OSE Immunotherapeutics Announces First Patient Dosed with Anti-PD1 Monoclonal Antibody OSE-279 in a Phase 1/2 Clinical Trial in Advanced Solid Tumors or Lymphomas

Nantes, France – December 22, 2022, 7:30 a.m. CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) announced today that the first patient has been dosed in the Phase 1/2 clinical trial evaluating OSE-279, a high affinity anti-PD1 blocking monoclonal antibody, in patients with advanced solid tumors or lymphomas.

This first-in-human open label Phase 1/2 dose escalation and expansion study aims to determine the Maximum Tolerated Dose and/or the recommended Phase 2 dose of OSE-279 as a monotherapy in advanced solid tumors or lymphomas. Secondary objectives include assessment of OSE-279's antitumor activity, evaluation of the safety profile, pharmacokinetic and receptor occupancy or pharmacodynamic profile.

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 cells and other cell types of the tumor microenvironment is a mechanism of tumor immune escape.

OSE-279 is the key anti-PD-1 backbone component of OSE's bifunctional checkpoint inhibitor BiCKI® platform that is targeting PD1 and other new immune targets. The first cytokine selected to be paired with the anti-PD1 in the bispecific antibody is Interleukin-7 (IL-7), which has been shown at preclinical stage to improve long-term immune functions and cancer immunotherapy efficacy. BiCKI®-IL-7 has potential to address the needs of a patient population in immune escape from checkpoint inhibitor treatment.

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, comments: *"We are very excited to begin first-in-human testing with our proprietary high affinity anti-PD1 monoclonal antibody, which is covered by a strong global patent portfolio in the US, Europe, Asia and South America. Dosing of the first patient marks a significant milestone in the development of OSE-279, and we look forward to the first results assessing the therapeutic potential of OSE-279 as a monotherapy treatment. Further internal clinical development of OSE-279 as a monotherapy would be conducted in pre-identified cancer niche indications to address patients with high unmet medical needs despite immuno-sensitive tumor type. This first clinical study will also allow us, at a later stage, to explore OSE-279, the backbone of OSE's BiCKI® platform, in combination with other OSE drug candidates or with external assets accessed through potential new partnerships with biotech or pharmaceutical companies."*

Given the advantages of owning a proprietary and protected anti-PD1 antagonist antibody in the new era of immuno-oncology, OSE Immunotherapeutics has developed a global intellectual property strategy protecting OSE-279 until at least 2039. This has been achieved through the grant in 2022 of patents for the US, Europe, China, Japan, Korea, Australia and Mexico to date. These patents protect the antibody sequences of OSE-279 associated with its innovative biological and manufacturing properties.

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): ongoing Phase 1/2 in solid tumors or lymphomas (first patient included). OSE-279 is the backbone therapy of the BiCKI® platform.
- **OSE-127/S95011** (humanized monoclonal antibody antagonist of IL-7 receptor) developed in partnership with Servier; ongoing Phase 2 in ulcerative colitis (sponsor OSE Immunotherapeutics) and ongoing Phase 2a in Sjögren's syndrome (sponsor Servier); ongoing pre-clinical research in leukemia (OSE Immunotherapeutics).
- **VEL-101/FR104** (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** (anti-SIRPα monoclonal antibody on CD47/SIRPα pathway): developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 dose escalation results of BI 765063 in monotherapy and in combination, in particular with anti-PD-1 antibody ezabenlimab; BI sponsored 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 immunotherapeutics:

- **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 15 April 2022, including the annual financial report for the fiscal year 2021, 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.