Boehringer Ingelheim and OSE Immunotherapeutics Announce Dosing Of the First Patient in a Phase 1 Trial of SIRPα Antagonist Monoclonal Antibody, BI 765063, in Patients with Advanced Solid Tumors

- *First-in-class checkpoint inhibitor BI 765063 licensed to and being developed under a collaboration agreement between Boehringer Ingelheim and OSE Immunotherapeutics*
- *Clinical Trial Authorization and dosing of the first patient triggers a total of €15 million milestone payments from Boehringer Ingelheim to OSE Immunotherapeutics*

Ingelheim, Germany and Nantes, France – June 17, 2019, 6:00 p.m. CET - Boehringer Ingelheim and OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announce that the first patient has been dosed in the first-in-human Phase 1 clinical trial evaluating BI 765063, formerly OSE-172, a first-in-class monoclonal antibody antagonist of SIRPα, being studied in patients with advanced solid tumors. The Phase 1 study is a dose finding study of 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 T-lymphocyte checkpoint inhibitor.

"We are very pleased with the progress achieved on BI 765063's program and having the first patient dosed marks a significant milestone in the product's development. The advancement of a myeloid cell checkpoint blocking monoclonal antibody into the clinic exemplifies Boehringer Ingelheim's commitment to the next wave of innovation in cancer immunology therapies, with the goal of meaningfully improving outcomes for patients with difficult-to-treat cancers," said Jonathon Sedgwick, Ph.D., Senior Vice President and Global Head, Cancer Immunology & Immune Modulation Research at Boehringer Ingelheim.

"We are excited to begin first-in-human testing with this novel SIRPα-targeting compound, which we believe has first-in-class potential in the treatment of solid tumors," said Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics. "This marks one of many anticipated milestones in the collaboration agreement with our partner Boehringer Ingelheim, and we look forward to advancing rapidly this potentially transformative treatment through the clinic. Milestones such as this one for the novel compounds our R&D teams develop have provided OSE with a stable financial base to grow steadily our first-in-class immuno-oncology pipeline."

The study is conducted by OSE Immunotherapeutics as part of a collaboration and license agreement under which Boehringer Ingelheim obtained exclusive rights to BI 765063. Under the terms of the collaboration and license agreement, the clinical trial authorization obtained in March 2019 and dosing of the first patient in this Phase 1 trial triggers milestone payments of a total of €15 million to OSE Immunotherapeutics from Boehringer Ingelheim. This trial aims to characterize safety, pharmacokinetics, pharmacodynamics and preliminary efficacy of the immunotherapy in patients with advanced solid tumours.

ABOUT BI 765063 (formerly OSE-172)

BI 765063 is a monoclonal antibody antagonist of the key myeloid cell checkpoint inhibitor SIRPα. BI 765063 prevents the SIRPα ligand CD47, from binding to SIRPα thereby preventing cellular signalling that can reduce the anti-tumorigenic properties of myeloid cells such as macrophages and dendritic cells. In March 2019, OSE Immunotherapeutics received Clinical Trial Authorization for a Phase 1 study by two health agencies (France and Belgium) to evaluate BI 765063 in patients with advanced solid tumors. The study is conducted by OSE Immunotherapeutics as part of a collaboration and license agreement under which Boehringer Ingelheim obtained exclusive rights to BI 765063, originally signed in April 2018.

Boehringer Ingelheim

Improving the health of humans and animals is the goal of the research-driven pharmaceutical company Boehringer Ingelheim. The focus in doing so is on diseases for which no satisfactory treatment option exists to date. The company therefore concentrates on developing innovative therapies that can extend patients' lives. In animal health, Boehringer Ingelheim stands for advanced prevention.

Family-owned since it was established in 1885, Boehringer Ingelheim is one of the pharmaceutical industry's top 20 companies. Some 50,000 employees create value through innovation daily for the three business areas human pharmaceuticals, animal health and biopharmaceuticals. In 2018, Boehringer Ingelheim achieved net sales of around 17.5 billion euros. R&D expenditure of almost 3.2 billion euros, corresponded to 18.1 per cent of net sales.

As a family-owned company, Boehringer Ingelheim plans in generations and focuses on long-term success. The company therefore aims at organic growth from its own resources with simultaneous openness to partnerships and strategic alliances in research. In everything it does, Boehringer Ingelheim naturally adopts responsibility towards mankind and the environment.

More information about Boehringer Ingelheim can be found on www.boehringer-ingelheim.com or in our annual report: http://annualreport.boehringer-ingelheim.com.

About Boehringer Ingelheim in Oncology

Cancer takes. Takes away time. Takes away loved ones. At Boehringer Ingelheim Oncology, we are giving patients new hope, by taking cancer on. We are dedicated to collaborating with the oncology community on a shared journey to deliver leading science. We are advancing a unique pipeline of cancer cell directed agents, immune oncology therapies and intelligent combination approaches. Our goal is treatment breakthroughs that can transform the lives of patients and help win the fight against cancer.

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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®, 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®. FR104 (an anti-CD28 mAb) has successfully completed Phase 1 testing and has potential to treat autoimmune diseases. BI 765063 (OSE-172) (anti-SIRPa monoclonal antibody) is under a license and collaboration agreement with Boehringer Ingelheim; this checkpoint inhibitor is currently under a Phase 1 clinical trial inadvanced solid tumors. BiCKI® is a bispecific fusion protein platform built on the key backbone component anti-PD-1 (OSE-279) and targeting innovative targets. 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.