OSE Immunotherapeutics and the FoRT Foundation Announce Completion of Enrollment in Combi-TED, a Phase 2 Clinical Trial Evaluating Tedopi® in Combination with Nivolumab or Docetaxel in Patients with Non-Small Cell Cancer

- **A total of 105 HLA-A2 positive patients enrolled in the Combi-TED study, which explores the combination of Tedopi® with either an anti-PD1 checkpoint inhibitor or chemotherapy as a second-line treatment for metastatic Non-Small Cell Lung Cancer following first-line chemo-immunotherapy.**
- **Top-line results expected in the second half of 2026.**

NANTES, France – ROME, Italy - September 11, 2025, 6:00 p.m. CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE), a biotechnology company focused on developing first-in-class therapies in immuno-oncology and immuno-inflammation, and the **FoRT Foundation (Fondazione Ricerca Traslazionale)** today announced the completion of patient enrollment in a Phase 2 clinical trial evaluating the neoepitope-based therapeutic cancer vaccine Tedopi® in combination with nivolumab or docetaxel in patients with Non-Small Cell Lung Cancer (NSCLC).

The clinical trial (NCT04884282) is sponsored and conducted by the Italian Foundation FoRT across sites in Italy, France and Spain.

Combi-TED is an open label, randomized, three-arm Phase 2 study evaluating Tedopi® in combination with the anti-PD1 immune checkpoint inhibitor Opdivo® (nivolumab) or Tedopi® plus docetaxel or docetaxel alone (reference arm) as second-line treatment in HLA-A2 positive patients with metastatic NSCLC and no evidence of EGFR mutations or ALK or ROS1 rearrangement, after first-line chemo-immunotherapy. The primary endpoint is 1-year survival rate. As planned, 105 patients were enrolled in the clinical study, and the readouts are expected in the second half of 2026 (Presentation at the ESMO 17-21 Oct. 2025: 2085eTrial in Progress (TiP): OSE2101 plus docetaxel or nivolumab as second line therapy in metastatic non-small-cell lung cancer (mNSCLC) progressing after first line chemoimmunotherapy (Combi-TED).

Federico Cappuzzo, M.D., Ph.D., Director Medical Oncology at Cancer Institute Regina Elena, Roma, Italy, and Chief Investigator of the study, comments: *"We are very pleased to announce the completion of enrollment in Combi-TED, an exploratory Phase 2 evaluating a new treatment strategy with the combination of therapeutic cancer vaccine Tedopi® which, by activating T lymphocytes, might efficiently optimize a checkpoint inhibitor or chemotherapy treatment. We are now looking forward to the results of this study, expected in 2026, as they will contribute to guiding the next steps in the development of new therapies for NSCLC patients progressing after at least three months (four cycles) of first-line chemo-immunotherapy, and eligible for treatment with docetaxel, a population who needs new treatment options".*

Silvia Comis, Chief Clinical and Medical Research Officer, concludes: *"We warmly thank Professor Federico Cappuzzo for reaching this important milestone in evaluating innovative second-line combinations of Tedopi® with either an immuno-therapeutic agent or chemotherapy. This achievement marks another step forward in the clinical development of Tedopi® for NSCLC. Building on the positive results of the ATALANTE-1 study, Tedopi® is currently being investigated as a monotherapy compared to docetaxel in the ARTEMIA pivotal trial, as second-line in HLA-A2 positive patients with metastatic NSCLC[1] and, differently from Combi-TED, with secondary resistance to Immune-Checkpoint Inhibitors (ICI), defined as disease progression after ≥ 6 months of first line chemo-immunotherapy[2]. Combi-TED will therefore provide further information on the relevance of Tedopi® when administered in combination as second-line in a broader metastatic NSCLC population, including patients with more aggressive disease".*

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.

[1] With no molecular alterations for which a treatment is locally available.
[2] Including at least 3 months of anti-PD(L)1 as maintenance monotherapy or in combination with another ICI prior to randomization.