OSE Immunotherapeutics Receives European Patent Notice of Allowance for First-in-Class CD28-Antagonist Immunotherapy FR104

The patent covers novel dosing regimen of FR104 in Europe through 2036 for therapeutic applications in autoimmune diseases, inflammatory diseases, transplantation and graft-versus-host disease

Nantes, France, October 12, 2020, 6:00PM CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnemo: OSE) announced the European Patent Office's (EPO) issuance of a notice of allowance for its Phase-2 ready product FR104, a first-in-class selective CD28-antagonist. Specifically, this European patent will provide additional protection covering novel dosing regimen of FR104 for the prevention and treatment of T-lymphocyte-mediated autoimmune diseases, inflammatory diseases, transplantation and graft-versus-host disease (GVHD) until 2036.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, commented, *"This new notice of allowance from the EPO broadens the global patent protection of FR104 and similar patent applications are pending in other countries. As a Phase 2-ready product with Phase 1 signals of clinical efficacy and strong safety profile, FR104 is a valuable asset with great potential for further development to meet patients' needs in a number of autoimmune conditions, in transplantation and as prevention of graft-versus-host disease following hematopoietic stem cell transplantation."*

CD28 blockade by FR104 tackles memory pathogenic T lymphocytes while favoring Treg suppressive function. This novel mechanism of controlling immune synapses potentially offers new therapeutic options in multiple inflammatory and autoimmune diseases, transplantation and GVHD where T cells are involved. The results from FR104's Phase 1 clinical study have shown initial signals of efficacy, a good safety profile and the recommended dose for a Phase 2, further supporting the continued clinical development of this asset.

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 several scientific and technological platforms including neoepitopes and agonist or antagonist monoclonal antibodies, all ideally positioned to fight cancer and autoimmune diseases. Its first-in-class clinical and preclinical portfolio has a diversified risk profile:

- **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®.
- **BI 765063** (OSE-172, anti-SIRPα monoclonal antibody): developed in **partnership with Boehringer Ingelheim**; myeloid checkpoint inhibitor in **Phase 1 in advanced solid tumors**.
- **FR104** (anti-CD28 monoclonal antibody): **positive Phase 1 results**; **Phase 2-ready asset in autoimmune diseases or in transplantation**.
- **OSE-127** (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) to start in Q4 2020.

- **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**.
- **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 end of 2020/early 2021**.
  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 could be impacted during the coming months.

For more information:
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Forward-looking statements

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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.