OSE Immunotherapeutics Announces Acceptance of the US Investigational New Drug (IND) Application Obtained by Veloxis Pharmaceuticals, Inc., its Partner in Transplantation, for CD28 Antagonist VEL-101/FR104

- ***Based on the global license agreement signed in April 2021, this first milestone triggers a €5 million payment from Veloxis Pharmaceuticals, Inc. to OSE Immunotherapeutics.***

Nantes, France – January 31, 2022 - 6:00PM CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnemo: OSE), today announced acceptance of the IND obtained by Veloxis Pharmaceuticals, Inc. from the Food & Drug Administration (FDA) for a clinical trial with VEL-101/FR104, a CD28 antagonist monoclonal antibody fragment. This trial will be sponsored and conducted by Veloxis Pharmaceuticals, Inc. in the United States.

This important milestone has been achieved by Veloxis Pharmaceuticals, Inc. as part of the global license agreement signed in April 2021 under which Veloxis Pharmaceuticals, Inc. obtained from OSE Immunotherapeutics worldwide rights to develop, manufacture and commercialize FR104, a CD28 antagonist monoclonal antibody fragment, for all transplant indications. Under this agreement, acceptance of the US IND application has triggered a milestone payment of €5 million from Veloxis Pharmaceuticals, Inc. to OSE Immunotherapeutics.

In parallel, OSE Immunotherapeutics retains all product rights to develop FR104 in autoimmune diseases.

Dominique Costantini, Chief Executive Officer of OSE Immunotherapeutics, comments: *"We thank Veloxis Pharmaceuticals, Inc. for this first key achievement which demonstrates their commitment and strong belief in the potential of this first-in-class CD28 antagonist as an innovative immunosuppressive treatment and marks a major step in enlarging the product's development in transplantation. The milestone payment, in line with our business model, will reinforce our cash position to advance our immuno-oncology and immunity & inflammatory pipeline."*

About Veloxis Pharmaceuticals, Inc.

Veloxis Pharmaceuticals, Inc., an Asahi Kasei company, is a fully integrated specialty pharmaceutical company committed to improving the lives of transplant patients. Headquartered in Cary, North Carolina, USA, Veloxis Pharmaceuticals, Inc. is focused on the direct commercialization of immunosuppression medications in the US, expansion of partnerships for markets around the world, and acquisition of assets utilized in transplant patients and by adjacent medical specialties. For further information, please visit www.veloxis.com.

About Asahi Kasei

The Asahi Kasei Group contributes to life and living for people around the world. Since its foundation in 1922 with ammonia and cellulose fiber business, Asahi Kasei has consistently grown through the proactive transformation of its business portfolio to meet the evolving needs of every age. With more than 40,000 employees around the world, the company contributes to sustainable society by providing solutions to the world's challenges through its three business sectors of Material, Homes, and Healthcare. Its healthcare operations include devices and systems for acute critical care, dialysis, therapeutic apheresis, transfusion, and manufacture of biotherapeutics, as well as pharmaceuticals and diagnostic reagents. For further information, please visit www.asahi-kasei.com.

ABOUT OSE Immunotherapeutics

OSE Immunotherapeutics is an integrated biotechnology company focused on developing and partnering therapies to control the immune system for immuno-oncology and autoimmune diseases. Its balanced first-in-class clinical and preclinical portfolio has a diversified risk profile:

Immuno-Oncology first-in-class products

- **Tedopi®** (innovative combination of neoepitopes): the company's most advanced product; positive results for Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in secondary resistance after checkpoint inhibitor failure.
  Other ongoing combination trials sponsored by cooperative clinical research groups in oncology:
  Phase 2 in pancreatic cancer (TEDOPaM), sponsor GERCOR.
  Phase 2 in ovary cancer, in combination with pembrolizumab (TEDOVA), sponsor ARCAGY-GINECO.
  Phase 2 in non-small cell lung cancer in combination with nivolumab, sponsor Italian foundation FoRT.
- **BI 765063** (OSE-172, anti-SIRPα mAb 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 with ezabenlimab (PD-1 antagonist); ongoing expansion Phase 1.
- **OSE-279**, anti-PD1 – advanced preclinical stage.
- **BiCKI®**: bispecific fusion protein platform built on the key backbone component of anti-PD1 combined with a new immunotherapy target (for example: BiCKI®-IL7, preclinical stage) to increase anti-tumor efficacy.

Immunity & Inflammation first-in-class products

- **OSE-127/S95011** (humanized monoclonal antibody antagonist of IL-7 receptor): developed in partnership with Servier; positive Phase 1 results; ongoing Phase 2 in ulcerative colitis (sponsor OSE) and ongoing Phase 2a in Sjögren's syndrome (sponsor Servier).
- **FR104** (anti-CD28 monoclonal antibody): licensing partnership agreement with Veloxis Pharmaceuticals, Inc. in transplantation; ongoing Phase 1/2 in renal transplant (sponsored by the Nantes University Hospital); US IND obtained by Veloxis Pharmaceuticals, Inc. for a clinical trial; Phase 2 planned in an autoimmune disease indication.
- **OSE-230** (ChemR23 agonist mAb): preclinical stage therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

CoVepiT: a prophylactic second-generation vaccine activating cytotoxic T lymphocytes against COVID-19, developed using optimized epitopes from SARS-CoV2 viral proteins, epitopes non impacted by multi-variants. Shows good tolerance and very good level of T cell immune response. Results from 6-month memory T cell responses expected Q1 2022.

For more information: https://ose-immuno.com/en/
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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 15 April 2021, including the annual financial report for the fiscal year 2020, 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.