OSE Immunotherapeutics Receives €8.4 M in Public Funding to Support the Registration Phase 3 Clinical Trial of Cancer Vaccine Tedopi® in Lung Cancer

Nantes, France – April 10, 2024 – 6:00 pm CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announced the Company has received €8.4 million in non-dilutive funding under the "i-Démo" call for projects as part of the plan "France 2030" operated by Bpifrance on behalf of the State. This plan aims at developing industrial companies in growth markets that create value and competitiveness for the French economy and also contribute to energy, ecological and digital transitions. This financial support applies from the feasibility study to marketing.

This public funding will support the registration Phase 3 clinical trial of neoepitope-based cancer vaccine Tedopi®, in second line treatment in HLA-A2 positive non-small cell lung patients with secondary (acquired) resistance to anti-PD-(L)1 immunotherapy. This new national support adds up to the €1.5 million funding from Bpifrance * announced in June 2023 to support the development of a companion diagnostic test (HLA-A2) associated with Tedopi®'s registration in the same indication.

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, comments: *« We thank the State and Bpifrance for renewing their confidence and supporting us with this funding. It will enable the Company to accelerate the last step of clinical development of our cancer vaccine Tedopi®. This innovation will meet the important medical need of non-small cell lung cancer patients who are failing after immunotherapy, and who do not have today any approved therapeutic options. Following FDA approval on the trial protocol in early 2024, we will be able to start this confirmatory Phase 3 in the United States in the coming weeks and then, once we receive approval from the EMA, in Europe and in France where many clinical sites will be set up. We thank particularly the international groups of clinical investigators and lung cancer experts who, from the beginning, support us and are committed to advance the clinical development of Tedopi® towards a potential new standard treatment in second line of metastatic or advanced lung cancer".*

Based on positive final survival, safety and quality of life results from the Phase 3 clinical trial in the third line of treatment in non-small cell lung cancer published in September 2023 in the internationally renowned Journal 'Annals of Oncology', a confirmatory pivotal Phase 3 trial in second line treatment is being prepared for launch. This trial is associated with the development of a unique companion

diagnostic test (collaboration with the company GenDx) to identify positive HLA-A2 patients eligible for treatment with Tedopi®.

The clinical trial application dossier to initiate the new confirmatory Phase 3 of Tedopi®, including the study protocol and the specific "diagnostic companion test" dossier, was approved by the Food & Drug Administration (FDA) in mid-January 2024, which should allow the trial to start in the United States in Q2 2024, after approval from the Ethic committees. The submission of the dossier to the European Medicines Agency (single European portal) is planned in the coming weeks to extend this study to a large number of clinical investigator sites in Europe, particularly in France.

** As part of an "R&D Innovation Loan" program*

The management of lung cancer is a major public health issue:

- 1st cause of cancer mortality for all populations combined (33,100 deaths in 2018[1] in France and 1.8 million per year worldwide[2]).
- -2nd most common cancer among solid tumors.
- Non-Small Cell Bronchial Cancer (NSCLC) is a serious disease with a short-term life-threatening prognosis. NSCLC represents 85% of lung cancers.
- Stage IV metastatic NSCLC: 2-year survival between 10% and 23%; 5-year survival <10%[3].
- Targeted population of patients identified as responders to Tedopi®[4]: HLA-A2+ patients (45% of stage IV patients with secondary resistance to anti-PD-(L)1 (approximately 50% of patients failing immunotherapy in NSCLC).

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2. WHO. Globocan 2020 Fact Sheet
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ABOUT OSE IMMUNOTHERAPEUTICS

OSE Immunotherapeutics is a biotech company dedicated to developing first-in-class assets in immuno-oncology (IO) and immuno-inflammation (I&I).
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-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); successful Phase 1 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-230** (ChemR23 agonist mAb) developed in partnership with AbbVie in chronic inflammation.

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

- **Pro-resolutive mAb platform** focused on targeting and advancing inflammation resolution and optimizing the therapeutic potential of targeting Neutrophils and Macrophages in I&I. **OSE-230** (licensed to AbbVie) is the first candidate generated by the platform, additional discovery programs ongoing on new pro-resolutive GPCRs.
- **Myeloid Checkpoint platform** focused on optimizing the therapeutic potential of myeloid cells in IO by targeting immune regulatory receptors expressed by Macrophages and Dendritic cells. **BI 765063** and **BI 770371** (licensed to Boehringer Ingelheim) are the most advanced candidates generated by the platform. Ongoing additional discovery programs, in particular with positive preclinical results obtained in monotherapy with new anti-**CLEC-1** mAbs.
- **Cytokine platform** focused on leveraging the Cis-Delivery of cytokine in IO and I&I. BiCKI® 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-7v** is the most advanced BiCKI® candidate targeting anti-PD1xIL-7. Ongoing additional discovery programs on Cis-Demasking technologies.

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

ABOUT FRANCE 2030 INVESTMENT PLAN

- ✓ **Reflects a double ambition**: sustainably transform key sectors of our economy (health, energy, automotive, aeronautics or space) through technological innovation, and position France not only as a player, but as a leader in the world of tomorrow. From basic research to the emergence of an idea to the production of a new product or service, France 2030 supports the entire life cycle of innovation until its industrialization.
- ✓ **Is unpublished by its magnitude**: €54 billion will be invested to ensure that our companies, universities and research organisations are fully successful in their transitions in these strategic sectors. The challenge: to enable them to respond competitively to the ecological and attractiveness challenges of the coming world, and to bring out the future leaders of our sectors of excellence. France 2030 is defined by two cross-cutting objectives consisting in dedicating 50% of its expenditure to the decarbonisation of the economy, and 50% to emerging players, who are the bearers of innovation without spending that is unfavourable to the environment (in the sense of the principle *Do No Significant Harm*).
- ✓ **Will be implemented collectively:** designed and deployed in consultation with economic, academic, local and European stakeholders to determine their strategic orientations and flagship actions. Project leaders are invited to submit their application via open, demanding and selective procedures to benefit from the support of the State.

- ✓ **Is led by the General Secretariat for Investment** on behalf of the Prime Minister and implemented by the Agence de la transition écologique (ADEME), the Agence nationale de la recherche (ANR), Bpifrance and the Banque des Territoires.
  More information on: france2030.gouv.fr | @SGPI_avenir

ABOUT BPIfrance

Bpifrance finances companies – at each stage of their development – with credit, guarantees and equity. Bpifrance supports them in their innovation projects and internationally. Bpifrance also support their export activity through a wide range of products. Consulting, university, networking and an acceleration program for start-ups, SMEs and mid-caps are also part of the support proposed to entrepreneurs. Thanks to Bpifrance and its 50 regional locations, entrepreneurs benefit from a close, unique and efficient contact to help them face their challenges.
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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.