OSE Immunotherapeutics Announces Granting of First European Patent Protecting Anti-IL-7 Receptor Antagonist OSE-127/S95011

Covers therapeutic applications of OSE-127/S95011 through 2037

Nantes, France, February 17, 2021 6:00PM CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnemo: OSE) today announced that it has strengthened intellectual property rights for its anti-interleukin-7 receptor (IL-7R) antagonist OSE-127/S95011 through the granting of a first patent by the European Patent Office (EPO). The patent covers the product and its therapeutic applications in autoimmune and inflammatory diseases through 2037.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, comments*: "This new European patent confirms OSE-127/S95011's novel and differentiated mechanism of action as an IL-7R full-antagonist and further strengthens our global intellectual property protection for the product. This patent grant is especially timely following the enrolment at the end of 2020 of the first patient in the Phase 2 study evaluating OSE-127/S95011 in patients with ulcerative colitis. This disabling chronic inflammatory bowel disease affects 3.3 million people in the U.S., Europe and Japan[1] and despite medical treatments acting on the clinical symptoms, the disease is characterized by a heavy burden on the patients' life. With only 25-30% of patients in remission[2] and 15% who fail to respond to all therapies and need surgery as last option[3], a large patient population is in need of new therapeutic options."*

OSE-127/S95011 is being developed in partnership with Servier[4] 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 trial 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 sponsorship. OSE is eligible to receive a €5 million milestone payment from Servier upon enrollment of the first patient in the Sjögren's syndrome Phase 2.

[1] Drugs Context. 2019; 8: 212572 – doi: 10.7573/dic.212572

[2] EvaluatePharma

[3] Scientific Reports volume 10, Article number: 12546 (2020)

[4] Servier is a global pharmaceutical Group governed by a non-profit Foundation

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 ULCERATIVE COLITIS (UC)

UC is a chronic inflammatory bowel disease causing mucosal inflammation of the rectum and the colon which is characterized by a relapsing and a remitting course. Ulcerative colitis is a lifelong disease observed mainly in Westernized countries and diagnosed mainly in young adults. The precise etiology is unknown. Ulcerative colitis arises from an interaction between genetic background and environmental factors, and medical therapy to cure the disease is not yet available.

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 combination.
  Due to the COVID-19 crisis, accrual of new patients in TEDOPaM should restart in 2021.
- **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, 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; in Phase 2 in ulcerative colitis (OSE sponsor) and an independent Phase 2 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:
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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.