OSE Immunotherapeutics is Pleased to Announce the Continuation of its Phase 2 Trial Testing Anti-IL-7 Receptor Antagonist OSE-127/S95011 in Ulcerative Colitis after the Interim Futility Analysis

Nantes, France – December 13, 2021, 6:00 p.m. CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) announces today that the trial's Independent Data Monitoring Committee (IDMC) completed the planned safety and efficacy assessment for futility of the ongoing Phase 2 clinical trial in Ulcerative Colitis patients and recommended continuation of the study.

The randomized, double-blind Phase 2 clinical trial aims at assessing the efficacy and the safety of OSE-127/S95011 versus placebo in patients with moderate to severe active ulcerative colitis who have previously failed or lost response or are intolerant to previous treatment(s).

The futility analysis has been conducted on the prespecified first 50 patients (i.e., 33% of the total patient enrollment in the study) having completed the Induction Phase. The primary endpoint for futility analysis was the efficacy assessment of OSE-127/S95011 versus placebo on the reduction of the modified Mayo Score*. Moreover OSE-127/S95011 has shown a good safety and tolerability profile in the whole patient population as already demonstrated in healthy volunteers in the Phase 1 study.

Based on the recommendation of the trial's IDMC, OSE Immunotherapeutics will proceed with the study.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, comments: *"We are pleased with the IDMC's recommendation to continue the Phase 2 trial. This is an important step toward understanding the safety and efficacy of IL-7R full-antagonist OSE-127 and establishing a potential new treatment for ulcerative colitis, a disabling chronic inflammatory bowel disease which, despite medical treatments acting on the clinical symptoms, is characterized by a heavy burden on the patients' life and a large patient population is still in need of new therapeutic options."*

OSE-127/S95011 is being developed in partnership with Servier as part of a collaboration agreement with license option upon completion of two Phase 2 clinical studies. Two independent Phase 2 studies are currently underway: in ulcerative colitis (sponsor OSE Immunotherapeutics) and in the Sjögren's syndrome (sponsor Servier). The product had already demonstrated Phase 1 positive results with a good safety and tolerability profile showing no signs of lymphopenia, cytokine release syndrome or T-cell compartment alterations.

* *The modified Mayo Score is a Disease Activity Index for Ulcerative Colitis*

ABOUT OSE-127/S95011

OSE-127/S95011 is a monoclonal immunomodulatory antibody targeting the CD127 receptor, the alpha chain of the interleukin-7 receptor (IL-7R) that induces a powerful antagonist effect on effector T lymphocytes.

Interleukin-7 is a cytokine which specifically regulates the tissue migration of human effector T lymphocytes, especially in the gut. The blockage of IL-7R prevents the migration of pathogenic T lymphocytes while preserving regulator T lymphocytes which have a positive impact in autoimmune diseases.

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 Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients after secondary resistance to checkpoint inhibitors.
  In Phase 2 in pancreatic cancer (TEDOPaM), sponsor GERCOR.
  In Phase 2 in ovary cancer, in combination with pembrolizumab (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. Clinical data (Nov. 2021) validating the multi-target vaccine show good tolerance and promising efficacy signals. Results from 6-month memory T cell responses expected Q1 2022.
- **Immuno-oncology platform**
- **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 or in combination with ezabenlimab (PD-1 antagonist); Expansion Phase 1 open for screening.
- **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 an autoimmune disease indication.
- **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 ongoing 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.