



## **Osivax Announces Promising Phase 2a Results with Universal Influenza Vaccine Candidate, OVX836, and Initiation of Additional Phase 2a Dose Optimization Study**

- **Phase 2a results demonstrate excellent safety profile alongside strong, dose-dependent immune response**
- **First patient enrolled in complementary Phase 2a dose optimization study**

**Lyon, France – December 21<sup>st</sup>, 2021** – [Osivax](#), a biopharmaceutical company focused on preventing the spread of constantly mutating global infectious diseases, including influenza and coronaviruses, announced today promising results of its Phase 2a clinical trial with [OVX836](#), Osivax' broad-spectrum influenza vaccine candidate developed using the company's proprietary [oligoDOM<sup>®</sup>](#) nanoparticle technology platform. Unlike conventional vaccines which target highly mutating surface proteins and need to be updated to match seasonal influenza strains, OVX836 targets the internal nucleoprotein (NP), a highly conserved antigen that is far less susceptible to mutations and would thus provide universal protection.

The randomized, double-blind, reference-controlled Phase 2a clinical trial was designed to evaluate the safety and immunogenicity of two dose-levels of OVX836 (90µg and 180µg). OVX836 exhibited an excellent safety profile for all tested dose-levels and demonstrated a strong and long-lasting NP-specific cellular immune response after one intramuscular injection with a stronger dose-response effect at 180µg. Notably, although the study was not designed to measure clinical efficacy, a first signal of protection against influenza symptoms in the 180µg arm was observed.

**Professor Geert Leroux-Roels, Professor Emeritus at Ghent University and member of Osivax' Clinical Advisory Board** commented, "We are encouraged by OVX836's ability to trigger strong and long-lasting cellular immune responses against the nucleoprotein. These findings support our belief that OVX836 has the potential to protect against current and future influenza strains and to act as a complementary approach to currently available vaccines targeting surface proteins."

The company additionally announced the enrollment of the first patient in an additional Phase 2a dose optimization clinical trial with OVX836. The randomized, double-blind, reference-controlled, single center, Phase 2a clinical study is designed to evaluate the immunogenicity and the safety of one single intramuscular administration of OVX836 at 300µg and 480µg in comparison to OVX836 at 180µg and against a placebo. The study will include 138 healthy subjects between the ages of 18-55 and will be conducted 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.

"It is exciting to announce the initiation of a third clinical trial with OVX836 to inform the optimal dose regimen of our lead candidate," commented **Alexandre Le Vert, CEO and co-founder of Osivax**, "Our past clinical trials suggest a protective effect at 180µg which confirms our starting hypothesis that T-cell mediated immune responses can play a critical role in preventing influenza. Both studies serve as an important step toward preventing the spread of highly mutating influenza viruses."

### **About OVX836**

Osivax' universal influenza vaccine, OVX836 targets the nucleoprotein (NP), a highly conserved internal antigen. Unlike surface antigens, NP is much less likely to mutate, alleviating the need for annual vaccination updates. Osivax' oligoDOM® technology enables the design and production of recombinant version of the NP which self-assembles into a nanoparticle, thus triggering powerful B- and T-cell immune responses. OVX836 has shown promising safety, immunogenicity, and efficacy in preclinical and clinical trials (Phase 1 and Phase 2a). OVX836 is currently being evaluated in a dose-optimization Phase 2a clinical study conducted at the Center for Vaccinology of the Ghent University (CEVAC).

### **About Osivax**

Osivax' mission is to prevent the spread of constantly mutating global infectious diseases. Leveraging its unique oligoDOM® technology platform, Osivax is developing a universal vaccine for both current and future influenza infections. The Company's universal flu vaccine candidate, OVX836 is in Phase 2a clinical development. Osivax is leveraging the same platform technology for the development of a universal vaccine against all existing and emerging coronavirus infections. Osivax is focused on providing proof-of-concept in influenza and coronavirus, and to applying its oligoDOM® platform broadly in other infectious and immune system-associated diseases.

For further information: [www.osivax.com](http://www.osivax.com)

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