



Osivax Announces Publication in *The Lancet Infectious Diseases* of Phase 2a Data for Broad-Spectrum Influenza Vaccine Candidate, OVX836

- **OVX836 demonstrated positive safety and immunogenicity data across three dose levels**
- **A notable signal of protection of 84% was observed against symptomatic influenza infection**

Lyon, France – July 28, 2023 – [Osivax](#), a biopharmaceutical company developing vaccines to provide broad-spectrum protection against highly mutating infectious viruses, today announced that *The Lancet Infectious Diseases* published results from the company's OVX836-003 study under the title, "Immunogenicity, safety and preliminary efficacy evaluation of OVX836, a nucleoprotein-based universal influenza A vaccine candidate: randomised, double-blind placebo-controlled, Phase 2a trial." The research article presents results of the study evaluating the safety and immunogenicity of OVX836, a broad-spectrum influenza vaccine, at three dose levels in healthy adults ([NCT05060887](#)). An efficacy assessment of OVX836 was also planned as an exploratory endpoint. The publication can be accessed at the following link: [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(23\)00351-1/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(23)00351-1/fulltext).

Applying Osivax' proprietary oligoDOM[®] technology platform, OVX836 is designed to target the nucleoprotein (NP), a highly conserved internal antigen. Unlike surface antigens, the NP is much less likely to mutate, alleviating the need for annual vaccination updates. OligoDOM[®] enables the transformation of the NP into a highly immunogenic antigen to trigger powerful T-cell immune responses.

In the OVX836-003 study, a total of 137 healthy subjects aged 18-55 years received one intramuscular injection of the study vaccine or placebo as follows: 33 received OVX836 180 µg, 35 received OVX836 300 µg, 36 received OVX836 480 µg and 33 received a placebo. The OVX836 vaccine was safe and immunogenic at all dose levels. OVX836 elicited significant humoral and cellular NP-specific immune responses, including CD4⁺ and CD8⁺ T-cells. Most of the immunological markers (anti-NP IgG, NP-specific IFN γ SFCs, NP-specific CD4⁺ T-cells) showed a dose-dependent response from 180 µg to 480 µg. Induction of a measurable CD8⁺ response against a non-adjuvanted recombinant protein vaccine is challenging in humans and rarely reported, thus warranting the further evaluation of OVX836 in larger Phase 2b/3 clinical trials. Importantly, OVX836 provided an 84% level of protection against PCR-confirmed symptomatic influenza compared to placebo.

A separate cohort of 100 older adults (65 years old and older) was vaccinated (same doses and randomisation ratio as younger subjects) and will be reported separately, with full results expected by Q4 2023.



*"The favorable safety profile, and strong dose-dependent immune responses observed in this study underscore the potential of OVX836 as a promising influenza vaccine," commented **Isabel Leroux-Roels, PhD, Principal Investigator at the Center for Vaccinology (CEVAC)**. "Notably, the observed signal of protection appears to be in line with the universal influenza vaccine target product profile set by the US National Institutes of Health, which is highly encouraging and certainly warrants closer evaluation in additional clinical trials."*

*"The publication of our Phase 2a data in the highly estimated Lancet ID journal is a significant appreciation and recognition of the robust nature of our study results," added **Alexandre Le Vert, CEO and Co-Founder of Osivax**. "We are strongly encouraged by these findings, particularly given that very few vaccine candidates pursuing a T-cell mechanism of action targeting the NP have elicited vaccine efficacy at this point in time. As such, we look forward to advancing OVX836 toward the next stages of clinical development as a truly universal influenza vaccine."*

About OVX836

OVX836 is a first-in-class influenza 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 5 clinical trials with 1200 participants so far, and has shown promising safety, immunogenicity, and efficacy read-outs.

About OVX836-003

The OVX836-003 trial is a Phase 2a, randomized, double-blind, controlled study comparing the immunogenicity and the safety of the OVX836 influenza vaccine candidate at two dose levels (300µg and 480µg) to a lower dose level (180µg) and to placebo in 137 healthy adult subjects ages 18-55 years old. One single dose of OVX836 influenza vaccine (180µg or 300µg or 480µg) or of placebo was administered intramuscularly in the healthy volunteers. A separate cohort of 100 older adults (65 years old and older) was vaccinated (same doses and randomisation ratio as younger subjects) and will be reported separately.

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, "universal" influenza candidate, OVX836, which is currently in Phase 2 clinical trials with over 1200 subjects 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 sarbecovirus in one single shot. The company will expand into other infectious disease indications through combinations and collaborations worldwide.

For further information: www.osivax.com



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