



Osivax Announces Last Patient Last Visit in Two Phase 2a Clinical Trials with Broad-Spectrum Influenza Vaccine Candidate OVX836

Lyon, France – December 21, 2022 – [Osivax](#), a biopharmaceutical company developing vaccines to provide broad-spectrum protection against highly mutating infectious viruses and diseases, today announced the Last Patient Last Visit (LPLV) in two Phase 2a clinical trials evaluating Osivax' lead T-cell based, broad-spectrum influenza vaccine candidate, OVX836. OVX836 has been developed using the company's proprietary oligoDOM[®] nanoparticle technology platform and is designed to produce immune responses against the nucleoprotein (NP), an internal antigen highly conserved across flu strains. The LPLVs were completed in: a dose-optimization study (OVX836-003) underway in Belgium, extended to include elderly participants aged 65 years and older, and a co-administration study being conducted in Australia (OVX836-004) with OVX836 and a quadrivalent inactivated influenza virus (QIV) vaccine. Topline results from both studies are anticipated in the first half of 2023.

"This announcement underscores the significant progress we continue to achieve in the clinical development of OVX836. As the number and prevalence of aggressive and dangerous influenza viruses continues to rise, the importance of developing new vaccines cannot be overstated," commented **Alexandre Le Vert, CEO and Co-Founder of Osivax**. *"We are eager to share the study outcomes next year as an important next step towards providing improved protective measures against these highly mutating viruses."*

Dr. Paul Willems, Chief Medical Officer of Osivax added, *"The data we gather from these Phase 2a studies will provide a solid foundation for the continued development of OVX836. Completing this stage marks a critical milestone for Osivax and we would like to extend a big thank you to all participating volunteers, investigators and their staff who have made this progress possible."*

About OVX836

Osivax' influenza vaccine, OVX836 targets the nucleoprotein (NP), a highly conserved internal antigen. Unlike surface antigens, 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 shown promising safety, immunogenicity, and efficacy in preclinical and clinical trials (Phase 1 and Phase 2a) and continues to be evaluated in additional studies.

About the OVX836-003 Trial

Based on promising safety data collected in the previous Phase 2a dose escalation study, Osivax initiated an additional Phase 2a dose optimization trial ([NCT05060887](#)). This study is evaluating the immunogenicity and safety of one intramuscular administration of OVX836 at two dose-levels, 300µg and 480µg in comparison to OVX836 at 180µg and



against a placebo. After successfully enrolling a first cohort of 138 healthy adults (18-55 years old) at the Center for Vaccinology at Ghent University (CEVAC), Osivax extended this trial to include 100 elderly participants aged 65 years and older following the same vaccination scheme and procedures.

About the OVX836-004 Trial

OVX836-004 is a randomized, double-blind, reference-controlled, single center Phase 2a clinical trial run in Australia ([NCT05284799](https://clinicaltrials.gov/ct2/show/study/NCT05284799)), to assess the co-administration of NP-based flu vaccine OVX836 at 480µg with a conventional seasonal, HA-based quadrivalent inactivated influenza virus vaccine (QIV), the current standard of care in flu vaccine market. The clinical study is evaluating the safety and level of immune response generated by each vaccine individually and when co-administered to confirm the absence of immune interference.

About Osivax

Osivax is a biopharmaceutical company leveraging its novel, self-assembling nanoparticle platform technology, oligoDOM[®], to transform current and new vaccines by generating superior T-cell responses in addition to strong and sustained B-cell responses against highly mutating viruses. The company is establishing proof of concept with its highly validated lead influenza candidate, OVX836, which is currently in Phase 2 testing with over 800 subjects tested. Osivax is also exploring the broader application of its technology in a variety of indications. The company will expand into other infectious disease indications through combinations and collaborations worldwide.

For further information: www.osivax.com

Contact

Alexandre Le Vert, CEO
contact@osivax.com
+33 (0)9 70 30 13 80

For Media Inquiries

Trophic Communications
Valeria Fisher or Desmond James
Osivax@trophic.eu
+49 (0) 175 804 1816 or +49 (0) 151 678 59086