OSE Immunotherapeutics Announces First Clinical Results for BI 770371, a Novel Anti-SIRPα Monoclonal Antibody

- **Novel antagonist anti-SIRPα monoclonal antibody (mAb) targeting both V1 and V2 SIRPα alleles makes SIRPα antagonists an option for more cancer patients.**
- **First clinical results of BI 770371 in monotherapy and in combination presented at ESMO 2023 conference.**

Nantes, France – October 23, 2023, 6:00pm CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announced that first Phase 1 results for BI 770371, a novel anti-SIRPα monoclonal antibody evaluated in advanced solid tumors, have been presented, at the European Society for Medical Oncology conference, held in Madrid, Spain (October 20 – 24, 2023).

BI 770371 is an IgG1 mAb that recognizes both the V1 and V2 variants of SIRPα. In many cancer types, CD47 forms a potent 'don't eat me' signaling complex with SIRPα that triggers a cascade of events that enables cancer cells to avoid detection by the innate immune system and inhibits the ability of macrophage cells to fight cancer. By blocking the interaction between SIRPα and cluster of differentiation 47 (CD47), SIRPα antagonism enhances innate immunity and restores the immune function of myeloid cells in the tumor microenvironment.

Nicolas Poirier, **Chief Executive Officer** of **OSE Immunotherapeutics**, commented:

*"We congratulate our partner Boehringer Ingelheim for this important new achievement, performed in the frame of our global collaboration and license agreement, which demonstrates their commitment to selective SIRPα inhibitors targeting myeloid cells. We are very pleased to potentially make our selective SIRPα inhibitor technology available to more patients through this strategic collaboration. With the V1 and V2 alleles being similarly expressed across humans in western countries, and V2 being more prevalent in the Asian region, the additional **BI 770371** program highlights a new step forward in our partnership with Boehringer Ingelheim aiming to provide this selective SIRPα innovation for the benefits of more patients."*

The BI 770371 development program will extend the therapeutic potential of selective SIRPα antagonists in various diseases or disorders, covering the most prevalent allelic variants* of SIRPα, V1 SIRPα and V2 SIRPα expressed on myeloid cells.

Boehringer Ingelheim is currently evaluating **BI 770371** as monotherapy and in combination with ezabenlimab, a PD1 inhibitor (BI 754091), in an open-label, dose escalation/dose expansion Phase I clinical trial (NCT05327946) conducted in Canada, USA and Japan in patients with advanced solid tumours. The first clinical results of BI 770371 presented at ESMO 2023 conference (Madrid, Abstract #697P) showed that adverse events were manageable during the on-treatment period, Maximal Tolerated Dose (MTD) has not been reached. This clinical trial is ongoing. Boehringer Ingelheim is also evaluating **BI 765063** (formerly OSE-172) in different combinations with patients with

recurrent/metastatic head and neck squamous cell carcinoma (HNSCC) or hepatocellular carcinoma (HCC) in a Phase 1b trial conducted in the United States, Europe and Asia (NCT05249426).

ESMO, Abstract #697P title:
Open-label, Phase I dose escalation/expansion trial of the anti-SIRPa monoclonal antibody BI 770371 in patients with advanced solid tumours, alone or in combination with the anti-PD-1 monoclonal antibody ezabenlimab -NCT05327946
Martin E. Gutierrez[1]*, Rahima Jamal[2], Noboru Yamamoto[3], Toshihiko Doi[4], Gunther Kretschmar[5], Javier Ferrada[5], Stephan Wojciekowski[6], Manish R. Patel[7]

[1] Hackensack University Medical Center at Hackensack Meridian Health, Hackensack, NJ, USA; [2] Centre Hospitalier de l'Université de Montréal (CHUM), Centre de recherche du CHUM, Montreal, QC, Canada; [3] National Cancer Center Hospital, Tokyo, Japan; [4] National Cancer Center Hospital East, Kashiwa, Japan; [5] Boehringer Ingelheim Pharmaceuticals, Ridgefield, CT, USA; [6] Boehringer Ingelheim Pharma GmbH & Co KG, Biberach an der Riss, Germany; [7] Florida Cancer Specialists/Sarah Cannon Research Institute, Sarasota, FL, USA

* Qu et al. Biomarker Research (2022)

ABOUT OSE Immunotherapeutics

OSE Immunotherapeutics is a biotech company dedicated to developing first-in-class assets in immuno-oncology and immuno-inflammation. The Company's current well-balanced first-in-class clinical pipeline includes:

- **Tedopi®** (immunotherapy activating tumor specific T-cells, off-the-shelf, neoepitope-based): this cancer vaccine is the Company's most advanced product; positive results from the Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in secondary resistance after checkpoint inhibitor failure. Other Phase 2 trials, sponsored by clinical oncology groups, of Tedopi® in combination are ongoing in solid tumors.
- **OSE-279** (anti-PD1): first positive results in the ongoing Phase 1/2 in solid tumors. OSE-279 is the backbone therapy of the BiCKI® platform.
- **OSE-127** - *lusvertikimab* (humanized monoclonal antibody antagonist of IL-7 receptor); ongoing Phase 2 in Ulcerative Colitis (sponsor OSE Immunotherapeutics); ongoing preclinical research in leukemia (OSE Immunotherapeutics).
- **FR-104/VEL-101** (anti-CD28 monoclonal antibody): developed in partnership with Veloxis Pharmaceuticals, Inc. in transplantation; ongoing Phase 1/2 in renal transplant (sponsor Nantes University Hospital); Phase 1 ongoing in the US (sponsor Veloxis Pharmaceuticals, Inc.).
- **BI 765063** and **BI 770371** (anti-SIRPα monoclonal antibody on CD47/SIRPα pathway) developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 dose escalation results in monotherapy and in combination, in particular with anti-PD-1 antibody ezabenlimab; international Phase 1b ongoing clinical trial in combination with ezabenlimab alone or with other drugs in patients with recurrent/metastatic head and neck squamous cell carcinoma (HNSCC) and hepatocellular carcinoma (HCC).

OSE Immunotherapeutics expects to generate further significant value from its two proprietary drug discovery platforms, which are central to its ambitious goal to deliver next-generation first-in-class immunotherapeutics:

- **BiCKI® platform** focused on immuno-oncology (IO) is a bispecific fusion protein platform built on the key backbone component of anti-PD1 combined with a new immunotherapy target to increase anti-tumor efficacy. BiCKI-IL-7 is the most advanced BiCKI® candidate targeting anti-PD1xIL-7.
- **Myeloid platform** focused on optimizing the therapeutic potential of myeloid cells in IO and immuno-inflammation (I&I). **OSE-230** (ChemR23 agonist mAb) is the most advanced candidate generated by the platform, with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

Additional information about OSE Immunotherapeutics assets is available on the Company's website: www.ose-immuno.com
Click and follow us on Twitter and LinkedIn

Contacts

OSE Immunotherapeutics
Sylvie Détry
sylvie.detry@ose-immuno.com

Nicolas Poirier
Chief Executive Officer
nicolas.poirier@ose-immuno.com

French Media: FP2COM
Florence Portejoie
fportejoie@fp2com.fr
+33 6 07 768 283

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 May 2, 2023, including the annual financial report for the fiscal year 2022, 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.