Osivax Announces First Participant Vaccinated in Phase 2a Clinical Booster Trial of Influenza Vaccine Candidate OVX836

- **Phase 2a study to evaluate safety and immunogenicity of a booster dose of influenza vaccine candidate OVX836, three to five years after initial administration**
- **Enrollment of over 150 participants anticipated in Belgium**

Lyon, France – Nov 14, 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 a Phase 2a clinical trial (NCT06582277) evaluating OVX836, its broad-spectrum influenza vaccine candidate as a booster in participants previously administered with OVX836.

Based on the encouraging data gathered so far, Osivax launched this study to further assess the safety and immunogenicity of a booster dose of OVX836. The booster dose will be administered to participants who were vaccinated three to five years ago in earlier Osivax studies at the same clinical site. The study is taking place at the Center for Vaccinology (CEVAC) at Ghent University Hospital.

The topline results from the trial are expected by the end of 2025.

"*We are pleased to support the ongoing evaluation of OVX836 through this Phase 2a influenza booster study*," commented **Prof. Isabel Leroux-Roels, Principal Investigator at CEVAC and Associate Professor at Ghent University**. *"We anticipate important insights that could significantly impact long-term influenza prevention."*

"This milestone is a significant step forward in our mission to develop a truly broad-spectrum, lasting flu vaccine capable of addressing the ever-evolving threat of influenza. By studying the effects of a booster dose, we aim to deepen our understanding of OVX836's potential to provide robust and sustained immune protection," said **Dr. Nicola Groth, CMO of Osivax**. *"Osivax is committed to leveraging innovative science to develop vaccines that protect individuals and help reduce the global healthcare burden associated with seasonal flu epidemics and potential pandemics."*

The single-center trial is a randomized, double-blind, Phase 2a clinical study evaluating the immunogenicity and safety of one single dose of OVX836 administered intramuscularly (IM) at either 180µg or 480µg. The study includes healthy participants ages 20-64 who previously received OVX836 (180µg to 480µg), Influvac® Tetra or placebo in the OVX836-002 (NCT04192500) and OVX836-003 (NCT05060887) studies.

About OVX836

OVX836 is a first-in-class influenza A 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 1,200 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, 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 volunteers 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.

For further information: www.osivax.com

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