OSE Immunotherapeutics Announces a Collaboration Agreement with GenDx for the Development of a Companion Diagnostic for Epitope-Based Cancer Vaccine Candidate Tedopi®

- **A development program to support in parallel the next confirmatory pivotal Phase 3 clinical trial under preparation.**
- **A companion diagnostic test to identify HLA-A*02 positive cancer patients eligible for treatment with Tedopi®.**

Nantes, France – November 21, 2023, 6:00pm CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announced that the Company has entered into a collaboration with GenDx (a Eurobio Scientific Company, a key player in the field of specialty in vitro diagnostics) to develop and validate a companion diagnostic (CDx) test to support the confirmatory pivotal Phase 3 clinical trial of Tedopi® cancer vaccine candidate in preparation in Non-Small Cell Lung Cancer (NSCLC) second line treatment. GenDx, one of the pioneering companies in the HLA field, is developing and marketing innovative molecular diagnostics, in particular in the field of high-resolution HLA typing and related molecular diagnostic testing.

Under the Master Collaboration Agreement, GenDx will develop and validate a companion diagnostic (CDx) unique test for a predictive immunological biomarker to identify patients with HLA-A*02 genotype [(1)] who are biological responders to Tedopi® epitopes. The CDx test, based on a simple blood sample and Next-Generation Sequencing technologies (NGS), will support the enrolment of eligible NSCLC patient in the upcoming registration pivotal Phase 3 of Tedopi®. The objective of this study will be to confirm the efficacy and safety of Tedopi® in second line treatment post-immune checkpoint inhibitor (ICI) failure in HLA-A*02 positive NSCLC patients to support Tedopi®'s registration in both United States and Europe.

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, comments:

*"We are very pleased to have initiated this collaboration with GenDx, the leading high-resolution HLA typing company. This companion diagnostic test is the first step to move forward in selecting HLA-A*02 eligible cancer patients and thus to accelerate the clinical development and regulatory registration of Tedopi® as a precision medicine innovative treatment."*

Maarten Penning, General Manager of GenDx, says: "*In this project, our regulatory expertise, being one of the first IVDR [(2)] compliant companies, and our extensive knowledge of developing software and reagents for accurate high resolution HLA typing using NGS, come together in the development of a companion diagnostic assay for HLA-A*02. We are very happy to enter in this strategic collaboration with OSE, as we aim to contribute to improve the quality of life and survival of patients.".*

In June 2023, OSE Immunotherapeutics had received €1.5 million in non-dilutive funding from Bpifrance - Direction Régionale de Nantes, as part of the "R&D Innovation Loan" program, to support the development of this companion diagnostic for the pivotal Phase 3 clinical trial of Tedopi® in NSCLC second line treatment. This upcoming clinical is planned to be conducted in the United States and in Europe.

*(1) NSCLC accounts for 85% of all lung cancers and the HLA-A*02 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-A*02 positive patients.*

(2) IVDR = In Vitro Diagnostic Regulation

About HLA-A*02

The Human Leukocyte Antigen (HLA) system comprises a diverse family of genes and allelic variants crucial for the human immune system, existing in most human cell types and interacting with T cell receptors (TCRs) to activate T cells, inducing adaptive immune responses. HLA typing enables the identification of specific nucleotide sequences. HLA-A*02 is one of the most common Major Histocompatibility Class I molecules in humans (about 45% of the NSCLC patient population). HLA-A*02 system presents tumor antigens as A2 epitopes to T cells to facilitate the immune system to recognize tumor allowing a potent activation of the protective specific CD8+ T cells.

About GenDx, a Eurobio Scientific company

Genome Diagnostics B.V., trading as GenDx, is a Dutch company specializing in molecular diagnostics. It focuses on the development, production, and sales of innovative assays and analysis software for transplantation and companion diagnostics. GenDx offers a range of HLA sequencing-based typing strategies, reagents, software, and custom laboratory services and is one of the first companies being IVDR compliant. GenDx Education also provides dedicated training courses worldwide for professionals in tissue typing, research laboratories, blood banks, and donor registries.

About Eurobio Scientific

Eurobio Scientific is a key player in the field of specialty in vitro diagnostics. It is involved from research to manufacturing and commercialization of diagnostic tests in the fields of transplantation, immunology and infectious diseases, and sells instruments and products for research laboratories, including biotechnology and pharmaceutical companies.

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 candidate 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.).
- **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 immunotherapies:

- **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

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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 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.