Osivax Publishes Phase 2a Results Supporting Co-Administration of OVX836 with Seasonal Flu Vaccine in Vaccines Journal

- **Co-administration of OVX836 with seasonal inactivated influenza vaccine (Fluarix® Tetra) was well-tolerated and demonstrated a favorable safety profile**
- **Robust complementary immune responses were induced, with no major interference observed**

Lyon, France – July 10, 2025 – Osivax, a biopharmaceutical company developing vaccines to provide broad-spectrum protection against highly mutating infectious viruses, today announced the publication of positive results from its Phase 2a, OVX836-004, study in the journal *Vaccines*. The study evaluated the safety and immunogenicity of co-administering OVX836, Osivax' broad-spectrum influenza vaccine candidate, with the hemagglutinin antigen (HA)-based inactivated influenza vaccine Fluarix® Tetra. The full article *"Safety and Immunogenicity of OVX836, a Nucleoprotein-Based Universal Influenza Vaccine, Co-Administered with Fluarix® Tetra, a Seasonal Hemagglutinin-Based Vaccine"* is now available online.

In the OVX836-004 study (NCT05284799), 180 healthy adults aged 18 to 55 years were randomized to each receive two concomitant intramuscular injections of Fluarix® Tetra and placebo, Fluarix® Tetra and OVX836 (480 µg), or OVX836 and placebo, both administered into the deltoid muscle of the non-dominant arm.

Key findings include:

- Favorable safety and tolerability profile of OVX836 when administered alone or in combination with Fluarix® Tetra; no severe or unsolicited adverse events were reported
- Comparable local and systemic reactions across all treatment groups
- Strong HA-specific antibody responses were observed in all groups immunized with Fluarix® Tetra, whether co-administered with OVX836 or as a stand-alone, with similar HAI titers across all four influenza strains
- Robust NP-specific immune responses, both humoral and cell-mediated, were measured in all groups receiving OVX836, whether co-administered with Fluarix® Tetra or as a stand-alone

"*The favorable safety profile and strong immune response observed in this study provide encouraging evidence that OVX836 can be co-administered with a standard seasonal influenza vaccine,*" commented **Dr. Nicola Groth, MD, CMO of Osivax**. "*These findings support the potential of OVX836 to lead to higher efficacy due to synergistic effects of the immune responses when combined with standard seasonal flu vaccine and to further reinforce the versatility of our vaccine candidate, marking an important milestone in our efforts to broaden protection against influenza in years of strain mismatches.*"

"*The results underscore OVX836's strong potential as a valuable component of combination approaches with seasonal vaccines,"* added **Alexandre Le Vert, CEO and Co-Founder of Osivax**. *"By inducing strong and complementary immune responses, our approach positions us to meaningfully advance influenza prevention on a broader scale. The data collected will support the continued development of OVX836 as we focus on a single-injection formulation that streamlines vaccination delivery and maximizes public health impact."*

About OVX836

OVX836 is a first-in-class influenza A vaccine candidate that targets the nucleoprotein (NP), a highly conserved internal antigen. Unlike surface antigens, the NP is much less likely to mutate, providing a broader and more universal immune response. Osivax' oligoDOM™ technology enables the design and production of a recombinant version of the NP, which self-assembles into a nanoparticle, thus triggering powerful T- and B-cell immune responses. OVX836 has been tested in 7 clinical trials with 1,400 participants so far, and has shown promising safety, immunogenicity, and efficacy read-outs.

About OVX836-004

OVX836-004 is a randomized, double-blind, reference-controlled, single-center Phase 2a clinical trial run in Australia (NCT05284799), to assess the co-administration of NP-based flu vaccine OVX836 at 480µg with a conventional seasonal, HA-based quadrivalent inactivated influenza virus vaccine (QIV), the current standard of care in the flu vaccine market. The clinical study is evaluating the safety and level of immune response generated by each vaccine individually and when co-administered to confirm the absence of immune interference.

About Osivax

Osivax is a clinical-stage biopharmaceutical company leveraging its novel, self-assembling nanoparticle platform technology, oligoDOM™, to develop transformative, first-in-class pan-respiratory virus vaccines generating superior T-cell responses in addition to strong and sustained B-cell responses. The company is establishing proof of concept with its broad-spectrum influenza vaccine candidate, OVX836, which is currently in Phase 2 clinical trials with over 1,400 volunteers tested and encouraging efficacy proof of concept data. Osivax' ambition is to develop a pan-respiratory virus vaccine to prevent all strains of influenza and all variants of Covid-19 in one single shot. The company will expand into other infectious disease indications through combinations and collaborations worldwide.

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