



## **OSE Immunotherapeutics and Veloxis Pharmaceuticals Enter Into Global License Agreement to Develop, Manufacture, and Commercialize FR104, a CD28 Antagonist, in the Organ Transplantation Market**

- **Agreement expands Veloxis' product portfolio and the continued commitment to improving the lives of transplant patients.**
- **OSE Immunotherapeutics to receive up to €315 million in potential milestones, including a €7 million upfront, and tiered royalties on sales.**

**Nantes, France – Cary, NC, United States, April 26, 2021 - 6:00PM CET – OSE Immunotherapeutics** (ISIN: FR0012127173; Mnemo: OSE) and **Veloxis Pharmaceuticals Inc.**, a subsidiary of Asahi Kasei, today announced a global license agreement granting Veloxis Pharmaceuticals worldwide rights to develop, manufacture and commercialize FR104, a CD28 antagonist monoclonal antibody fragment, for all transplant indications. In parallel, OSE Immunotherapeutics retains all product rights to develop FR104 in autoimmune diseases. Through this license agreement, Veloxis plans to develop FR104 to provide a new therapeutic option for prophylaxis of organ rejection in patients receiving a solid organ transplant.

According to the agreement, OSE Immunotherapeutics will receive up to €315 million in potential milestones from Veloxis, including a €7 million upfront payment; development, registration and commercialization milestone payments; as well as additional tiered royalties on potential future sales. Veloxis will assume all production, development and commercialization costs in the transplant indications for FR104.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, comments: *"We are excited to begin this collaboration with Veloxis, a leading transplantation company, and the perfect partner for clinical advancement of FR104 in this field. This partnership demonstrates the outstanding value and great potential of our clinical stage product to meet patients and physicians' needs in transplantation."*

Ulf Meier-Kriesche MD, Chief Scientific Officer of Veloxis, a board-certified Nephrologist with over 20 years of practical clinical experience in transplantation, comments: *"We are very excited about the opportunity to develop this new molecular entity as a potential alternative to CNI's in the immunosuppressive regimen following kidney transplantation. The range of successful non-clinical pharmacologic, mechanistic and toxicology studies already conducted with FR-104 as well as the first-in-man data that have been generated provide us a good foundation to advance the product development. We believe this is a significant step towards addressing some of the critical unmet medical needs in transplantation. It also reinforces our commitment to our patients and the transplant community we serve."*



#### **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 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](http://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 health care 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](http://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. The company's immunology research and development platform is focused on three areas: T-cell-based vaccination, Immuno-Oncology (focus on myeloid targets), Auto-immunity & Inflammation. Its balanced first-in-class clinical and preclinical portfolio has a diversified risk profile:

##### **Vaccine platform**

- **Tedopi®** (innovative combination of neoepitopes): the company's most advanced product; positive results for Step-1 of the Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer post checkpoint inhibitor failure. In Phase 2 in pancreatic cancer (TEDOPaM, sponsor GERCOR). In Phase 2 in ovary cancer (TEDOVA, sponsor ARCAGY-GINECO) in combination with pembrolizumab. *Due to the COVID-19 crisis, accrual of new patients in TEDOPaM should restart in 2021.*
- **CoVepiT:** a prophylactic second-generation vaccine against COVID-19, developed using SARS-CoV-2 optimized epitopes against multi variants. Positive preclinical and human ex vivo results in August 2020. In clinical Phase 1.

##### **Immuno-oncology platform**

- **BI 765063** (OSE-172, anti-SIRPα mAb on SIRPα/CD47 pathway): developed in partnership with Boehringer Ingelheim; myeloid checkpoint inhibitor in Phase 1 in advanced solid tumors.
- **CLEC-1** (novel myeloid checkpoint target): identification of mAb antagonists of CLEC-1 blocking the "Don't Eat Me" signal that increase both tumor cell phagocytosis by macrophages and antigen capture by dendritic cells.
- **BiCKI®:** bispecific fusion protein platform built on the key backbone component anti-PD-1 (OSE-279) combined with new immunotherapy targets; 2<sup>nd</sup> generation of PD-(L)1 inhibitors to increase antitumor efficacy.

##### **Auto-immunity and inflammation platform**

- **FR104** (anti-CD28 monoclonal antibody): positive Phase 1 results; ongoing Phase 1/2 in renal transplant (sponsored by the Nantes University Hospital); Phase 2-ready asset in a niche indication in autoimmune diseases.
- **OSE-127/S95011** (humanized monoclonal antibody targeting IL-7 receptor): developed in partnership with Servier; positive Phase 1 results; in Phase 2 in ulcerative colitis (OSE sponsor) and an independent Phase 2 planned in Sjögren's syndrome (Servier sponsor).



- **OSE-230** (ChemR23 agonist mAb): first-in-class therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

For more information:

Click and follow us on Twitter and LinkedIn



#### Contacts

##### **OSE Immunotherapeutics**

Sylvie Détry  
Sylvie.detry@ose-immuno.com  
+33 153 198 757

##### **French Media: FP2COM**

Florence Portejoie  
fportejoie@fp2com.fr  
+33 607 768 283

##### **U.S. Media: LifeSci Communications**

Darren Opland, Ph.D.  
darren@lifescicomms.com  
+1 646 627 8387

##### **U.S. and European Investors**

Chris Maggos  
chris@lifesciadvisors.com  
+41 79 367 6254

#### 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.