OSE Immunotherapeutics Announces Enrolment of First Patient with Ulcerative Colitis in Phase 2 Trial Testing Anti-IL-7 Receptor Antagonist OSE-127/S95011

Nantes, France, December 21, 2020, 6:00PM CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnemo: OSE) today announced enrolment of the first patient in its Phase 2 clinical trial evaluating the benefits of anti-IL-7 receptor antagonist OSE-127/S95011 for moderate to severe active ulcerative colitis patients.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, comments: *"The first patient enrolled in the Phase 2 trial marks a major step in the clinical development of OSE-127/S95011. This study is based on a firm foundation with encouraging Phase 1 results and novel and differentiated mechanism of action of OSE-127/S95011, the only full-antagonist of IL-7R. We look forward to confirming the product's efficacy in the large population of patients suffering from ulcerative colitis, a debilitating and chronic inflammatory bowel disease representing 12.2 per 100,000 people by year. *"*

The first patient has been enrolled in the randomized, double-blind Phase 2 clinical trial aiming 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 study population (patients with moderate to severe ulcerative colitis who have failed or are intolerant to immunosuppressors, anti-tumor necrosis factor (TNF)-α, anti-integrin, ustekinumab and/or corticosteroids) was selected since this population consists of patients who are in need of alternative new therapies to avoid for as long time as possible the complications linked to the disease and in whom the safety profile of OSE-127/S95011 can be reliably assessed.

Patricia Belissa-Mathiot, Director of clinical development and R&D Chief Medical Officer at Servier, concludes: "*We are very pleased with the progress achieved with OSE-127/S95011, now at the Phase 2 stage in ulcerative colitis under OSE's sponsorship. On our side, Servier has received clinical trial authorization from the French, Spanish, U.S., U.K, Hungarian, German and Australian health agencies to initiate in parallel a Phase 2 study with OSE-127/S95011 in patients with Sjögren's syndrome. Our R&D team is actively preparing this step, which is anticipated to start shortly.*"

OSE-127/S95011 is being developed in partnership with Servier under an option agreement up to the completion of both Phase 2 clinical studies and exercise of the option upon successful completion of at least one of these Phase 2 trials. The Phase 2 in ulcerative colitis is being conducted under OSE Immunotherapeutics' sponsorship while in parallel, another Phase 2 in Sjögren's syndrome is planned to start shortly under Servier's[1] sponsorship.

[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*

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 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 monotherapy and in combination with checkpoint inhibitor Opdivo®.
- **CoVepiT**: a prophylactic vaccine against COVID-19, developed using SARS-CoV-2 optimized neo-epitopes. Positive preclinical and human ex vivo results in August 2020, clinical trial expected to start in Q1 2021.

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; two independent Phase 2 planned in ulcerative colitis (OSE sponsor) and 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.

Due to the COVID-19 crisis, accrual of new patients in the clinical trial TEDOPaM is temporarily suspended and initiation timelines for both Phase 2 trials of OSE-127/S95011 could be impacted during the coming months.

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.