

OSE Immunotherapeutics Announces Dosing of the First Healthy Volunteer in Phase 1 Clinical Trial of its Multi-Variant Second-Generation COVID-19 Vaccine

- **First-in-human study evaluating CoVepiT, a multi-variant T cell COVID-19 vaccine for people at risk and vulnerable populations.**
- **CoVepiT is a peptide-based vaccine aiming to induce CD8+T-cell-mediated immune response against 11 different proteins of SARS-CoV-2 virus to provide a long-term cellular immunity with memory T cells.**
- **Phase 1 study expected to read-out in September 2021.**

Nantes, France - May 26, 2021, 7:30 a.m. CET - OSE Immunotherapeutics (ISIN: FR0012127173; Mnemo: OSE) today announced that the first healthy volunteer has been enrolled and dosed in the Phase 1 clinical trial evaluating its COVID-19 vaccine, named CoVepiT.

This Phase 1 clinical trial is evaluating the safety, reactogenicity and immunogenicity of two dose regimen of CoVepiT in 48 healthy adult volunteers, previously vaccinated or not by an authorized COVID-19 vaccine (NCT04885361).

Alexis Peyroles, Chief Executive Officer of Immunotherapeutics, comments: *“We are delighted with the progress achieved on the CoVepiT program to date with this first dosing being a significant milestone in our COVID-19 vaccine candidate’s development. We look forward to confirming our vaccine’s efficacy, providing people with broad and long-term protection against COVID-19 and its variants, particularly for more vulnerable population subgroups. The next phases of CoVepiT development are already under preparation, potentially expanding to other European countries while progressing with industrialization and manufacturing efforts. This further development is supported by a recent €10.7 million public funding from the French government via Bpifrance.”*

The Phase 1 clinical trial of CoVepiT is based on the results from preclinical and human *ex vivo* studies demonstrating its potential to generate sentinel memory T cells with long-term protective effect against COVID-19. Targeting 11 virus proteins (including Spike, M, N and several non-structural proteins), this second-generation vaccine is designed to cover all initial and novel or upcoming SARS-CoV-2 variants.

ABOUT CoVepiT

CoVepiT is a next-generation multi-target, multi-variant vaccine against SARS-CoV-2 in clinical Phase 1. The vaccine candidate was designed using optimized epitopes selected after screening more than 67,000 global SARS-CoV-2 genomes, as well as those of previous human-infective CoVs, SARS and MERS, to identify vaccine targets with the lowest chance of natural mutation. Targeting 11 virus proteins including Spike, M, N and several non-structural proteins, this second-generation vaccine covers all initial and novel SARS-CoV-2 variants identified globally to date. In preclinical testing, CoVepiT demonstrated the ability to activate T cell defenses through CD8 T-cell multi-epitope responses for long-term T memory cell immunity.

ABOUT OSE Immunotherapeutics

OSE Immunotherapeutics is an integrated biotechnology company focused on developing and partnering therapies to control the immune system for immuno-oncology and autoimmune diseases. The company's immunology research and development platform is focused on three areas: T-cell-based vaccination, Immuno-Oncology (focus on myeloid targets), Auto-immunity & Inflammation. Its balanced first-in-class clinical and preclinical portfolio has a diversified risk profile:

Vaccine platform

- **Tedopi®** (innovative combination of neoepitopes): the company's most advanced product; positive results for Step-1 of the Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer post checkpoint inhibitor failure. In Phase 2 in pancreatic cancer (TEDOPaM, sponsor GERCOR) In Phase 2 in ovary cancer (TEDOVA, sponsor ARCAGY-GINECO) *Due to the COVID-19 crisis, accrual of new patients in TEDOPaM should restart in 2021.*
- **CoVepiT**: a prophylactic second-generation vaccine against COVID-19, developed using SARS-CoV-2 optimized epitopes against multi variants. Positive preclinical and human ex vivo results in August 2020. In clinical Phase 1.

Immuno-oncology platform

- **BI 765063** (OSE-172, anti-SIRPα mAb on SIRPα/CD47 pathway): developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 results in monotherapy and BI 765063 dose escalation study ongoing in combination with Ezabemlimab (PD-1 antagonist).
- **CLEC-1** (novel myeloid checkpoint target): identification of mAb antagonists of CLEC-1 blocking the "Don't Eat Me" signal that increase both tumor cell phagocytosis by macrophages and antigen capture by dendritic cells.
- **BiCKI®**: bispecific fusion protein platform built on the key backbone component anti-PD-1 (OSE-279) combined with new immunotherapy targets; 2nd generation of PD-(L)1 inhibitors to increase antitumor efficacy.

Auto-immunity and inflammation platform

- **FR104** (anti-CD28 monoclonal antibody): Licensing partnership agreement with Veloxis in the organ transplantation market; ongoing Phase 1/2 in renal transplant (sponsored the Nantes University Hospital); Phase 2-ready asset in a niche indication in autoimmune diseases.
- **OSE-127/S95011** (humanized monoclonal antibody targeting IL-7 receptor): developed in partnership with Servier; positive Phase 1 results; in Phase 2 in ulcerative colitis (OSE sponsor) and an independent Phase 2a planned in Sjögren's syndrome (Servier sponsor).
- **OSE-230** (ChemR23 agonist mAb): first-in-class therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

For more information:

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Forward-looking statements

This press release contains express or implied information and statements that might be deemed forward-looking information and statements in respect of OSE Immunotherapeutics. They do not constitute historical facts. These information and statements include financial projections that are based upon certain assumptions and assessments made by OSE Immunotherapeutics' management in light of its experience and its perception of historical trends, current economic and industry conditions, expected future developments and other factors they believe to be appropriate.

These forward-looking statements include statements typically using conditional and containing verbs such as "expect", "anticipate", "believe", "target", "plan", or "estimate", their declensions and conjugations and words of similar import.



Although the OSE Immunotherapeutics management believes that the forward-looking statements and information are reasonable, the OSE Immunotherapeutics' shareholders and other investors are cautioned that the completion of such expectations is by nature subject to various risks, known or not, and uncertainties which are difficult to predict and generally beyond the control of OSE Immunotherapeutics. These risks could cause actual results and developments to differ materially from those expressed in or implied or projected by the forward-looking statements. These risks include those discussed or identified in the public filings made by OSE Immunotherapeutics with the AMF. Such forward-looking statements are not guarantees of future performance. This press release includes only summary information and should be read with the OSE Immunotherapeutics Universal Registration Document filed with the AMF on 15 April 2021, including the annual financial report for the fiscal year 2020, available on the OSE Immunotherapeutics' website. Other than as required by applicable law, OSE Immunotherapeutics issues this press release at the date hereof and does not undertake any obligation to update or revise the forward-looking information or statements.