OSE Immunotherapeutics Welcomes FDA Orphan Drug Designation Granted to Pegrizeprument (VEL-101)

Nantes, France, January 21, 2026 – 6pm CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE), today acknowledges the announcement by its partner Veloxis Pharmaceuticals, Inc. that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to pegrizeprument (VEL-101) for the prevention of organ rejection in patients undergoing liver transplantation.

Veloxis' full press release is available here.

Pegrizeprument (also known as VEL-101) is a novel investigational immunomodulatory monoclonal 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.

"This designation underscores the need for better options in solid organ transplantation and marks an important step in pegrizeprument's development. We congratulate Veloxis on this achievement, which highlights the promise of this innovative therapeutic approach," said **Sonya Montgomery, Chief Development Officer, OSE Immunotherapeutics**.

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 PEGRIZEPRUMENT

Pegrizeprument 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 naturally helps keep the body's immune responses in check. VEL-101 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. Pegrizeprument is currently being developed to prevent rejection following kidney transplantation (NCT07290777).

Pegrizeprument, 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 pegrizeprument 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.

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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.