Osivax Announces Vaccination of First Participant in First-in-Human Trial Evaluating Sarbecovirus Vaccine Candidate OVX033

- **Phase 1 study to evaluate safety and immunogenicity of sarbecovirus (coronavirus) vaccine candidate, OVX033, at ascending dose levels**
- **The trial will enroll 48 participants in France**

Lyon, France – Feb 15, 2024 – Osivax, a biopharmaceutical company developing vaccines to provide broad-spectrum protection against highly mutating infectious viruses, today announced that the first participant has been vaccinated in its new Phase 1 trial (NCT06128382) evaluating OVX033, a broad-spectrum sarbecovirus vaccine candidate.

Recently, preclinical data published in *Frontiers in Immunology* demonstrated OVX033's proof of cross-protection against three SARS-CoV-2 variants of concern. In a rabbit toxicology study, the vaccine candidate also showed an excellent safety and tolerance profile after intramuscular administration. The first-in-human study will be conducted at the Clinical Investigation Center in Vaccinology Cochin Pasteur (CIC) in Cochin Hospital in Paris (AP-HP, Inserm) under the supervision of Odile Launay, MD, PhD, Professor at Paris Cité University.

"*OVX033 has been shown in preclinical models to effectively provide broad protection across multiple strains of coronavirus*," commented **Prof. Odile Launay, the Principal Investigator**. *"We are proud to participate in this first-in-human study to evaluate the vaccine candidate's role in preventing the pandemic-level spread of current and future SARS-CoV-2 variants."*

"Transitioning our second broad-spectrum vaccine candidate into the clinic further validates our self-assembling nanoparticle platform, OligoDOM™, and our position as a pioneer in the advancement of a new class of vaccines," said **Alexandre Le Vert, CEO & Co-Founder of Osivax**. *"With the Phase 1 initiation for OVX033 underway, we hope to advance a broad-spectrum coronavirus vaccine that can be positioned against all SARS-CoV-2 variants and against future coronavirus pandemic threats."*

The single-center trial is a randomized, double-blind, placebo-controlled Phase 1 clinical study evaluating the safety and immunogenicity of OVX033 at three dose levels (100 µg, 250 µg, and 500 µg). One single dose of OVX033 vaccine or of placebo will be administered intramuscularly in 48 healthy subjects aged 18-49 years.

OVX033 is based on Osivax' cutting-edge technology, OligoDOM™, which has already established promising proof-of-concept data with OVX836, a broad-spectrum influenza A vaccine candidate currently being evaluated in several Phase

2 clinical studies. Results on immunogenicity, safety and preliminary efficacy were published in *The Lancet Infectious Disease* in 2023.

About OVX033

OVX033 is a first-in-class coronavirus vaccine candidate that targets the nucleocapsid (N), a highly conserved internal antigen. Unlike surface antigens such as Spike (S), N is much less likely to mutate, providing a broader and more universal immune response, with the objective inducing broad-spectrum protection against all current and future variants of SARS-CoV-2 as well as against future pandemic coronavirus strains. Osivax' oligoDOM™ technology enables the design and production of a recombinant version of the nucleocapsid which self-assembles into a nanoparticle, thus triggering powerful T- and B-cell immune responses. OVX033 has demonstrated a preclinical proof of concept for cross-protective efficacy in a hamster challenge model published in *Frontiers in Immunology*. Further preclinical studies and a First-In-Human clinical trial are ongoing.

This project is supported by the French government, through France 2030, "Programme Investissements d'Avenir" operated by Bpifrance.

About Osivax

Osivax is a clinical-stage biopharmaceutical company leveraging its novel, self-assembling nanoparticle platform technology, oligoDOM™, to develop transformative, first-in-class pan-respiratory virus vaccines generating superior T-cell 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 1,200 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 Covid-19 in one single shot. The company will expand into other infectious disease indications through combinations and collaborations worldwide.

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