Boehringer Ingelheim and OSE Immunotherapeutics To Present Phase 1 Results with First-in-Class SIRPα Inhibitor BI 765063 in Advanced Solid Tumors at ESMO 2021

- **BI 765063, a first-in-class SIRPα inhibitor in the SIRPα/CD47 "Don't eat me" pathway, is being developed under collaborative agreement between OSE Immunotherapeutics and Boehringer Ingelheim.**

Nantes, France – September 13, 2021, 7:30 AM CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announced that promising data from dose escalation Phase 1 of selective SIRPα inhibitor BI 765063 in patients with advanced solid tumors (ePoster 983P) will be presented[(1)] at the 2021 European Society for Medical Oncology (ESMO) Virtual Conference to be held on September 16 – 21, 2021.

This Phase 1 clinical trial aims to evaluate the safety and efficacy of BI 765063 as monotherapy and in combination with ezabenlimab (BI 754091; anti-PD-1 mAb) in patients with advanced solid tumours.

The dose escalation part (Step 1) of the Phase 1 trial has enrolled SIRPα V1/V1 homozygous or V1/V2 heterozygous patients with advanced solid tumours who failed or were not eligible for standard therapies. Two dose levels of BI 765063 (18 and 24 mg/kg IV every 3 weeks) were evaluated in combination with BI 754091 (240 mg IV every 3 weeks).

As of April 2021, a total of 12 patients had received at least one or more doses of each therapy. The combination BI 765063 + BI 754091 has shown a good safety profile and demonstrated clinical activity in two patients, including a tumor shrinkage in a patient with colonic adenocarcinoma and a confirmed partial response in a patient with endometrial carcinoma. Both patients were Micro Satellite Stable (MSS) and PD-1 treatment naïve.

Micro Satellite Instable (MSI) biomarkers are recognized as effective for immunotherapy by checkpoint inhibitor alone. The majority of colorectal and endometrial cancers are MSS and achieve limited benefit from immune checkpoint inhibitor monotherapy [(2)]. Updated data of June 2021 on this dose escalation part of Phase 1 will be featured in an ePoster presentation at the upcoming 2021 ESMO meeting.

The Phase 1 clinical study of BI 765063 is being conducted by OSE Immunotherapeutics as part of a collaboration and license agreement under which Boehringer Ingelheim obtained exclusive rights to the product.

On-demand ePoster presentation – From September 16, 2021

(1) *983P - Phase I dose escalation study in patients (pts) with advanced solid tumours receiving first-in-class BI 765063, a selective signal-regulatory protein α (SIRPα) inhibitor, in combination with ezabenlimab (BI 754091), a programmed cell death protein 1 (PD-1) inhibitor*
Presentation Number: 983P
Speaker : Nuria Kotecki (Brussels, Belgium)

(2) *Puccini A., Battaglin F., Laia M.L. et al. Overcoming resistance to anti-PD1 and anti-PD-L1 treatment in gastrointestinal malignancies. Immunother Cancer 2020;8:e000404. doi:10.1136/jitc-2019-000404.*
Manz S., Losa M., Fritzch R. et A. Efficacy and side effects of immune checkpoint inhibitors in the treatment of colorectal cancer. Ther Adv Gastroenterol 2021, Vol. 14: 1–12.
Green A.K., Feinberg J., Makker V. A Review of Immune Checkpoint Blockade Therapy in Endometrial Cancer. 2020 ASCO educational book.
Cao W., Ma X., Fischer JV. et al. Immunotherapy in endometrial cancer: rationale, practice and perspectives. Cao et al. Biomarker Research (2021) 9:49

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.

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, in combination with pembrolizumab (TEDOVA), sponsor ARCAGY-GINECO.
  In Phase 2 in non-small cell lung cancer in combination with nivolumab, sponsor Italian foundation FoRT.
- **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. Voluntary and temporary Phase 1 enrollment suspension on-going (July 2021).

Immuno-oncology platform

- **BI 765063** (OSE-172, anti-SIRPα mAb on SIRPα/CD47 pathway): developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 results in monotherapy and BI 765063 dose escalation study ongoing in combination with Ezabenlimab (PD-1 antagonist).
- **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 transplant market; ongoing Phase 1/2 in renal transplant (sponsored by the Nantes University Hospital); Phase 2-ready asset in an autoimmune disease indication.

- **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 is being conducted 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: https://ose-immuno.com/en/
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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.