

## **OSE Immunotherapeutics Welcomes FDA Orphan Drug Designation Granted to Pegrizeprium (VEL-101) for Prevention of Organ Rejection in Heart Transplant Patients**

**Nantes, France, April 27, 2026 – 7:30am CEST - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE),** today welcomes the announcement by its partner Veloxis Pharmaceuticals, Inc. that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to pegrizeprium (VEL-101) for the prophylaxis of heart allograft rejection in patients receiving a heart transplant. This follows the recent ODD granted in January 2026 for prevention of organ rejection in patients receiving a liver transplant.

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

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 global development, manufacturing, and future commercialization of the product.

### **ORPHAN DRUG DESIGNATION**

The FDA Orphan Drug Designation program grants orphan status to investigational drugs and biologics which aim to prevent, diagnose or treat rare diseases and medical conditions that affect fewer than 200,000 people in the United States. This law encourages development of treatments for patients with rare diseases whose conditions are traditionally undertreated.

### **ABOUT PEGRIZEPRUM**

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.

Pegrizeprium, also known as VEL-101 and 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 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](http://www.ose-immuno.com). Follow us on [LinkedIn](#).

## Contacts

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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 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.