

## NEWS RELEASE

# Osivax Completes Enrollment for Phase 1 Trial with Broad-Spectrum Sarbecovirus Vaccine Candidate, OVX033

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- 48 healthy volunteers enrolled in first-in-human trial
- Topline data read-out expected by Q4 2024

LYON, France--(BUSINESS WIRE)-- **Osivax**, a biopharmaceutical company developing vaccines to provide broad-spectrum protection against highly mutating respiratory viruses, today announced that it has completed enrollment in its Phase 1 trial (**NCT06128382**) with OVX033, the company's broad-spectrum vaccine candidate against sarbecoviruses.

The study is designed to evaluate the safety and immunogenicity of OVX033 at three dose levels (100 $\mu$ g, 250 $\mu$ g and 500 $\mu$ g). To date, no safety concerns or signals have been observed at any dose level, justifying a dose escalation up to the maximum dose level of 500 $\mu$ g. The single-center, randomized, double-blind, placebo-controlled Phase 1 clinical study is being conducted at the Clinical Investigation Center in Vaccinology Cochin Pasteur (CIC) in Cochin Hospital in Paris (AP-HP, Inserm).

"Sarbecoviruses remain a threat as evidenced by the Covid-19 pandemic, which continues to have long-term consequences for global health. By completing enrollment for our Phase 1 trial with OVX033, we are taking a significant step forward in addressing the need for a broad-spectrum vaccine to provide protection against these rapidly mutating viruses," said **Dr. Nicola Groth, CMO of Osivax**.

"The data gathered from the Phase 1 trial with OVX033 will be critical to its further development as an effective and safe protective measure against various strains of sarbecoviruses. We look forward to sharing the data readout

later this year and thank all volunteers participating in this study," commented **Prof. Odile Launay, MD, PhD, Professor at Paris Cité University, the Principal Investigator.**

## About OVX033

OVX033 is a first-in-class coronavirus vaccine candidate that targets the nucleocapsid (N), a highly conserved internal antigen. Unlike surface antigens such as Spike (S), N is much less likely to mutate, providing a broader and more universal immune response, with the objective of inducing broad-spectrum protection against all current and future variants of SARS-CoV-2 as well as against future pandemic coronavirus strains. Osivax' oligoDOMTM technology enables the design and production of a recombinant version of the nucleocapsid which self-assembles into a nanoparticle, thus triggering powerful T- and B-cell immune responses. OVX033 has demonstrated a preclinical proof of concept for cross-protective efficacy in hamster challenge model published in *Frontiers in Immunology*. Further preclinical studies and a First-In-Human clinical trial are ongoing.

This project is supported by the French government, through France 2030, "Programme Investissements d'Avenir" operated by Bpifrance as projects DOS0123291, DOS0152140 and DOS0152141.

## About Osivax

Osivax is a clinical-stage biopharmaceutical company leveraging its novel, self-assembling nanoparticle platform technology, oligoDOMTM, 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 1,200 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.

For further information: [www.osivax.com](http://www.osivax.com)

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