Osivax Provides Clinical Development Update on Lead Influenza Vaccine Candidate OVX836

- **Excellent safety continues to be observed in ongoing Phase 2a dose optimization study (OVX836-003)**
- **Phase 2a dose optimization study extended to elderly population cohort (OVX836-003)**
- **Additional Phase 2a trial combining OVX836 with conventional quadrivalent influenza vaccine (QIV) initiated with first participants enrolled in Australia (OVX836-004)**

Lyon, France – May 25, 2022 – Osivax, a biopharmaceutical company developing vaccines to provide broad-spectrum protection against highly mutating infectious viruses and diseases, today provided an update on the clinical development plan of its lead candidate, OVX836. OVX836 is Osivax' T-cell based influenza candidate developed using the company's proprietary oligoDOM® nanoparticle technology platform and designed to produce immune responses against the nucleoprotein (NP), a highly conserved internal antigen across flu strains. Based on positive safety data from the ongoing Phase 2a trial, the company has initiated two additional Phase 2 clinical trials: a dose-escalation study in elderly subjects and a combination trial with a seasonal quadrivalent influenza vaccine (QIV), to broaden the scope of OVX836's application in an effort to provide improved protection against influenza across strains.

"Our goal is to improve influenza protection globally and the expansion of our development strategy for OVX836 will enable us to maximize the reach of our pan-influenza approach," **commented Alexandre Le Vert, CEO and Co-Founder of Osivax**. "These new studies allow us to further evaluate the potential of our platform as well as, for the first time, create a combination vaccine approach that could set a new standard for how we address vaccine development, accessing multiple technologies to achieve the most advantageous training of the immune system."

"We are highly encouraged by the excellent safety profile of OVX836 even at higher dose levels, which is a key feature for successful use in mass vaccination. Besides evaluation as a standalone, this profile opens the path to further development also in combination with existing vaccines, without adding burden on safety or reactogenicity. A synergistic approach combining the cell-based immune mechanism of our vaccine with the humoral immunity conferred by conventional vaccines would constitute a promising addition to available flu immunization options, particularly for subjects with decreased immunocompetencies who need them most," **commented Dr. Paul Willems, Chief Medical Officer of Osivax**.

Clinical Updates:

Ongoing Phase 2a Dose-Optimization Study (OVX836-003)
Based on promising safety data collected in the previous Phase 2a dose escalation study recently published in *Frontiers in Immunology*, 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. Osivax has now successfully enrolled a first cohort of 138 healthy adults (18-55 years old) at the Center for Vaccinology at Ghent University (CEVAC). Results are planned to be reported by the end of 2022. Excellent safety readouts at all dose levels were observed to-date and warrant further evaluation in older adults.

Extension of Phase 2a Dose-Optimization Study (OVX836-003)
The ongoing dose-optimization trial has been extended to include 100 elderly participants aged 65 years and older following the same treatment scheme and procedures as the active phase of the study in subjects aged 18-55 years. The first participant has been enrolled and additional participants will be registered in the upcoming weeks.

The primary endpoints of the study include change of NP-specific IFNγ T-cell activity measured by ELISpot and proportion of subjects reporting solicited local and systemic symptoms.

Phase 2a Combination Trial with OVX836 and QIV Vaccine (OVX836-004)
The first participant has been enrolled in the Phase 2a clinical trial in Australia (NCT05284799), combining OVX836 at 480µg with a conventional seasonal, B-cell based quadrivalent inactivated influenza virus vaccine (QIV), one of the most commonly used flu vaccines on the market. The randomized, double-blind, reference-controlled, single center, Phase 2a clinical study will evaluate the immune response generated by each vaccine individually and when co-administered to confirm the absence of immune-interference as well as potential vaccine synergies.

Healthy volunteers will be allocated to three groups of 60 participants to receive either OVX836 combined with the QIV, QIV alone or a placebo. Participants will be observed for safety and immunogenicity over a period of six months. Primary endpoints include the number of seroconversions determined using Hemagglutination-Inhibition assay for the four influenza strains contained in the Quadrivalent Influenza Vaccine as well as proportion of subjects reporting solicited local and systemic symptoms. Secondary endpoints include NP-specific IFNγ T-cell activity measured by ELISpot.

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 is also exploring the broader application of its technology in both mRNA and subunit vaccines against a variety of indications. The company will expand into other infectious disease indications through combinations and collaborations worldwide.

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