OSE Immunotherapeutics Announces Voluntary Pause of Enrollment in the CoVepiT Phase 1 Study

Nantes, France, July 19, 2021, 6:00PM PM CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnémo: OSE) today announced a voluntary and temporary pause of enrollment and dosing in its ongoing Phase 1 clinical trial for CoVepiT, the company's investigational prophylactic COVID-19 vaccine candidate.

OSE Immunotherapeutics notified the Belgian Health Authorities that the Company is voluntarily pausing its Phase 1 clinical study of CoVepiT in healthy volunteers. This pause was decided after receiving a preliminary update by the trial's principal investigator at the Center for Vaccinology, Ghent University, regarding a limited number of Grade 1 and one Grade 2 adverse events, in particular, persistent nodules around injection points (subcutaneous, with no pain, no inflammation, no fever, no impact on everyday life and without any systemic symptoms). Out of an abundance of caution, and in agreement with the independent Safety Monitoring Committee (SMC), the Company has decided to voluntarily pause dosing in its ongoing clinical study and assess the evolution of these nodules before determining the best way forward for this product and its target population. The Company will carefully review all available data to determine the future clinical development strategy of CoVepiT.

"As always, patient safety and wellbeing is our utmost priority, and we are working to resolve this unfortunate trial delay," stated Alexis Peyroles, CEO of OSE Immunotherapeutics. *"We will maintain an open dialogue with the SMC and with the trial's principal investigator at the University of Ghent on the modalities to resume the clinical development of CoVepiT. In an ever-changing COVID-19 vaccine environment, where multiple lines of defences could be useful, in particular, for populations at higher risk, we believe it is valuable to have a candidate targeting 11 viral proteins and designed to cover all initial and new emerging SARS-CoV-2 variants."*

About CoVepiT

CoVepiT is a next-generation multi-target, multi-variant vaccine against SARS-CoV-2 designed to generate robust CD8 T cell responses and supported by Bpifrance[1,2] and in clinical Phase 1 (EudraCT 2021-000572-11 and clinicaltrials.gov identifier: NCT04885361). The study seeks to assess CD8+ T Cell responses to spike and additional non-spike antigens from SARS-CoV-2 with aim of augmenting clinical protection against spike variants of concern. 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 nonstructural 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.

[1] https://ose-immuno.com/wp-content/uploads/2021/05/EN_210518_Bpifrance.pdf

[2] https://ose-immuno.com/wp-content/uploads/2020/12/EN_201218__CoVepiT-Bpifrance_VF.pdf

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.
  In Phase 2 in non-small cell lung cancer in combination with nivolumab, sponsor Italian foundation FoRT.
- **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 Ezabenlimab (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 efficacity.

Auto-immunity and inflammation platform

- **FR104** (anti-CD28 monoclonal antibody): Licensing partnership agreement with Veloxis in the organ transplant market; ongoing Phase 1/2 in renal transplant (sponsored by 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: https://ose-immuno.com/en/
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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.