Boehringer Ingelheim and OSE Immunotherapeutics Announce First Patient Dosed in a Phase 1 Expansion Trial of SIRPα Antagonist Monoclonal Antibody BI 765063, Targeting Myeloid Cells in Immuno-Oncology

- **Initiation of the Phase 1 clinical expansion trial triggers a €10 million milestone payment from Boehringer Ingelheim to OSE Immunotherapeutics.**
- **The trial is being conducted in advanced hepatocellular carcinoma and head and neck cancer patients in combination in particular with anti-PD-1 antibody Ezabenlimab.**

Nantes, France – May 3, 2022, 6:00pm CET – Boehringer Ingelheim and OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announced a new step achieved through their global collaboration and license agreement under which Boehringer Ingelheim obtained exclusive rights to BI 765063, a first-in-class SIRPα inhibitor on the SIRPα/CD47 myeloid pathway. In particular, a milestone has been achieved upon the first patient dosed in the Phase 1 expansion trial conducted by Boehringer Ingelheim in difficult to treat advanced cancers.

This international Phase 1 aims at evaluating BI 765063 in patients with recurrent/metastatic hepatocellular carcinoma (HCC) or head and neck squamous cell carcinoma (HNSCC)*.

Dominique Costantini, Chief Executive Officer of OSE Immunotherapeutics, comments: *"We thank Boehringer Ingelheim for this important new step which demonstrates their commitment and strong belief in the potential of BI 765063 targeting myeloid cells. Through our partnership, the product is now being explored in two additional oncology indications and debilitating tumor types, the advanced HCC and H&N cancer. The associated milestone payment will strengthen OSE's cash position to advance the development of our first-in-class portfolio."*

BI 765063 is being evaluated in parallel in Europe in combination with Ezabenlimab in a Phase 1 expansion clinical trial in patients with microsatellite stable (MSS) advanced colorectal cancer and MSS advanced endometrium cancer whose disease relapsed after standard of care and who received no prior anti-PD-L1 inhibitors. The study is being conducted by OSE Immunotherapeutics.

*More information: Clinicaltrials.gov

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

Immuno-Oncology first-in-class products

- **Tedopi®** (innovative neoepitope combination): 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.

Immuno-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. In clinical testing, a long-term memory response was confirmed at 6 months.

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 2022, including the annual financial report for the fiscal year 2021, 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.