prevent all strains of influenza and all variants of sarbecovirus in one single shot. The company will expand into other infectious disease indications through combinations and collaborations worldwide.

For further information: https://osivax.com/

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