OSE Immunotherapeutics Reports Positive Topline Results of TEDOVA Phase 2 Trial with Tedopi® in Recurrent Ovarian Cancer

- Topline results to be presented by Alexandra Leary, MD, PhD, on May 30, 2026, at the 2026 Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago
- OSE Immunotherapeutics to host a KOL webcast on June 10, 2026

Nantes, France, May 22, 2026 – 7:30am CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE), a clinical-stage biotech company dedicated to developing first-in-class therapies in immuno-oncology and immuno-inflammation, today announced the release of the abstract selected for an oral presentation at the upcoming ASCO 2026 Annual Meeting, unveiling topline results from the TEDOVA/GINECO-OV244b/ENGOT-ov58 academic, international, Phase 2 trial sponsored by ARCAGY-GINECO and evaluating Tedopi® (OSE2101), with or without pembrolizumab, as a maintenance treatment in patients with platinum-sensitive recurrent ovarian cancer (PSOC).

Alexandra Leary, MD, PhD, Deputy Head of the Department of Medical Oncology at Gustave Roussy (Paris, France), oncologist specialising in gynaecological cancers, Chair of the GINECO group and Lead Investigator of the TEDOVA Phase 2 clinical trial of Tedopi®, commented: *"Ovarian cancer (OC) patients treated with platinum sensitive relapse post bevacizumab and PARP-inhibitors represent an unmet medical need with a progression free survival (PFS) of less than 3 months post platinum-based chemotherapy. In this difficult to treat setting, the combination of OSE2101 and pembrolizumab as maintenance significantly improved PFS. TEDOVA brings the 1st proof of concept for a vaccine strategy in OC, and actually the 1st positive trial in platinum sensitive OC in years!"*

The TEDOVA Phase 2 trial enrolled 185 patients with PSOC who have progressed after or were ineligible for PARP inhibitors and bevacizumab. Patients with complete response, partial response, or stable disease after platinum-based therapy were randomized (1:1:2) to receive maintenance treatment with either best supportive care (control arm A), Tedopi® monotherapy (arm B), or Tedopi® in combination with pembrolizumab (arm C). The primary endpoint was progression-free survival (PFS) comparing Arm C vs Arm A. (NCT04713514)

The primary endpoint was met and results showed a statistically significant improvement in PFS for the combination of Tedopi® and pembrolizumab compared to best supportive care (median PFS: 4.1 months vs 2.8 months; HR=0.53; p<0.001). When comparing the two investigational arms, the addition of pembrolizumab to Tedopi® resulted in a 28% reduction in the risk of progression or death (HR=0.72, p=0.074).

The combination with pembrolizumab to Tedopi® was associated with an increased incidence of adverse events, including immune-related events, consistent with the mechanism of action of immunotherapy.

These results will be presented on May 30, 2026, at the ASCO 2026 Annual Meeting in Chicago by Lead Investigator Alexandra Leary, MD, PhD.

In addition, OSE will be hosting a KOL webcast on June 10, 2026, to discuss how Tedopi® could benefit patients affected by multiple oncology indications with key opinion leaders **Stephen Liu, MD** (MedStar Georgetown University Hospital), **Benjamin Besse, MD** (Gustave Roussy Institute, Paris) and **Alexandra Leary, MD, PhD** (Gustave Roussy Institute, Paris).

Marc Le Bozec, Chief Executive Officer, commented: *"Thanks to the collaboration with ARCAGY-GINECO, these results provide further clinical evidence supporting the potential of Tedopi® in difficult-to-treat cancers such as ovarian cancer. The data highlight both the clinical activity of Tedopi® as monotherapy and its strong synergy in combination with anti-PD-1 therapy in heavily pretreated patients. These findings reinforce our strategy to advance Tedopi® in Phase 3 development in non-small cell lung cancer, as well as in combination approaches through investigator-sponsored trials in ovarian, pancreatic, and lung cancers in collaboration with leading academic groups, with data expected through 2026."*

KOL Webcast on Wednesday, June 10, 2026
6pm CET / noon ET

Live in English with optional French subtitles
Link to Webcast: http://bit.ly/4tMxhzG

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.

ABOUT ARCAGY-GINECO

ARCAGY-GINECO (*Groupe d'Investigateurs National pour l'Étude des Cancers de l'Ovaire et du sein*) is a cooperative group founded in 1993 and accredited by the French National Cancer Institute (INCa). It specializes in clinical and translational research in the field of women's cancers (gynecologic cancers and metastatic breast cancer). Its mission is to help improve survival and quality of life for patients by initiating and coordinating clinical trials in France and internationally. ARCAGY-GINECO contributes to the validation of scientific hypotheses by defining new standards of treatment and disseminating these results worldwide. More information on www.arcagy.org and our LinkedIn page.

ABOUT ENGOT

ENGOT (European Network for Gynecological Oncological Trial groups) is a research network of the European Society of Gynecological Oncology (ESGO) and was founded in 2007. Currently, ENGOT includes 21 cooperative groups from 33 European countries. Visit ENGOT website https://engot.esgo.org/ of LinkedIn page.

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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.