Boehringer Ingelheim and OSE Immunotherapeutics To Present Biomarker Analyses from the Phase 1 Clinical Trial with First-in-Class SIRPα Inhibitor BI 765063 in Advanced Solid Tumors

At American Association for Cancer Research Annual Meeting 2022 New Orleans, April 8 – 13

Nantes, France - March 9, 2022 - 7:30AM CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnemo: OSE), today announced that early biomarker analyses from the ongoing Phase 1 clinical trial with SIRPα inhibitor BI 765063 in patients with advanced solid tumors have been selected for presentation [(1)] in an in-person poster session at the American Association Cancer for Research (AACR) annual meeting to be held on April 8 – 13, 2022 in New Orleans, Louisiana.

The goal of the biomarker analyses from the Phase 1 trial with first-in-class SIRPα inhibitor BI 765063 was to characterize the impact of the product on peripheral blood immune cells (PBMCs), as well as on the tumor microenvironment.

The early biomarker analyses of paired tumor biopsies from patients with a wide range of solid tumors and treated with BI 765063 show encouraging signs of mode-of-action related changes, both in peripheral blood and in the tumor, in particular an increase in CD8 T-cell infiltration and activation.

These new data confirm preclinical results showing that T lymphocytes initially blocked at the tumor's margin could penetrate efficiently into the tumor when blocking SIRPα in parallel. Crossing this barrier is associated with positive modulation of macrophage expression and secretion of chemokines allowing the penetration of T lymphocytes into the heart of the tumor.

The Phase 1 clinical trial with BI 765063 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)] **Title:** *Biomarker analyses from the Phase I clinical trial of the first-in-class SIRPa immune checkpoint inhibitor BI765063 in patients with advanced solid tumors*

Session Category: Clinical Research Excluding Trials
Session Title: Inflammation / Modifiers of the Tumor Microenvironment
Session Date and Time: Monday Apr 11, 2022, 1:30 PM - 5:00 PM
Location: New Orleans Convention Center, Exhibit Halls D-H, Poster Section 32
Poster Board Number: 5

ABOUT BI 765063

BI 765063, a monoclonal antibody antagonist of the key myeloid cell checkpoint inhibitor SIRPα selectively blocks the SIRPα/CD47 interaction and thus increases the function of myeloid cells: phagocytosis of tumor cells by

macrophages and presentation of tumor antigens by dendritic cells. BI 765063 is also a selective inhibitor of SIRPα that by virtue of this specificity and lack of binding and blocking of a very similar receptor called SIRPɣ, ensures that response of T lymphocytes is retained to enable T cell-mediated tumor killing.

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. Its balanced first-in-class clinical and preclinical portfolio has a diversified risk profile:

Immuno-Oncology first-in-class products

- **Tedopi®** (innovative combination of neoepitopes): the company's most advanced product; positive results for Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in secondary resistance after checkpoint inhibitor failure.
  Other ongoing combination trials sponsored by cooperative clinical research groups in oncology:
  Phase 2 in pancreatic cancer (TEDOPaM), sponsor GERCOR.
  Phase 2 in ovary cancer, in combination with pembrolizumab (TEDOVA), sponsor ARCAGY-GINECO.
  Phase 2 in non-small cell lung cancer in combination with nivolumab, sponsor Italian foundation FoRT.
- **BI 765063** (OSE-172, anti-SIRPα mAb on CD47/SIRPα pathway): developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 dose escalation results of BI 765063 in monotherapy and in combination with ezabenlimab (PD-1 antagonist); ongoing expansion Phase 1.
- **OSE-279**, anti-PD1 – advanced preclinical stage.
- **BiCKI®**: bispecific fusion protein platform built on the key backbone component of anti-PD1 combined with a new immunotherapy target (for example: BiCKI®-IL7, preclinical stage) to increase anti-tumor efficacy.

Immunity & Inflammation first-in-class products

- **OSE-127/S95011** (humanized monoclonal antibody antagonist of IL-7 receptor): developed in partnership with Servier; positive Phase 1 results; ongoing Phase 2 in ulcerative colitis (sponsor OSE) and ongoing Phase 2a in Sjögren's syndrome (sponsor Servier).
- **FR104** (anti-CD28 monoclonal antibody): licensing partnership agreement with Veloxis Pharmaceuticals, Inc. in transplantation; ongoing Phase 1/2 in renal transplant (sponsored by the Nantes University Hospital); US IND obtained by Veloxis Pharmaceuticals, Inc. for a clinical trial; Phase 2 planned in an autoimmune disease indication.
- **OSE-230** (ChemR23 agonist mAb): preclinical stage therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

CoVepiT: a prophylactic second-generation vaccine activating cytotoxic T lymphocytes against COVID-19, developed using optimized epitopes from SARS-CoV2 viral proteins, epitopes non impacted by multi-variants. Shows good tolerance and very good level of T cell immune response. Results from 6-month memory T cell responses expected Q1 2022.

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.