OSE Immunotherapeutics Announces Positive Results from Phase 1 Clinical Study of Anti-IL-7 Receptor Antagonist OSE-127

- **Planned Phase 2 Studies in Ulcerative Colitis and Sjögren's Syndrome to Start in 2020**

Nantes, France, December 2, 2019 – 6:00 p.m. CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnémo: OSE) today announced completion and positive results from the Phase 1 study of OSE-127, a humanized monoclonal antibody with a differentiated mechanism of action as a full-antagonist of the CD127 receptor, the alpha chain of the interleukin-7 receptor (IL-7R). OSE-127 has been shown in previous studies to induce a powerful antagonistic effect on effector T lymphocytes responsible for causing autoimmune diseases.

The Phase 1 study results show a good safety and tolerability profile for OSE-127. All pharmacokinetic and pharmacodynamic parameters are consistent and demonstrate a dose-proportionality across the several dose-levels up to 10 mg/kg. These findings will help determine the dosing and administration schedule for the two planned Phase 2 trials in ulcerative colitis and Sjögren's syndrome. Both trial initiations are expected in 2020.

"These encouraging Phase 1 findings, together with the novel and differentiated mechanism of action of OSE-127, the only full-antagonist of IL-7R, provide a firm foundation for further clinical development. These data support the potential of this compound to be a relevant therapy in ulcerative colitis, a chronic inflammatory bowel disease, representing 12.2 per 100,000 people by year and Sjögren's syndrome, representing 7 per 100,000 people by year**. We look forward to evaluating the product's efficacy in both indications through two independent Phase 2 studies expected to be initiated in 2020,"* said Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics.

This study was a first-in-human dose-escalation, randomized, double-blind, placebo-controlled Phase 1 trial, aimed to evaluate the safety and tolerability of single- and multiple-ascending intravenous and subcutaneous doses of OSE-127 in 63 healthy volunteers. Secondary endpoints included measures of pharmacokinetics, pharmacodynamics and immunogenicity to help assess and understand how the drug is absorbed and metabolized.

OSE-127 is being developed in partnership with Servier [1] under an option agreement up to the completion of a Phase 2 clinical trial planned in autoimmune bowel diseases. In parallel, Servier plans to develop OSE-127 in Sjögren's syndrome.

[1] Servier is an independent international pharmaceutical company, governed by a non-profit foundation, with headquarters based in France.

* *Loftus EV, Jr., Shivashankar R, Tremaine WJ, Harmsen WS, Zinsmeiseter AR. Updated Incidence and Prevalence of Crohn's Disease and Ulcerative Colitis in Olmsted County, Minnesota (1970-2011). ACG 2014 Annual Scientific Meeting. October 2014*

** *Qin B. et al; Epidemiology of primary Sjögren's syndrome:a systematic review and meta-analysis Ann Rheum Dis 2014*

ABOUT OSE-127

OSE-127 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 a clinical-stage biotechnology company focused on developing and partnering therapies to control the immune system for immuno-oncology and autoimmune diseases. The company has a diversified first-in-class clinical portfolio consisting of several scientific and technological platforms including neoepitopes and agonist or antagonist monoclonal antibodies, all ideally positioned to fight cancer and autoimmune diseases. The most advanced therapeutic-candidate, Tedopi®, is a proprietary combination of 10 neo-epitopes aimed at stimulating T-lymphocytes and is currently in Phase 3 development in non-small cell lung cancer (NSCLC) in patients in failure after checkpoint inhibitor treatment (anti PD-1 and anti PD-L1) and in Phase 2 testing in pancreatic cancer in combination with checkpoint inhibitor Opdivo®. BI 765063 (OSE-172) (anti-SIRPa monoclonal antibody) is under a license and collaboration agreement with Boehringer Ingelheim; this checkpoint inhibitor is currently under Phase 1 clinical trial in advanced solid tumors. BiCKI® is a bispecific fusion protein platform built on the key backbone component anti-PD-1 (OSE-279) and targeting innovative targets. FR104 (an anti-CD28 mAb) has successfully completed Phase 1 testing and has potential to treat autoimmune diseases. OSE-127 (monoclonal antibody targeting the CD127 receptor, the alpha chain of the interleukin-7 receptor) is partnered with Servier under an option agreement up to the completion of a Phase 2 clinical trial planned in autoimmune bowel diseases; in parallel, Servier plans a development in the Sjögren syndrome. The Phase 1 clinical phase of OSE-127 is completed and has shown positive results; planned Phase 2 studies in ulcerative colitis and Sjögren's syndrome to start in 2020.

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 Reference Document filed with the AMF on 26 April 2019, including the annual financial report for the fiscal year 2018, 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.