



Approval of Osivax' First in Human Clinical Trial for its Universal Influenza Vaccine Candidate

Osivax announced today that the Belgian health authority approved the initiation of a first-in-human clinical trial evaluating the safety and immunogenicity of OVX836 in healthy volunteers

Lyon, France – June 4, 2018 – Osivax, a clinical stage biopharmaceutical company currently focused on the development of a universal influenza vaccine candidate, announced today that the Belgian health authority approved the initiation of a first-in-human clinical trial evaluating the safety and immunogenicity of OVX836, a universal influenza vaccine candidate, in healthy volunteers.

This first-in-human phase I study is a randomized, observer-blind, placebo-controlled dose escalating trial, conducted in the Centre for the Evaluation of Vaccination (CEV) at the University of Antwerp. 72 healthy subjects between 18 to 49 years old will be enrolled and followed during 22 weeks to evaluate the safety and the immune response of OVX836. The recruitment is on schedule with the first volunteer starting mid June.

Preclinical immunogenicity studies conducted in different species including mice, ferrets and rabbits demonstrated that OVX836 vaccination induces both humoral and cellular responses specific of NP and especially robust CD8+ T cells responses. Pharmacology studies demonstrated OVX836 efficacy in protecting mice and ferrets against influenza challenges. OVX836 also showed an excellent safety and tolerance profile after intramuscular and intranasal administration in a rabbit's toxicology study.

The trial will take place in the Centre for the Evaluation of Vaccination (CEV) of the University of Antwerp, which was founded in 1994 by Prof Pierre Van Damme, full professor at the University of Antwerp, Faculty of Medicine and Health Sciences. The CEV is recognized as a 'Centre of Excellence' of the University of Antwerp and functions as a WHO Collaborating Centre for the WHO European Region for the control and prevention of infectious diseases. The center also works in collaboration with PATH, CDC, ECDC, EU and the Bill & Melinda Gates Foundation.

Pr Pierre Van Damme, Vaccinologist and Head of the Centre for the Evaluation of Vaccination (CEV) of the University of Antwerp, and principal investigator of the trial said: "The preclinical results of the vaccine candidate OVX836 provide good evidence that OVX836 could protect subjects from moderate to severe influenza symptoms. The potential of OVX836 to provide a broad-spectrum (and maybe universal) protection is of high interest and we are very proud to be participating in this First in Human study"

Alexandre Le Vert, CEO and cofounder of Osivax, said: ". The approval of this First in Human trial by the Belgian health authorities is a key milestone for the development of OVX836, our universal influenza vaccine. We remain highly committed to supporting the development of this vaccine candidate, as it could



have a profound impact on the community by addressing the unmet medical needs caused by influenza worldwide”

About Influenza

With 250,000 to 500,000 deaths annually globally, including tens of thousands in the US and Europe (56,000 deaths in the US alone in 2012), Influenza remains a devastating disease.

Current seasonal vaccines are only partially effective, especially for patients over 65 years old (25% effectiveness in the 2016-17 season in the US, according to the CDC, the Atlanta, GA based Center for Disease Controls and Prevention).

About OVX836

OVX836 is a breakthrough, wide-spectrum influenza vaccine that is in clinical development, with a phase I clinical trial starting in June 2018.

OVX836 activates a CD8 T-cell immune response against the influenza nucleoprotein (NP), a well-conserved internal protein essential to the replication of the virus. Vaccines triggering such immune response (CD8 T-cell responses against NP) represent a disruptive and promising path to a breakthrough improvement of current flu vaccines.

OVX836 will be used in combination with seasonal influenza vaccines.

About Osivax

Osivax is a biopharmaceutical company focused on vaccines and leveraging on oligoDOM®, a patented technology platform spun-off from Imaxio SA. Osivax focuses on its flagship project: OVX836, a breakthrough influenza vaccine candidate.

The company partners with international renown academic structures, including the Jenner Institute at Oxford University (UK), the German Cancer Research Center (DKFZ), Inserm, CNRS and the Léon Bérard Cancer Center (France).

Osivax was founded in 2017 as a spin-off of Imaxio SA.

About the Centre for the Evaluation of Vaccination

The Centre for the Evaluation of Vaccination, University of Antwerp, has a long-standing tradition in running national and international vaccine safety & immunogenicity trials (HBV, HPV, polio, influenza, Ross River, Dengue, Ebola ...). Over the last 25 years, the CEV conducted more than 350 vaccine trials.

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