Osivax Announces First Participant Vaccinated in Phase 2b Trial Evaluating Broad-Spectrum Influenza A Vaccine Candidate, OVX836

- **Phase 2b to assess efficacy, safety, and immunogenicity**
- **2,850 participants to be enrolled across European countries**

Lyon, France and Liège, Belgium – September 16, 2025 – 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 Phase 2b clinical trial (NCT05569239) evaluating OVX836, the company's broad-spectrum influenza A vaccine candidate.

OVX836 has previously demonstrated favorable safety, immunogenicity, and cross-reactivity results in multiple Phase 1 and Phase 2a studies, together with promising signals of efficacy (exploratory endpoints). This Phase 2b trial marks the first large-scale evaluation of OVX836's efficacy in a large population, representing a key step forward in Osivax' mission to develop a novel best-in-class influenza vaccine.

Prof. Isabel Leroux-Roels, Principal Investigator at CEVAC and Associate Professor at Ghent University, commented, *"Seasonal influenza remains a major public health challenge, and evaluating new vaccine approaches is key to improving prevention strategies. As an investigator in this trial, I am looking forward to working closely with the study participants and our research teams to generate robust clinical evidence during the upcoming flu season."*

"The initiation of this Phase 2b study marks a critical milestone for Osivax as we continue to advance our broad-spectrum influenza A vaccine candidate, OVX836", commented **Dr. Nicola Groth, Chief Medical Officer of Osivax**. *"We are grateful for the close collaboration with all our investigators, clinical partners, and internal teams who have made it possible to launch this large-scale efficacy trial well ahead of the flu season."*

This randomized, double-blind, multicenter trial will enroll approximately 2,850 participants, ages 18-59, at 16 sites across multiple European countries (full list of participating clinical sites available on clinicaltrials.gov NCT05569239). The study is designed to assess the efficacy, safety, and immunogenicity of OVX836 in protecting against influenza infections during the upcoming flu season.

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 7 clinical trials with over 1,400 participants so far, and has shown promising safety, immunogenicity, and efficacy read-outs.

About Osivax

Osivax is a clinical-stage biopharmaceutical company developing a portfolio of differentiated influenza vaccines generating superior T-cell responses in addition to strong and sustained B-cell responses, thanks to its novel, self-assembling nanoparticle platform technology, oligoDOM™. The company's lead candidate, OVX836, is a broad-spectrum influenza A vaccine candidate currently in Phase 2b clinical trials with over 1,400 volunteers tested and encouraging efficacy proof of concept data. By combining OVX836 with standard flu vaccines, Osivax is advancing toward a best-in-class seasonal flu vaccine to prevent all strains of influenza. Osivax collaborates with leading global health agencies, including US-based BARDA and NIH, and European-based institutions and top-tier pharmaceutical companies, reinforcing its mission to prevent all types of seasonal and pandemic influenza. The company will expand into other infectious disease indications through combinations and collaborations worldwide.

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