

## **OSE Immunotherapeutics Receives a Milestone Payment of €5.4 Million From Bpifrance for SIRP $\alpha$ -Antagonist Monoclonal Antibody BI 765063**

- **First-in-Class Myeloid Checkpoint Inhibitor BI 765063\* is Currently in Phase 1 Clinical Development in Advanced Solid Tumors in Partnership with Boehringer Ingelheim**
- **Milestone Endorses OSE's Business Model and Marks Continued Progress as Planned**

**Nantes, September 18, 2019 – 6:00PM CET– OSE Immunotherapeutics SA** (ISIN: FR0012127173; Mnémo: OSE) announces today that the Company received a €5.4 million payment from Bpifrance triggered by the successful completion of development milestones related to its collaborative program EFFI-CLIN. This program is focused on evaluating BI 765063\*, a SIRP $\alpha$ -antagonist and myeloid checkpoint inhibitor.

*“This milestone payment reflects the significant progress made with BI 765063, which is currently in clinical development in collaboration with Boehringer Ingelheim. We view today's announcement as an endorsement of the Company's partnership and collaboration business model based on innovative products candidates for partnerships and public-private collaborative projects generating significant non-dilutive financing. Since early 2019, in addition to this €5.4 million payment, the Company has received a €15 million in payment from BI upon clinical trial authorization and first patient dosed in the Phase 1. Our business model has allowed OSE to successfully advance its research and clinical development projects without the need for dilutive funding since 2015. With four clinical stage products and financial visibility until end of 2020, OSE is today ideally positioned to become one of the leaders of Immunotherapy in Europe,”* commented Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics.

This first milestone of €5.4 million, as part of the EFFI-CLIN “Invest in the Future Program” for BI 765063, was triggered by reaching several steps including initiation of studies characterizing the SIRP $\alpha$ /CD47 axis and determining preclinical efficacy, completion of regulatory preclinical toxicology studies, manufacturing of GMP compliant batches and development of a tool used to characterize the immune profile and biomarkers found in patients.

BI 765063, being developed in partnership with Boehringer Ingelheim, is in Phase 1 testing in advanced solid tumors and the first patient was enrolled and dosed in June, 2019. This first-in-human Phase 1 trial is a dose finding study of BI 765063 administered as a single agent and in combination with Boehringer Ingelheim's monoclonal antibody PD-1 antagonist BI 754091, a T-lymphocyte checkpoint inhibitor. The trial aims to characterize safety, pharmacokinetics, pharmacodynamics and preliminary efficacy of the immunotherapy in patients with advanced solid tumors.

\* BI 765063, previously OSE-172

### **ABOUT THE EFFI-CLIN PROGRAM**

OSE Immunotherapeutics is the leader of the EFFI-CLIN program consortium which also includes the European Center for Transplantation and Immunotherapy (CESTI), a public organization based in Nantes, and HISTALIM, a SME based in

Montpellier. This project has total funding of €9.2 million for OSE Immunotherapeutics to evaluate the safety and the clinical efficacy of new cancer immunotherapy candidate BI 765063 as a monotherapy and in combination in various indications where myeloid cells represent a poor prognosis factor. The project's scope includes the product manufacturing which is to be compliant with pharmaceutical standards, translational studies conducted from tumour tissues to measure the presence of immunological targets including SIRP $\alpha$ , a clinical program planned until Phase 2, as well as other exploratory research under the SIRP family.

## ABOUT Bpifrance

Bpifrance, a subsidiary of Caisse des Dépôts and the French State, is a trusted partner of entrepreneurs which provides companies with credit, collateral and equity financing support from start up through to stock exchange listing. Bpifrance also provides guidance services and enhanced support for innovation, external growth and export, in partnership with Business France. Bpifrance offers companies a continuum of financing for each key stage of their development and an offer adapted to specific regional features.

With 47 regional offices (90% of decisions are made regionally), Bpifrance offers entrepreneurs a tool for economic competitiveness. Bpifrance works in support of the public policies pursued nationally and regionally by the French government, to meet three objectives:

- support the growth of businesses;
- prepare for future competitiveness;
- contribute to the development of a favourable ecosystem for entrepreneurship.

With Bpifrance, companies have a strong and effective local contact to meet all their financial, innovation and investment needs.

For more information, please visit: [www.bpifrance.fr](http://www.bpifrance.fr)—<http://investissementsdavenir.bpifrance.fr>—Twitter: @bpifrance

## 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) in patients in failure after checkpoint inhibitor treatment (anti PD-1 and anti PD-L1) and in Phase 2 testing in pancreatic cancer in combination with checkpoint inhibitor Opdivo<sup>®</sup>. BI 765063 (OSE-172) (anti-SIRP $\alpha$  monoclonal antibody) is under a license and collaboration agreement with Boehringer Ingelheim; this checkpoint inhibitor is currently under Phase 1 clinical trial in advanced solid tumors. BiCKI<sup>®</sup> is a bispecific fusion protein platform built on the key backbone component anti-PD-1 (OSE-279) and targeting innovative targets. FR104 (an anti-CD28 mAb) has successfully completed Phase 1 testing and has potential to treat autoimmune diseases. 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 2019, including the annual financial report for the fiscal year 2018, 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.