OSE Immunotherapeutics Announces Positive Clinical Progress for Late-Stage Proprietary Cancer Vaccine Tedopi®

- **ARTEMIA: Clinical trial protocol approved globally. Most countries and sites activated, with full activation expected in H1 2025. First patients enrolled in this international Phase 3 registration study of Tedopi® in monotherapy in second-line Non-Small Cell Lung Cancer (NSCLC).**
- **TEDOVA: Completion of patient enrollment in the Phase 2 study of Tedopi® alone or in combination with Keytruda® in ovarian cancer; a trial sponsored and conducted by the French oncology cooperative group ARCAGY-GINECO. Readouts expected in Q2 2026.**
- **CombiTED: Completion of patient enrollment in Phase 2 study of Tedopi® in combination with Opdivo® in second-line NSCLC expected in Q1 2025; a trial sponsored and conducted by the Italian foundation FoRT. Readouts expected in the H2 2026.**
- **TEDOPaM: Patient enrollment completed last year in the Phase 2 study of Tedopi® in combination with chemotherapy in advanced or metastatic pancreatic ductal adenocarcinoma; a trial sponsored and conducted by the French oncology cooperative group GERCOR. Results expected in H1 2025.**

NANTES, France, December 11, 2024 – 6:00pm CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE), today provided a clinical update on Tedopi® (OSE-2101), the *'off-the-shelf'* neoepitope-based therapeutic cancer vaccine, under evaluation in a range of cancer indications where there is large unmet medical need.

Silvia Comis, MD, Head of Clinical Development and Regulatory Affairs, OSE Immunotherapeutics said*: "Tedopi® is currently being evaluated in monotherapy and in combination through four clinical trials and three cancer indications. Not only is the clinical program fully on track, but our progress highlights the potential to address diverse medical needs. This 'pipeline in a product' approach underscores our commitment to bringing innovative solutions to patients who need them most. The enrollment of the first patients this year in Artemia, our global Phase 3 registration study signifies a pivotal milestone, advancing us towards the final phase before the registration of Tedopi® for the treatment of NSCLC. Enrollment has also been completed in the combination Phase 2 trial, TEDOVA, in ovarian cancer and we are nudging towards completion of patient enrollment for the Phase 2 study in NSCLC. For both TEDOVA and CombiTED we are expecting readouts in 2026. Finally, we can expect the Phase 2 readouts for the study TEDOPaM in pancreatic cancer early next year."*

Dr Alexandra Leary, M.D., Ph.D., Chief Investigator of TEDOVA study from Gustave Roussy cancer center, comments: *"We are very grateful to the investigators and to the patients involved in TEDOVA for this key clinical achievement. This is the first trial evaluating an innovative maintenance strategy for patients with ovarian cancer in relapse post-bevacizumab and PARP inhibitors, a patient population which does not respond to checkpoint inhibitors alone, and which urgently needs novel maintenance*

strategies to prolong chemotherapy-free intervals. We now look forward to the study's results to confirm the potential of Tedopi® as a novel maintenance therapy for these women."

TEDOVA is a two-arm Phase 2 study evaluating Tedopi® as a maintenance treatment, alone or in combination with anti-PD-1 immune checkpoint inhibitor Keytruda® (pembrolizumab) versus best supportive care in patients with first or second platinum-sensitive recurrent ovarian cancer with controlled disease after platinum-based chemotherapy who have already received both bevacizumab and a PARP (Poly ADP-Ribose Polymerase) inhibitor. The primary criterion is to evaluate the benefit by the Progression Free Survival (PFS) of the maintenance of Tedopi® alone or in combination with a PD1 inhibitor after platinum-based chemotherapy in relapsed ovarian cancer. A total of 180 patients were included in the trial and the readouts are expected in Q2 2026 *(NCT04713514, sponsor: ARCAGY-GINECO)*.

CombiTED is a three-arm Phase 2 study evaluating Tedopi® in combination with anti-PD1 immune checkpoint inhibitor Opdivo® (nivolumab) or Tedopi® plus chemotherapy or chemotherapy alone as second-line treatment in HLA-A2 positive patients with metastatic NSCLC after first-line chemo-immunotherapy. A total of 105 patients are planned for the trial and enrollment completion is expected in Q1 2025. The readouts are expected in H2 2026 *(NCT04884282, sponsor: FoRT).*

TEDOPaM is a non-comparative Phase 2 trial evaluating Tedopi® plus FOLFIRI chemotherapy versus FOLFIRI as maintenance treatment in patients (HLA-A2 genotype) with advanced or metastatic pancreatic ductal adenocarcinoma (PDAC) with no progression after eight cycles of FOLFIRINOX induction chemotherapy. The primary endpoint of the trial is the one-year overall survival (OS) rate (Fleming- futility analysis; null hypothesis ≤25%; alternative hypothesis ≥ 50%), and the key secondary endpoint is the progression-free survival. A total of 136 patients were recruited in the Phase 2 trial and readouts are expected in H1 2025 *(NCT03806309, sponsor: GERCOR)*.

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 X and LinkedIn

Contacts

Fiona Olivier
fiona.olivier@ose-immuno.com

Sylvie Détry
sylvie.detry@ose-immuno.com

French Media: FP2COM
Florence Portejoie
fportejoie@fp2com.fr
+33 6 07 768 283

U.S. Media Contact
RooneyPartners LLC
Kate Barrette
kbarrette@rooneypartners.com
+1 212 223 0561

Forward-looking statements

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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, 2024, including the annual financial report for the fiscal year 2023, 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