Osivax Announces First Volunteers Enrolled in Phase 2a clinical trial of OVX836 Universal Influenza Vaccine Candidate

-- Phase 2a clinical trial on 300 healthy volunteers run under US IND --

Lyon, France – January21, 2020 – OSIVAX, a clinical stage biopharmaceutical company currently focused on the development of a universal influenza vaccine candidate, enrolled the first participant in Phase 2a trial on the 11th Dec 2019. The study is comparing the immunogenicity (cellular immune response) and safety of OVX836 with that of a currently marketed quadrivalent flu vaccine.

Osivax has obtained authorisation from the Belgian Health Authorities (FAMHP) and the study will be performed under an IND application of the US Health Authorities (FDA).
The trial is a single-centre, randomized, double-blind, controlled study run by principal investigator Prof. Dr. Isabel Leroux-Roels, in the Center for Vaccinology (CEVAC) at the Ghent University (Ghent, Belgium).
This Phase 2a study aims at evaluating the safety and immunogenicity of a single vaccination with OVX836 at two dose levels (90 µg and 180 µg) compared to a seasonal quadrivalent vaccine (Influvac Tetra™) in healthy subjects aged 18-65 years. Three hundred (300) volunteers are randomly allocated to 3 groups of 100 subjects to be administered either 90µg or 180 µg of OVX836, or a standard dose of the quadrivalent vaccine. The participants will be followed for 6 months.

The top line results from the trial are expected by the first quarter of 2021.

Alexandre Le Vert, **CEO and co-founder** of Osivax commented "The enrollment of the first participant in our phase 2a study is an important milestone in the assessment of the immunogenicity of our universal flu vaccine candidate OVX836. We are very optimistic about the results of this Phase 2a trial, which will provide data to further support OVX836, thus tackling the unmet medical needs caused by influenza worldwide."

"We are pleased with the progress we are making in recruiting the first volunteers in this important Phase 2a study and we expect that it will generate important insights about the immungenicity and safety of OVX836" said **Dr Isabel Leroux-Roels, principal investigator of the clinical trial**. "We are proud to be on the path to offering a highly safe vaccine with the potential to revolutionize flu prevention."

About the Center of Vaccinology
The Center for Vaccinology of the Ghent University (CEVAC) has a large track record in conducting vaccine trials for numerous infectious diseases: hepatitis B, combined hepatitis A-B- C, influenza, HPV, HSV, VZV, RSV, CMV, HIV, tuberculosis, malaria, for a wide number of sponsors. CEVAC has developed a large portfolio of assays to measure humoral and cellular immune responses following rapid blood sample on-site processing.

About Osivax

Osivax's mission is to revolutionize influenza prevention with a universal flu vaccine for both current and future influenza infections by leveraging its unique oligoDOM® technology platform. The OVX836 universal flu vaccine candidate is in Phase 2a clinical development. Osivax is focused on providing proof-of-concept in influenza firstly to save lives and secondly to apply the oligoDOM® platform to other infectious and immune system-associated diseases. For further information: www.osivax.com

Osivax
Alexandre Le Vert, CEO
contact@osivax.com
+33 (0)4 37 65 55 03

For Media Inquiries:
Trophic Communications
Joanne Tudorica or Valeria Fisher
tudorica@trophic.eu or fisher@trophic.eu
+49 (0)89 23 88 77 30