

OSE Immunotherapeutics Welcomes First Patient Dosed by Veloxis in the Phase 2 RENGEVITY-201 Trial Evaluating Pegrizeprium (VEL-101) for the Prevention of Organ Rejection in Kidney Transplant Recipients

Nantes, France, September 9, 2026 – 6pm CEST – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) (the “Company”) welcomes the announcement by its licensee Veloxis Pharmaceuticals, Inc. that the first patient has been dosed in RENGEVITY-201, a Phase 2 clinical trial evaluating pegrizeprium (VEL-101) for the prevention of organ rejection in kidney transplant recipients.

Pegrizeprium (also known as VEL-101) is a novel investigational immunomodulatory monoclonal monovalent antibody fragment originally discovered and developed by OSE Immunotherapeutics and licensed to Veloxis in 2021 for all transplant-related indications. Veloxis is responsible for the worldwide development, manufacturing and future commercialization of the product.

Veloxis’ full press release is available [here](#).

ABOUT PEGRIZEPRUMENT

Pegrizeprium is a pegylated monoclonal monovalent 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 naturally helps keep the body’s immune responses in check. Pegrizeprium is, therefore, expected to have a dual mechanism of action where in a direct manner, it blocks CD28-mediated T cell activation, and indirectly, it allows for CTLA-4 mediated immunosuppressive functions. Pegrizeprium is currently being developed for the prevention of rejection in solid organ transplant recipients.

The U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to pegrizeprium for the prevention of organ rejection in patients receiving a liver transplant in December 2025 and for the prophylaxis of heart allograft rejection in patients receiving a heart transplant in March 2026.

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

ABOUT OSE IMMUNOTHERAPEUTICS

OSE Immunotherapeutics is a biotech company dedicated to developing first-in-class assets in immuno-oncology (IO) and immuno-inflammation (I&I) that address the unmet patient needs of today and tomorrow. We partner with leading academic institutions and biopharmaceutical companies in our efforts to develop and bring to the market transformative medicines for people with serious diseases. OSE Immunotherapeutics is based between Nantes and Paris and is listed on Euronext. Additional information about OSE Immunotherapeutics assets is available on the Company’s website: www.ose-immuno.com. Follow us on [LinkedIn](#).

Contacts

OSE Immunotherapeutics: investors@ose-immuno.com

FP2COM (Media Relations): Florence Portejoie: fportejoie@fp2com.fr | +33 6 07 768 283

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 considering 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 April 30, 2025, including the annual financial report for the fiscal year 2024, 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.