OSE Immunotherapeutics Receives Authorization for Phase 1 Clinical Trial of its Multi-Target Multi-Variant COVID-19 Vaccine

- **CoVepiT is a SARS-COV-2 vaccine activating T cell defenses through CD8 T-cell multi-epitope* responses.**
- **CoVepiT epitopes are selected from 11 viral protein targets and designed to cover all initial and new emerging SARS-CoV-2 variants.**
- **CoVepiT, as second-generation vaccine, potentially provides long-term cellular immunity with memory T cells.**

Nantes, France, April 1, 2021 6:00PM CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnemo: OSE) today announced that the Belgian Federal Agency for Medicines and Health Products (*Agence Fédérale des Médicaments et des Produits de Santé* - AFMPS) and the Belgian Ethics Committee approved the Phase 1 trial evaluating its COVID-19 vaccine, named CoVepiT, on 48 healthy volunteers. First subjects are expected to be enrolled shortly.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, comments: *"The last year has demonstrated that the COVID-19 is a fast-mutating virus and that vaccination with broader coverage will be needed in the coming months and years, in particular in vulnerable populations. CoVepiT is based on the identification of multiple immuno-dominant epitopes that generate a T memory lymphocyte response and combining them in the vaccine. These epitopes target 11 viral proteins including Spike protein. These epitopes are selected in the protein domains of the virus with a very low level of mutations, and as such, cover the initial and all novel SARS-CoV-2 variants identified to date, potentially providing people with broad, long-term protection against COVID-19, even if it continues to mutate. The objective of the clinical development for our next-generation vaccine CoVepiT is to evaluate its safety and benefit, particularly for people at risk, i.e., vulnerable populations."*

This Phase 1 clinical trial will evaluate the safety, reactogenicity and immunogenicity of CoVepiT in healthy adult volunteers.

Professor Isabel Leroux-Roels, at the Center for Vaccinology, Ghent University and Hospital, Ghent, Belgium, will serve as the trial's Principal Investigator.

** T Epitope: small fragment of protein (8 and 11 amino acids in length) recognized by the immune system.*

ABOUT CoVepiT

CoVepiT is a next-generation multi-target, multi-variant vaccine against SARS-CoV-2. 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 combination.
  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 Phase 1 clinical phase in Belgium.

Immuno-oncology platform

- **BI 765063** (OSE-172, anti-SIRPα mAb on SIRPα/CD47 pathway): 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; ongoing Phase 1/2 in renal transplant, 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 2 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 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.