OSE Immunotherapeutics and Nantes University Hospital Announce Completion of Patient Enrollment in the FIRsT Clinical Trial, a Phase 1/2 Study Evaluating FR104/VEL-101 Immunotherapy in Renal Transplantation

Nantes, France – July 11, 2023, 6:00pm CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) and Nantes University Hospital announced today the completion of patient enrollment in the FIRsT Study. This Phase 1/2 clinical trial is the first study to evaluate the immunotherapy FR104/VEL-101, a monoclonal antibody fragment CD28 antagonist, in patients undergoing renal transplant. This study is sponsored and conducted by the University Hospital of Nantes as part of a collaboration agreement with OSE Immunotherapeutics.

The purpose of this Phase 1/2 clinical trial is to investigate the safety, tolerability, and pharmacokinetics of FR104/VEL-101, a novel antagonist pegylated anti-CD28 Fab' antibody fragment, as well as its potential clinical efficacy on acute rejection prophylaxis and renal function in a *de novo* renal transplant population receiving an allograft from standard criteria donors (NCT number: NCT04837092). A longer-term follow-up assessment will be performed one year after transplantation. One-year safety and efficacy of FR104/VEL-101 will be evaluated in terms of renal function, incidence of rejection and suspected potential related adverse events.

Pr. Gilles Blancho, Head of the ITUN (*Institut de transplantation en urologie-néphrologie*) in Nantes, commented: *"Despite progress in immunosuppressive treatments, renal transplant recipients still need medical advances. The key issue in organ transplant remains to find efficient immunosuppressive treatments with minimal side effects, particularly on renal function in order to preserve patients' quality of life, and long-term control of post-transplant immune reaction. Based on our previous preclinical and now clinical evaluation of FR104, we are hoping to contribute developing an innovative and promising immunotherapy for a patient population in need for lifelong immunosuppressor treatment."*

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, concluded: "*We are pleased to complete the enrollment for the Phase 1/2 evaluation of FR104/VEL-101, a key step in the product's clinical development. We thank the University Hospital of Nantes and their team of excellence at the European Center for Transplantation and Immunotherapy Sciences (CESTI) for our long-standing collaboration and their commitment to tackle this therapeutic challenge. We are now looking forward to the results of the patients' post-transplant immune response and the one-year safety and efficacy results of FR104/VEL-101 in the FIRsT Study. To continue the clinical development program initiated in Nantes, a larger Phase 2 clinical trial to evaluate FR104/VEL-101 in patients undergoing kidney transplantation will be initiated by our partner, Veloxis Pharmaceuticals."*

ABOUT FR104/VEL-101

FR104/VEL-101 is a pegylated monoclonal antibody fragment that binds to and blocks CD28-mediated effector-T cell co-stimulation, without blocking CTLA-4, an important protein receptor found on T cells that acts as a natural brake on the body's immune responses. FR104/VEL-101 is, therefore, expected to have a dual-

mechanism of action where in a direct manner, it blocks CD28-mediated T cell activation, and in an indirect way, it allows for CTLA-4 mediated immunosuppressive functions.

ABOUT Veloxis Pharmaceuticals

Veloxis Pharmaceuticals, an Asahi Kasei company, is a fully integrated specialty pharmaceutical company committed to improving the lives of transplant patients. Headquartered in Cary, N.C., USA, Veloxis is focused on the global development and commercialization of medications utilized by transplant patients and by patients with serious related diseases. For further information, please visit www.veloxis.com.

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** - *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 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

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.