OSE Immunotherapeutics is Pleased to Announce that Veloxis Pharmaceuticals, Inc., its Partner in Transplantation, has Obtained FDA Fast-Track Designation for CD28 Antagonist VEL-101/FR104

Nantes, France - February 17, 2022 - 6:00pm CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announced that Veloxis Pharmaceuticals, Inc., an Asahi Kasei company, has obtained fast track designation from the U.S. Food & Drug Administration (FDA) for VEL-101/FR104, a novel investigational maintenance immunosuppressive agent being developed for prophylaxis of renal allograft rejection in recipients of kidney transplants. Fast track designation is granted by the FDA to facilitate the development and expedite the review of drugs that treat serious conditions and fill an unmet medical need.

"We are encouraged to receive fast-track designation for VEL-101 because it shows that the FDA recognizes the serious need to improve outcomes in kidney transplant recipients," said Mark Hensley, CEO of Veloxis. *"Veloxis is committed to developing innovative therapeutics in an effort to improve the lives of the thousands of individuals who receive kidney transplants every year."*

"We are very pleased with the FDA fast-track designation granted to VEL-101/FR104. We thank our partner Veloxis for this major milestone and for their commitment in advancing the clinical development of a promising candidate addressing a key therapeutic challenge", comments Dominique Costantini, CEO of OSE Immunotherapeutics.

VEL-101 is a pegylated monoclonal antibody fragment that binds to and blocks CD28-mediated effector-T cell costimulation, without blocking CTLA-4, an important protein found on T cells that acts as natural brakes on the body's immune responses. VEL-101 is, therefore, expected to impact immune function both directly by blocking CD28-mediated T cell activation, and indirectly through preservation of CTLA-4 mediated immunoregulatory function.

"Despite short-term improvements in outcomes, long-term kidney transplant outcomes have not improved in part due to the challenges of maintaining long-term immunosuppression," said Dr. Ulf Meier-Kriesche, Veloxis's chief scientific officer and transplant nephrologist. *"By receiving fast track designation for the VEL-101 clinical development program, we hope that more frequent interactions with the FDA and potential rolling regulatory submissions may shorten the time it will take to make VEL-101 available for kidney transplant recipients."*

About the VEL-101 Clinical Program

VEL-101 has been evaluated in a first-in-human study to assess the safety, pharmacokinetics, pharmacodynamics, and potency of IV administrations in healthy subjects (read about the study **here** [(1)]). VEL-101, a pegylated monoclonal antibody fragment CD28 antagonist, selectively blunts CD28 co-stimulation while sparing the CTLA-4 co-inhibitory signal. The net effect of CD28 antagonism is downregulating effector T cells while potentially promoting regulatory T-cell (Treg) activity.

VEL-101, also known as FR104, was licensed by Veloxis Pharmaceuticals, Inc. from OSE Immunotherapeutics in April 2021. As part of the license agreement, Veloxis Pharmaceuticals, Inc. obtained worldwide rights to develop, manufacture, and commercialize VEL-101 for all transplant indications.

(1) Poirier N., et al. J Immunol 2016; 197:4593-4602

About Veloxis Pharmaceuticals, Inc.

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 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 Health Care. 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.