OSE Immunotherapeutics and Boehringer Ingelheim Present Positive Phase 1 Results with First-in-Class SIRPα inhibitor BI 765063 in Advanced Solid Tumors at ASCO 2021

- **BI 765063, a first-in-class SIRPα inhibitor on the SIRPα/CD47 "Don't eat me" pathway, is under collaborative development with Boehringer Ingelheim.**
- **Data indicate BI 765063 was well tolerated and showed monotherapy activity in heavily pre-treated solid tumor patients.**

Nantes, May 20, 2021, 7:30AM CET - OSE Immunotherapeutics (ISIN: FR0012127173; Mnemo: OSE) and its development partner **Boehringer Ingelheim** announced today acceptance of an upcoming poster presentation at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, being held June 4 – 8, 2021, covering promising initial data from Phase 1 dose escalation of selective SIRPα inhibitor BI 765063 in patients with advanced solid tumors (Abstract #2623).

The data to be presented at ASCO 2021 indicate that OSE Immunotherapeutics' first-in-class signal regulatory protein α (SIRPα) inhibitor BI 765063 was well-tolerated, showed sustained receptor occupancy (RO) saturation and monotherapy activity. Clinical benefit was observed in 45% of patients evaluable per RECIST* criteria. A durable partial response was observed in an advanced hepatocellular carcinoma (HCC) patient, and the on-treatment biopsy of the responder showed an increase in CD8 T-cell infiltration and activation. Furthermore, the on-treatment biopsy also showed an increase in PD-L1 expression on tumor cells. A BI 765063 dose escalation study in combination with Ezabenlimab (PD-1 antagonist) is ongoing and will help determine the recommended dose for further Phase 2 clinical development in patients with advanced solid tumors.

Alexis Peyroles, CEO of OSE Immunotherapeutics commented: "*OSE Immunotherapeutics is moving forward to deliver highly innovative, first-in-class and best-in-class compounds. The promising data presented at ASCO includes no serious dose limiting toxicities, as well as early evidence of efficacy, suggesting that selective myeloid cell targeting of SIRPα to modulate CD47-dependent inhibition of anti-tumor immunity including the 'Don't Eat Me' axis is a sound therapeutic strategy in solid tumors. These promising data presented at ASCO 2021 on BI 765063 confirm the quality of our science and we look forward to continuing to accelerate our clinical development and pipeline diversification over the coming years.*"

*RECIST: Response Evaluation Criteria in Solid Tumours

PRESENTATION DETAILS

Title: ***"Safety, pharmacokinetics, efficacy, and preliminary biomarker data of first-in class BI 765063, a selective SIRPα inhibitor: results of monotherapy dose escalation in phase 1 study in patients with advanced solid tumors"***

The abstract #2623 was posted on ASCO.org on May 19, 2021 at 5:00PM ET and 11:00PM CEST

From June 4th at 3:00PM CEST:
Virtual poster presentation on demand
Poster session: Developmental Therapeutics – Immunotherapy
Presenting Author: Stéphane Champiat, MD, PhD, Institut de Cancérologie, Gustave Roussy, Villejuif

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 Phase 2 in ovary cancer (TEDOVA, sponsor ARCAGY-GINECO)
  Due to the COVID-19 crisis, accrual of new patients in TEDOPaM should restart in 2021.
- **CoVepiT**: a prophylactic second-generation vaccine against COVID-19, developed using SARS-CoV-2 optimized epitopes against multi variants. Positive preclinical and human ex vivo results in August 2020. In clinical Phase 1.

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): Licensing partnership agreement with Veloxis in the organ transplantation market; ongoing Phase 1/2 in renal transplant (sponsored the Nantes University Hospital); 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 2a 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.

For more information:
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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 Universal Registration Document filed with the AMF on 15 April 2021, including the annual financial report for the fiscal year 2020, 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.