# OSE Immunotherapeutics Provides COVID-19 Vaccine Update on CoVepiT, its Multi-Target and Long-Lasting Vaccine Candidate

- **Primary Objective Achieved in Human *Ex Vivo* Study**
- **New Coronavirus Mutated Variants Strengthen the Multi-Epitope T Lymphocytes Vaccine Versus 11 Viral Proteins Approach**
- **Clinical Trial Expected to Start in Q1 2021**
- **Update Provided in an Oral Presentation at the Annual World Immunotherapy Congress (2-6 November 2020)**

**Nantes, France, November 5, 2020, 6:00PM CET – OSE Immunotherapeutics** (ISIN: FR0012127173; Mnemo: OSE) announces successful completion of its human *ex vivo* study with CoVepiT, a prophylactic vaccine based on optimized epitopes selected to induce a lasting sentinel T lymphocyte immune response against SARS-CoV-2, the virus that causes COVID-19. In parallel, OSE Immunotherapeutics gave an overview on the development of this multi-target vaccine at the World Immunotherapy Congress, or Festival of Biologics, held virtually November 2-6, 2020. This is the first presentation on a second-generation memory T cell COVID-19 vaccine at a scientific congress.

The human *ex vivo* clinical study, named CoVepiT 1, was conducted in 120 convalescent COVID-19 subjects versus unexposed subjects. It aimed at assessing the memory T cell immune response at a distance from a resolving infection with SARS-CoV-2 adults. The main objective of the study was achieved: the identification of T memory immuno-dominant epitopes after infection with COVID-19 and incorporation in the vaccine composition.

Scientists warn of new SARS-CoV-2 variants spreading rapidly across Europe and bearing mutation in some key targets of the virus, in particular the Spike protein and Nucleoprotein. Based on new analyses of up to 167 000 different virus sequences taken globally, the OSE Immunotherapeutics bioinformatic team confirmed that mutations did not emerge in the highly stable viral genome region of the 11 targets selected by OSE and that the CoVepiT vaccine continues to cover all initial and novel SARS-CoV-2 strains and variants.

These results from both preclinical and human *ex vivo* studies as well as the expected emergence of new SARS-CoV-2 variants build a strong basis for supporting the development of CoVepiT as a novel and differentiated COVID-19 vaccine designed against multiple coronavirus targets with vaccinal technology known to induce long-lasting memory T lymphocytes.

Nicolas Poirier, Chief Scientific Officer of OSE Immunotherapeutics, commented*: "The identification of T memory immuno-dominant epitopes, selected for their high potential for immunogenicity, is a major step to move into clinical testing early 2021. We warmly thank all the subjects included and the clinical teams led by Dr Didier Debieuvre, of the Hospital Center Emile Müller of Mulhouse, and Dr Valérie Heyer, of the Marine Firefighters of Marseille, for their participation in our clinical study and*

*commitment to the COVID-19 vaccine development program. We are also very pleased to be the first company to present a second-generation COVID-19 memory T cell vaccine with potential for protecting future endemic pan-coronaviruses at a scientific congress."*

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, concluded*: "Using expertise and knowledge gained from our Memopi® epitope vaccinal technology allowed us to quickly develop a COVID-19 vaccine based on peptides, as part of our T cell-based vaccine platform. This same technology, already in use with Tedopi® in advanced lung cancer, has shown efficacy and good tolerance in this indication and should help accelerate the development process of our COVID-19 vaccine focused on memory CD8 T cell technology."*

The CoVepiT program is based on a clinically validated technology now shown to induce tissue-resident memory T lymphocytes (Trm) sentinel response against multiple parts of SARS-CoV-2, suggesting it provides a long-term protective immunity. In addition, this vaccine is designed to anticipate ongoing recurrent virus mutation and evolution, that should reinforce its long-term protective potential.

The oral presentation given by Dr. Nicolas Poirier at the virtual 2020 Immunotherapy Congress, titled "*CoVepiT: Multiple CD8 T-cell epitopes second-generation SARS-CoV-2 vaccine, long-term lasting tissue-resident memory T cells,"* is available on: **https://tinyurl.com/yx94gush.**

## 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 monotherapy and in combination with checkpoint inhibitor Opdivo®.
- **CoVepiT**: a prophylactic vaccine against COVID-19, developed using SARS-CoV-2 optimized neo-epitopes. Positive preclinical and human ex vivo results in August 2020, clinical trial expected to start end of 2020/early 2021.

**Immuno-oncology platform**

- **BI 765063** (OSE-172, anti-SIRPα mAb): developed in partnership with Boehringer Ingelheim; myeloid checkpoint inhibitor in Phase 1 in advanced solid tumors.
- **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 efficacity.

**Auto-immunity and inflammation platform**

- **FR104** (anti-CD28 monoclonal antibody): positive Phase 1 results; Phase 2-ready asset in autoimmune diseases or in transplantation.
- **OSE-127** (humanized monoclonal antibody targeting IL-7 receptor): developed in partnership with Servier; positive Phase 1 results; two independent Phase 2 planned in ulcerative colitis (OSE sponsor) and in Sjögren's syndrome (Servier sponsor) to start in Q4 2020.
- **OSE-230** (ChemR23 agonist mAb): first-in-class therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.
  *Due to the COVID-19 crisis, accrual of new patients in the clinical trial TEDOPaM is temporarily suspended and initiation timelines for both Phase 2 trials of OSE-127 could be impacted during the coming months.*

For more information:
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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 2020, including the annual financial report for the fiscal year 2019, 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.