OSE Immunotherapeutics Receives €1.3 Million Milestone Payment from Bpifrance for OSE-127/S95011

- **Milestone as part of the collaborative program named EFFIMab marks continued clinical progress**
- **Interleukin-7 receptor antagonist (IL-7R) OSE-127/S95011 is currently in a Phase 2 clinical trial in ulcerative colitis, sponsored by OSE**

Nantes, France, January 25, 2021 7:30AM CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnemo: OSE) today announced it received a milestone payment of €1.3 million from Bpifrance related to the Company's collaborative program, EFFIMab, focused on evaluating interleukin-7 receptor antagonist OSE-127/S95011, partnered with Servier[1].

This new milestone payment of €1.3 million was triggered by achieving several key steps in the development of OSE-127/S95011 including reinforcement of preclinical and translational data in ulcerative colitis (UC), completion of the Phase 1 clinical trial, obtaining the Phase 2 regulatory authorization as well as specific manufacturing steps.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, commented: *"This new milestone payment reflects the significant progress made with OSE-127/S95011, which is now in Phase 2 under OSE's sponsorship in ulcerative colitis, a disabling chronic inflammatory bowel disease affecting 3.3 million people in the U.S., Europe and Japan. With 70-75% of ulcerative colitis patients*[2] *either not responding or losing response to current treatments, ulcerative colitis represents a substantial medical need. There is a large potential market in ulcerative colitis for OSE-127/S95011 as it is the only full-antagonist of IL-7R, with a novel and differentiated mechanism of action. We look forward to confirming the product's efficacy in both ulcerative colitis and Sjögren's syndrome, another debilitating autoimmune disease, with a trial launching soon and conducted by our partner Servier."*

OSE-127/S95011 Phase 2 in ulcerative colitis

The Phase 2 clinical trial with OSE-127/S95011 in UC started in December 2020 under OSE Immunotherapeutics' sponsorship. This study aims to assess the efficacy and safety of OSE-127/S95011 versus placebo in patients with moderate to severe active UC who have previously failed or lost response or are intolerant to previous treatment(s). In parallel to the trial being conducted in UC, an independent Phase 2 clinical study is planned to start shortly in Sjögren's syndrome under Servier's sponsorship. Under the terms of the license option agreement, OSE is eligible to receive a €5 million milestone payment from Servier upon enrollment of the first patient in this Phase 2. OSE-127/S95011 is being developed in partnership with Servier under an option agreement up to the completion of both Phase 2 clinical studies.

Ulcerative colitis background

UC is a debilitating inflammatory bowel disease that affects 3.3 million patients in the U.S., Europe and Japan. Despite multiple approved therapeutic options, remission rates are 25-30%[2], leaving most patients in therapeutic failure and in need of alternative new therapies. The current standard of care

is largely comprised of two main therapeutic classes (5-ASAs and TNFα) with a total market size of $6.3 billion[3].

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

B

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

[3] EvaluatePharma

ABOUT THE EFFIMab PROGRAM

This collaborative program is headed by OSE Immunotherapeutics as the leader of the consortium to develop OSE-127/S95011, a monoclonal immunomodulatory antibody targeting the CD127 receptor, the alpha chain of the interleukin-7 receptor (IL-7R). The funding from Bpifrance is planned to cover the product's development until the Phase 2 clinical stage. The total amount of the OSE-127/S95011 program, being developed by OSE Immunotherapeutics in collaboration with INSERM and Nantes University Hospital, is €20 million with €9.1 million allotted by Bpifrance.

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.
- **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; 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.

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:
Click and follow us on Twitter and LinkedIn

Contacts

OSE Immunotherapeutics
Sylvie Détry
Sylvie.detry@ose-immuno.com
+33 153 198 757

French Media: FP2COM
Florence Portejoie
fportejoie@fp2com.fr
+33 607 768 283

Bpifrance
Sophie Santandrea
Sophie.santandrea@bpifrance.fr
+33 1 45 65 51 62

U.S. Media: LifeSci Communications
Darren Opland, Ph.D.
darren@lifescicomms.com
+1 646 627 8387

U.S. and European Investors
Chris Maggos
chris@lifesciadvisors.com
+41 79 367 6254

ABOUT BPIFRANCE

Bpifrance is the French national investment bank: it finances businesses – at every stage of their development – through loans, guarantees, equity investments and export insurances. Bpifrance also provides extra-financial services (training, consultancy.). to help entrepreneurs meet their challenges (innovation, export…).
For more information, please visit: www.bpifrance.fr and presse.bpifrance.fr - Follow us on Twitter: @Bpifrance - @BpifrancePresse

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.