OSE Immunotherapeutics Announces Global Launch of Artemia Phase 3 Registration Study for Cancer Vaccine Tedopi® in Second-Line Non-Small Cell Lung Cancer

- **Trial begins in the United States, Canada, Europe and United Kingdom after successful regulatory authorizations in 14 countries.**
- **Trial in Progress presentation at the 2024 *World Conference on Lung Cancer* in San Diego and at the *European Society for Medical Oncology* congress 2024 in Barcelona.**

Nantes, France – September 10, 2024 – 7:30 am CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announced the launch of its international Phase 3 clinical trial named 'Artemia' of Tedopi®, the *'off-the-shelf'* neoepitope-based therapeutic cancer vaccine, in second-line treatment in patients with metastatic non-small cell lung cancer (NSCLC). This dossier, reviewed and accepted in 14 countries by international health agencies (US FDA, Canada, Europe and the United Kingdom) is a pivotal study supporting the registration of the product Tedopi®, in parallel with the companion diagnostic for HLA-A2 positive patients.

Artemia is an international, randomized, open-label Phase 3 trial comparing the efficacy and safety of Tedopi® monotherapy versus standard of care in HLA-A2 positive patients with metastatic NSCLC with secondary resistance* to immune checkpoint inhibitor (ICI). The primary endpoint is overall survival. This confirmatory pivotal trial will include 363 patients, and aims at supporting the regulatory registration of Tedopi® in second-line treatment of NSCLC in Europe and North America.

Silvia Comis, Head of Clinical development and Regulatory affairs of OSE Immunotherapeutics, comments: *"We are very pleased to start the last registration development step of our cancer vaccine Tedopi® in monotherapy in second-line treatment, supported by the positive and promising results from our first Phase 3 in third-line treatment in NSCLC. These results demonstrated that re-arming the immune system with vaccine in metastatic patients can extend survival and preserve quality of life in the targeted population."*

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, said: "*This international registration trial is now on track, and we look forward to confirming the therapeutic benefit of Tedopi® for metastatic cancer patients. Tedopi® is the most advanced therapeutic cancer vaccine in clinical development and the first treatment option to address the high unmet medical need and large untapped market in advanced and metastatic second-line NSCLC. "*

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. Given the large use of anti-

PD(L)1 and based on ICI failure data, the targeted population for Tedopi® in second line could be estimated up to 46,000 patients per year in seven major markets across the US, Europe and Japan.

A Trial in Progress poster, entitled ***"Phase 3 Trial of OSE2101 Versus Docetaxel in Patients with Non-Small Cell Lung Cancer & Secondary Resistance to Immunotherapy"*** was presented by **Dr Stephen Liu**, associate professor and director of Thoracic Oncology at Georgetown University Lombardi Comprehensive Cancer Center (Washington DC, United States), coordinating investigator for the United States and member of the Steering committee of the Artemia trial, at the 2024 ***World Conference on Lung Cancer*** (September 7-10, San Diego, CA, USA).

Dr Liu said: *"I am excited to see the Artemia trial activated in the US. With an off-the-shelf vaccine approach, we can offer a safer and more tolerable approach than chemotherapy for patients with advanced lung cancer. By properly engaging a patient's own immune system, we hope to significantly extend survival."*

A second Trial in Progress poster, entitled: **"*Phase III trial of the therapeutic cancer vaccine OSE2101 versus docetaxel in patients with metastatic non-small cell lung cancer and secondary resistance to immunotherapy*"** will also be presented by Dr Stephen Liu at the upcoming ***European Society for Medical Oncology congress*** (September 13-17, Barcelona, Spain).

** Secondary resistance: after at least 12 weeks of ICI maintenance treatment without cytotoxic therapy (Task force SITC 2020 - Kluger H et al. 2020). Kluger et al. 2023*
*** Bray, F et al. CA Cancer J. Clin. 2018; Sung, H et al. CA Cancer J. Clin. 2021*

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): most advanced therapeutic cancer vaccine in development; positive results from a randomized Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in third-line secondary resistance after checkpoint inhibitor failure. Ongoing randomized registration Phase 3 study (Artemia) in second-line NSCLC in HLA-A2+ patients with secondary resistance. Other Phase 2 trials, sponsored by clinical oncology groups, of Tedopi® in combination are ongoing in solid tumors.
- **OSE-127** - *lusvertikimab* (humanized monoclonal antibody antagonist of IL-7 receptor); Positive Phase 2 (CoTikiS) study in Ulcerative Colitis; ongoing preclinical research in leukemia.
- **OSE-279** (anti-PD1): first positive results in the ongoing Phase 1/2 in solid tumors.
- **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.).
- **Anti-SIRPα monoclonal antibody** developed in partnership with Boehringer Ingelheim in advanced solid tumors and cardiovascular-renal-metabolic diseases (CRM); positive Phase 1 dose escalation results in monotherapy and in combination; Phase 2 in CRM diseases planned to be initiated end of 2024.
- **ABBV-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. **ABBV-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.
- **BiCKI® Platform** is a bifunctional fusion protein platform built on the key backbone component of anti-PD1 combined with a new immunotherapy target to increase anti-tumor efficacy by "cis-potentiating" tumor-specific T cells. A first program has been acquired by Boehringer Ingelheim.
- **mRNA Therapeutic platform** allows local delivery into the inflammatory site of innovative immunotherapies encoded by RNA to locally controls and/or suppress immune responses and inflammation.

Additional information about OSE Immunotherapeutics assets is available on the Company's website: www.ose-immuno.com
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Forward-looking statements

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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 April 30, 2024, including the annual financial report for the fiscal year 2023, 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.