OSE Immunotherapeutics Receives €1.5 M in Funding from Bpifrance for the Development of a Companion Diagnostic for the Cancer Vaccine Tedopi® in Non-Small Cell Lung Cancer

- **A €1.5 million funding from "Bpifrance – Direction Régionale de Nantes" as part of an "R&D Innovation Loan" program.**

- **Development of a companion diagnostic test to identify HLA-A2 positive non-small cell lung cancer (NSCLC) patients eligible for treatment with Tedopi® in the next pivotal Phase 3 clinical trial under preparation.**

Nantes, France – June 20, 2023, 6:00 p.m. CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announced that the Company has received €1.5 million in non-dilutive funding from Bpifrance - Direction Régionale de Nantes. The "R&D Innovation Loan" program aims at supporting the development of a companion diagnostic for the pivotal Phase 3 clinical trial of Tedopi® in NSCLC second line treatment.

The funding from Bpifrance aims at accelerating the development of an innovative companion diagnostic test based on a simple blood sample. The companion diagnostic is a unique test for a predictive immunological biomarker to identify patients with HLA-A2 genotype who are biological responders to Tedopi®. The companion diagnostic will be used for the enrolment of the patient subpopulation in the upcoming registration pivotal Phase 3 of Tedopi®. The objective of this final clinical development stage is to confirm the efficacy and safety of Tedopi® in second line treatment post-immune checkpoint inhibitor (ICI) failure in HLA-A2 positive NSCLC patients.

NSCLC accounts for 85% of all lung cancers and the HLA-A2 phenotype represents about 45% of the population. Based on selection of patients after ICI failure data, the targeted population for Tedopi® in second line is hence considered as rare with high unmet medical needs. Up to 100,000 patients per year are estimated to potentially benefit from Tedopi® in 7 major markets across the US, Europe, China and Japan. Tedopi® has obtained an orphan drug status designation in the United States and is considered as a precision medicine in Europe for HLA-A2 positive patients.

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, comments: "*We warmly thank Bpifrance – Direction Régionale de Nantes for funding the development of this unique companion diagnostic test to accelerate the final clinical development phase of our cancer vaccine Tedopi® in preparation to support the regulatory registration in advanced NSCLC for the HLA-A2 patient subpopulation".*

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): ongoing Phase 1/2 in solid tumors or lymphomas (first patient included). 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.).
- **OSE-172/BI 765063** (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
+33 1 53 198 757

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.