Osivax Announces Publication of Phase 2a Trial Results for Influenza Vaccine Candidate OVX836 in *Frontiers in Immunology*

- **Data also discussed in context of OVX836 clinical development update presentation at 2022 World Vaccine Congress**

Lyon, France – April 21, 2022 – Osivax, a biopharmaceutical company developing vaccines to protect against highly mutating infectious diseases, announced today that the Phase 2a results for its broad-spectrum influenza vaccine candidate, OVX836, have been published under the title "Randomized, Double-Blind, Reference-Controlled, Phase 2a Study Evaluating the Immunogenicity and Safety of OVX836, A Nucleoprotein-Based Influenza Vaccine" in the journal *Frontiers in Immunology*. Developed using Osivax' proprietary self-assembling nanoparticle technology, OVX836 targets an internal nucleoprotein (NP), a highly conserved antigen that is less susceptible to the constant mutations of surface antigens of the influenza virus. The study demonstrated that OVX836 induced a significant increase of NP-specific cellular immune responses, including CD4+ and CD8+ T cells, and initial efficacy signals while being safe and well-tolerated in 300 adult subjects.

"The publication of the comprehensive data set in *Frontiers in Immunology* provides an overview of OVX836's ability to generate strong and persistent nucleoprotein-specific immune responses including T cells," commented **Alexandre Le Vert, CEO and Co-Founder of Osivax**. "In addition to meeting the primary endpoints of the trial, an important element of this study was the signal of efficacy demonstrated with a decrease in the number of symptomatic influenza-like illness thanks to OVX836 at 180µg. Based on these results, we believe that the combination of our universal approach together with current seasonal vaccines can provide broader and more effective protection to influenza and we intend to test this concept as we continue the clinical development of OVX836."

In the study, 300 healthy volunteers between the ages of 18 and 65 enrolled in the randomized, monocenter, reference-controlled, parallel-group, double-blind Phase 2a clinical trial to receive a single administration of OVX836 at 90µg, OVX836 at 180µg or the quadrivalent seasonal influenza subunit vaccine Influvac Tetra™. Results from the study indicate that vaccination with OVX836 at both dose levels was safe and well-tolerated, with signals and symptoms both locally and systemically similar to Influvac Tetra™. Beyond the favorable safety profile, OVX836 was able to significantly increase NP-specific interferon-gamma (IFNg) spot forming cells (SFCs), NP-specific CD4+ T cells and anti-NP IgG responses, which indicates a protective effect and confirms the critical role that T cell mediated immune responses can play in preventing influenza viruses.

The open access article is available via this link. Topline data from the Phase 2a study were announced previously in December of 2021 and also have been

presented yesterday, April 20, at the 2022 World Vaccine Congress being held from April 18-21 in Washington DC.

Osivax is currently conducting a Phase 2a dose optimization study (NCT05060887) to evaluate the immunogenicity and safety of single administrations of OVX836 at 300µg and 480µg in comparison to OVX836 at 180µg and against a placebo. The study in 138 healthy subjects between the ages of 18 and 55 is underway at the Center for Vaccinology at Ghent University (CEVAC). The trial is supported by Bpifrance and the European Union's Horizon 2020 Research and Innovation Program.

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 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).

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 500 subjects tested. Osivax' additional pipeline candidates include vaccine against coronaviruses and HPV. The company will expand into other infectious disease indications through combinations and collaborations worldwide.

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