OSE Immunotherapeutics Presents First Positive Clinical Results With its anti-PD1 OSE-279 in Advanced Solid Tumors

Nantes, France – October 16, 2023, 7:30am CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) presented the first Phase 1/2 positive clinical results with high affinity anti-PD1 monoclonal antibody OSE-279 in advanced solid tumors at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, held in Boston, MA (October 11 – 15, 2023 - Abstract number 35371, Poster C063).

Silvia Comis, Head of Clinical Development and Regulatory Affairs of OSE Immunotherapeutics, comments: *"These first efficacy and safety positive results from clinical Phase 1/2 assessing the therapeutic potential of our proprietary anti-PD1 monoclonal antibody OSE-279 in advanced solid tumors are very promising. These results encourage further clinical development of OSE-279 in the future as a monotherapy treatment in pre-identified cancer niche indications, with still high unmet medical needs. This product will also be available for combination with other OSE drug candidates or with external assets opening new potential partnerships."*

The communication reported on the first positive results from the Phase 1/2 clinical trial evaluating OSE-279 monotherapy in patients with advanced solid tumors, with no therapeutic option available. These data have shown a manageable safety profile with preliminary signs of efficacy in the first 13 patients included with 8 tumor types and treated by a dose of 100 and 300 mg every 3 weeks (q3w) or 600 mg every 6 weeks (q6w). One confirmed partial response in a hepatocellular carcinoma patient (-81% tumor shrinkage) after a single dose of OSE-279 300 mg and 2 yet unconfirmed partial responses in anal squamous cell carcinoma (-46% tumor shrinkage) and undifferentiated pleomorphic sarcoma (-33% tumor shrinkage) with OSE-279 600 mg, were reported out of 11 patients with at least one post baseline tumor assessment. Furthermore, stable disease longer than 16 weeks was observed in 3 patients (Disease Control Rate: 55%). Pharmacokinetic profile showed good exposure and dose-proportionality and both pharmacokinetic and pharmacodynamic profiles were consistent with modelling. Receptor occupancy was maintained and within the boundaries of simulation. A Phase 2 dose (RP2D) of 300 mg was recommended every 3 weeks and 600 mg appears to be a good candidate for the RP2D every 6 weeks.

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. OSE-279 is also the key anti-PD1 backbone component of OSE's bifunctional checkpoint inhibitor BiCKI® platform that is targeting PD1 and other new immune targets.

The first-in-human open label Phase 1/2 dose escalation and expansion study 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 rates. 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-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 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

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.