

## **OSE Immunotherapeutics Announces Clinical Trial Authorization for a Phase 1 by two Health Agencies (France and Belgium) to Evaluate the Selective SIRP $\alpha$ antagonist BI 765063\* under Development in Collaboration with Boehringer Ingelheim in Patients with Advanced Solid Tumors**

- **First-in-class SIRP $\alpha$  checkpoint inhibitor**
- **Discovered and validated on OSE's immune target discovery platform**

**Nantes, France, March 5, 2019, 18:00 p.m. CET – OSE Immunotherapeutics** (ISIN: FR0012127173; Mnémo: OSE), today announced authorization by the French National Agency for Medicines and Health Products Safety (ANSM) and by the Belgian Federal Agency for Medicines and Health Products (FAMHP) to initiate a Phase 1 clinical trial for checkpoint inhibitor BI 765063\*, a selective SIRP $\alpha$  antagonist monoclonal antibody, exclusively licensed to and being developed in collaboration with Boehringer Ingelheim.

The clinical Phase 1 is a dose finding study of monoclonal antibody SIRP $\alpha$  antagonist BI 765063\*, a myeloid checkpoint inhibitor administered as a single agent and in combination with Boehringer Ingelheim's monoclonal antibody PD-1 antagonist BI 754091, a lymphocyte T checkpoint inhibitor. The study is conducted by OSE as part of a collaboration and license agreement with Boehringer Ingelheim under which Boehringer Ingelheim obtained exclusive rights to BI 765063. This trial aims to characterize safety, pharmacokinetics, pharmacodynamics and preliminary efficacy in patients with advanced solid tumours.

Under the terms of the collaboration and license agreement, the clinical trial authorization and the upcoming first dosing of a patient will trigger milestone payments of a total of €15 million to OSE Immunotherapeutics from Boehringer Ingelheim.

Alexis Peyroles, CEO of OSE Immunotherapeutics, said: *“Clinical trial authorization for this Phase 1 trial of BI 765063 (OSE-172) as a monotherapy and in combination marks a major step of investigation into the potential of the anti-SIRP $\alpha$  checkpoint inhibitor with PD-1 blockade. We are very pleased by the rapid progression of this innovative program. These two significant green lights allow us to finalize the clinical entry in premier oncology Phase 1 European cancer centers.”*

\* BI 765063, previously OSE-172

### **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<sup>®</sup>, 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) after checkpoint inhibitor failure (anti PD-1 and anti PD-L1) and in Phase 2 testing in pancreatic cancer in combination with checkpoint inhibitor Opdivo<sup>®</sup>. FR104 (an anti-CD28 mAb) has successfully completed Phase 1 testing and has potential to treat autoimmune diseases. In April 2018, Boehringer Ingelheim and OSE signed a global license and collaboration agreement to develop preclinical checkpoint inhibitor BI 765063 (OSE-172, an anti-SIRP $\alpha$  monoclonal antibody) in multiple cancer indications. 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. OSE-127 is currently under Phase 1 clinical trial.

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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 2018, including the annual financial report for the fiscal year 2017, 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.