Boehringer Ingelheim and OSE Immunotherapeutics 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.**
- **Data from Phase 1 dose escalation indicate that BI 765063 monotherapy or in combination with ezabenlimab is well tolerated and shows promising activity in heavily pre-treated solid tumor patients.**

Nantes, France – September 16, 2021, 6:00 PM CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announces that promising data from dose escalation Phase 1 of selective SIRPα inhibitor BI 765063 in patients with advanced solid tumors (Poster 983P) have been presented[(1)] at the 2021 European Society for Medical Oncology (ESMO) Virtual Conference held on September 16 – 21, 2021.

Alexis Peyroles, CEO of OSE Immunotherapeutics commented: *" The data presented at ASCO in June and now at ESMO are very interesting as they show early evidence of clinical efficacy of BI 765063 combined with anti-PD-1 BI 754091 in patients with MSS tumors for which anti-PD-1 in monotherapy have shown limited activity and whose medical need is very strong. Based on these Phase 1 escalation dose promising results, we look forward advancing the trial's expansion phase to confirm the potential of a combination approach as a relevant therapeutic strategy in solid tumors."*

The dose escalation part (Step 1) of the Phase 1 trial evaluating BI 765063 alone and in combination with BI 754091 (ezabenlimab) in advanced solid tumors has been completed.

As of June 2021, a total of 18 patients have been treated (with 16 evaluable for efficacy).

Presentation Highlights:

- The combination of anti-SIRPα BI 765063 with BI745091 was well tolerated with no dose-limiting toxicities (DLTs) and the maximum tolerated dose (MTD) not reached.
- Promising early efficacy was observed with three partial responses (PR) in patients with microsatellite stable (MSS) advanced endometrium or colorectal cancer.
- The recommended Phase 2 dose and dosing schedule of BI 765063 was determined as 24 mg/kg with full receptor occupancy using a once every three weeks dosing schedule.

The trial is currently recruiting MSS advanced colorectal and advanced endometrium cancer patients in the expansion Phase 1 trial (Step 2).

Micro Satellite Instable (MSI) tumors can be effectively treated with immune checkpoint inhibitors alone. However, Micro Satellite Stable (MSS) colorectal and endometrial cancers represent the majority of these cancer patients where monotherapy with immune checkpoint inhibitors has limited benefit [(2)], highlighting the need for effective newcombination therapies such as BI 765063 and BI 754091 for these patients.

The previous data presented at the 2021 ASCO meeting indicated that BI 765063 was well tolerated and showed monotherapy activity in heavily pre-treated solid tumor patients. In particular, a durable partial response was observed in an advanced hepatocellular carcinoma (HCC) patient (data presented at the ASCO 2021).

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

[(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 in CD47/SIRPα 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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Contacts

OSE Immunotherapeutics
Sylvie Détry
sylvie.detry@ose-immuno.com
+33 153 198 757

Investor Relations
Thomas Guillot
thomas.guillot@ose-immuno.com
+33 607 380 431

Media

U.S. Media: LifeSci Communications
Darren Opland, Ph.D.
darren@lifescicomms.com
+1 646 627 8387

Guillaume van Renterghem – LifeSci Advisors
gvanrenterghem@lifesciadvisors.com
+41 76 735 01 31

French Media: FP2COM
Florence Portejoie
fportejoie@fp2com.fr
+33 607 768 283

Forward-looking statements

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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.