OSE Immunotherapeutics Provides Positive Long Term Memory Responses with CoVepiT, its T Lymphocyte Multi-Target Anti-COVID Vaccine

- **Positive long term immunological results at 6 months in healthy volunteers with strong T cell memory responses against virus proteins.**
- **CoVepiT, based on 13 peptides, elicits durable T-cell immunity against a wide range of structural and non-structural viral proteins.**
- **The vaccine remains independent of mutations identified in current and emerging variants*.**

Nantes, France – March 16, 6:00PM CET - OSE Immunotherapeutics (ISIN: FR0012127173; Mnemo: OSE) today announces positive analysis of the long-term immune T cell responses of CoVepiT, its prophylactic vaccine candidate against COVID-19, with positive immunological results obtained at 6 months on T cell memory response in the vaccinated subjects. In parallel, the resolution of local indurations related to T cell mechanism of action [(1)] and the good safety profile were confirmed.

This durability and longevity of the T cell memory response at 6 months come in addition to the initial immune T cell results achieved at Week 6 as primary endpoint for all subjects of the clinical trial. This long term positive immune response is of strong interest [(2)] as more multispecific memory T cells are expected to be efficient for immunocompromised patients in case of any new emerging coronavirus or variants of concern.

Dominique Costantini CEO of OSE Immunotherapeutics, comments: *"It was important for OSE Immunotherapeutics to validate the concept and paradigm that long-term immunity against coronavirus could be achieved in human with its T-cell vaccine platform inducing durable memory T lymphocytes, with additional properties as T cells resident in the lung already described in preclinical studies. For immunocompromised patients, it is established that they are more exposed to COVID-19 hospitalizations. New treatments like monoclonal antibodies or anti-viral treatments are available for immunocompromised patients. Additional booster shots of registered vaccines are also recommended for this fragile population with a poor antibody response. Given the new therapeutics and multiple boosters recommended in these patients, additional clinical development of CoVepiT is difficult under the current circumstances. The strategy for OSE is now to leverage these long-term T cell response positive results and to select the most relevant peptides allowing an easier industrial scale-up to be ready for any new pandemic crisis with a novel variant of concern. We thank Bpifrance who supports this project, including its industrial dimension."*

**These epitopes, fragments of viral proteins, are antigenic determinants recognized by T cell receptors during an adaptive T immune response. They are not currently impacted by the mutations described for the various current variants (in particular Delta, Omicron) and emerging variants due to the epitopes selected in the conserved regions of the virus without recurrent mutations.*

(1) Heitmann, J. S. et al. Nature 2022
(2) Swaddling et al. Nature 2022

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, Membrane, Nucleocapsid 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. In clinical testing, a long-term memory response was confirmed at 6 months.
Project supported by Nantes Métropole and Bpifrance ('Capacity Building' and 'PSCP-COVID').

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. Its balanced first-in-class clinical and preclinical portfolio has a diversified risk profile:

Immuno-Oncology first-in-class products

- **Tedopi®** (innovative combination of neoepitopes): the company's most advanced product; positive results for Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in secondary resistance after checkpoint inhibitor failure.
  Other ongoing combination trials sponsored by cooperative clinical research groups in oncology:
  Phase 2 in pancreatic cancer (TEDOPaM), sponsor GERCOR.
  Phase 2 in ovary cancer, in combination with pembrolizumab (TEDOVA), sponsor ARCAGY-GINECO.
  Phase 2 in non-small cell lung cancer in combination with nivolumab, sponsor Italian foundation FoRT.
- **BI 765063** (OSE-172, anti-SIRPα mAb on CD47/SIRPα pathway): developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 dose escalation results of BI 765063 in monotherapy and in combination with ezabenlimab (PD-1 antagonist); ongoing expansion Phase 1.
- **OSE-279**, anti-PD1 – advanced preclinical stage.
- **BiCKI®**: bispecific fusion protein platform built on the key backbone component of anti-PD1 combined with a new immunotherapy target (for example: BiCKI®-IL7, preclinical stage) to increase anti-tumor efficacy.

Immunity & Inflammation first-in-class products

- **OSE-127/S95011** (humanized monoclonal antibody antagonist of IL-7 receptor): developed in partnership with Servier; positive Phase 1 results; ongoing Phase 2 in ulcerative colitis (sponsor OSE) and ongoing Phase 2a in Sjögren's syndrome (sponsor Servier).
- **FR104** (anti-CD28 monoclonal antibody): licensing partnership agreement with Veloxis Pharmaceuticals, Inc. in transplantation; ongoing Phase 1/2 in renal transplant (sponsored by the Nantes University Hospital); US IND obtained by Veloxis Pharmaceuticals, Inc. for a clinical trial; Phase 2 planned in an autoimmune disease indication.
- **OSE-230** (ChemR23 agonist mAb): preclinical stage therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

CoVepiT: a prophylactic second-generation vaccine activating cytotoxic T lymphocytes against COVID-19, developed using optimized epitopes from SARS-CoV2 viral proteins, epitopes non impacted by multi-variants. Shows good tolerance and very good level of T cell immune response. In clinical testing, a long-term memory response was confirmed at 6 months.

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.