OSE Immunotherapeutics Announces Positive Recommendation from Independent Data Monitoring Committee (IDMC) to Continue Pivotal Phase 3 ARTEMIA Trial Evaluating Tedopi® in Non-Small Cell Lung Cancer

NANTES, France, November 17, 2025 – 6:00pm CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE), a clinical-stage biotechnology company developing immunotherapies for cancer and autoimmune diseases, today announced that the Independent Data Monitoring Committee (IDMC) overseeing the Company's international pivotal Phase 3 clinical trial, ARTEMIA, evaluating Tedopi® in non-small cell lung cancer (NSCLC), has issued a positive recommendation to continue the study without modifications.

As outlined in the study protocol of ARTEMIA, the IDMC meets on a regular basis to review data from the ongoing trial. The IDMC is a group of independent experts including one US and one European lung cancer expert and an independent statistician who are external to the study. Their role is to assess the progress, safety data and critical efficacy endpoints of the clinical trial for safeguarding the interest of study participants. The IDMC provides the sponsor and the Steering committee with recommendations regarding study modification, continuation or termination. IDMCs are customary for large, randomized, multi-site studies, such as ARTEMIA.

Dr. Silvia Comis, Chief Clinical and Medical Research Officer at OSE Immunotherapeutic, said. *"We are very pleased with the IDMC's recommendation to continue our Phase 3 trial without changes. As of early October, date of the IDMC meeting, 102 patients had been randomized in the trial. We are now approaching 120, fully aligned with our enrollment projections for 2025."*

The ARTEMIA trial was launched in September 2024 and is designed to compare Tedopi® monotherapy to standard-of-care docetaxel in HLA-A2 positive patients with metastatic NSCLC who have developed secondary resistance to immune checkpoint inhibitors. The study is being conducted across multiple international sites in Europe, UK, USA and Canada and aims to provide confirmatory data to support regulatory submission.

A second IDMC review is anticipated in Q1 2026. Completion of recruitment in the ARTEMIA trial is foreseen for end of 2026, with readout for primary endpoint of overall survival in Q1 2028.

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 quoted on Euronext.
Additional information about OSE Immunotherapeutics assets is available on the Company's website: www.ose-immuno.com. Click and 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.