OSE Immunotherapeutics Provides Update on Clinical Results With OSE-279 in Advanced Solid Tumors

Nantes, France – February 26, 2024, 6:00 pm CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) presented an update on the positive results of OSE-279 in the Phase 1/2 clinical evaluation in advanced solid tumors at the 2024 ESMO Targeted Anticancer Therapies Congress (ESMO TAT) held in Paris, France (February 26 – 28, Abstract #368; FPN 30P).

Silvia Comis, Head of Clinical Development and Regulatory Affairs of OSE Immunotherapeutics, comments: *"We are very pleased to share this positive update on the preliminary efficacy and safety results from a Phase 1/2 study assessing the therapeutic potential of our proprietary high affinity anti-PD1 monoclonal antibody OSE-279 in advanced solid tumors. These new results and additional signal of efficacy with a high anti-tumor response rate in difficult-to-treat patients, highlight the value of OSE-279 as a potential strong anti-PD1 therapy and encourage further clinical development in the future in pre-identified cancer niche indications, with still high unmet medical needs. In parallel to OSE-279 monotherapy development, new cohort testing combinations with other OSE drug candidates, including cancer vaccine, are being explored."*

The ESMO-TAT communication reported on the positive results from the Phase 1/2 clinical trial (NCT05751798) evaluating OSE-279 monotherapy in patients with advanced solid tumors, with no therapeutic option available.

The updated data show a good pharmacokinetic/pharmacodynamic (PK/PD) and manageable safety profile in line with previous anti-PD1 development and with a high signal of efficacy in the first 20 patients representing 13 different tumor types. Four confirmed ongoing partial responses (PR) with 600 mg every six weeks (q6w), with a response rate of 36%, were reported in patients with anal squamous cell carcinoma, undifferentiated pleomorphic sarcoma, oncocytic thyroid cancer, and alveolar soft part sarcoma. One still ongoing confirmed PR (81% reduction of target lesions) has been observed in a patient with hepatocellular carcinoma after one single dose of OSE-279 300 mg. Five stable diseases (SD) were reported at multiple dose levels. Treatment is ongoing in seven patients. Pharmacokinetic (PK) showed dose-proportionality and favorable exposure. Receptor occupancy (RO) was maintained. At 600 mg q6w, no dose-limiting toxicities (DLTs) were reported in 10 patients. Further to the recommendation of a Phase 2 dose (RP2D) of 300 mg q3w, the dose of 600 mg q6w has been selected as the second RP2D.

OSE-279 is a high affinity humanized anti-PD1 monoclonal antibody blocking both PD-L1 and PD-L2, the ligands of PD1 overexpressed by tumor cells and tumor microenvironment. Overexpression of PD-L1 and PD-L2 on tumor and myeloid cells in the tumor microenvironment is a mechanism of tumor immune escape.

Given the advantages of owning a proprietary and protected high affinity anti-PD1 antagonist antibody, OSE Immunotherapeutics has developed a global intellectual property strategy protecting OSE-279 until at least 2039. This has been achieved through recent grants of patents in the U.S., various European countries, China, Japan, Korea, Australia, and Mexico to date. These patents protect the original antibody sequences of OSE-279 associated with its innovative biological and manufacturing properties.

The first-in-human open label Phase 1/2 dose escalation and expansion study, initiated in December 2022, aims to determine the Maximum Tolerated Dose (MTD) and/or the RP2D of OSE-279 as a monotherapy in advanced solid tumors with two possible administration regimens. Secondary objectives include assessment of OSE-279's antitumor activity, evaluation of the safety profile, pharmacokinetic and receptor occupancy or pharmacodynamic profile (NCT05751798).

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-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 antibodies 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
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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 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.