OSE Immunotherapeutics Reports Additional Positive Results of Combi-TED Phase 2 Randomized Trial with Tedopi® (OSE2101) in metastatic Non-Small Cell Lung Cancer

- Final positive readout for primary and several secondary endpoints presented by Federico Cappuzzo, MD, PhD, on October 25, 2026, at the Annual Meeting of the European Society for Medical Oncology (ESMO) in Madrid
- 12-month OS rate and median OS point in favour of combining Tedopi® with chemotherapy docetaxel or immunotherapy nivolumab
- OSE Immunotherapeutics to host a KOL webcast on November 4, 2026

Nantes, France, October 29, 2026 – 6:00pm 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 reported final positive results from the Combi-TED academic Phase 2 international clinical trial of Tedopi® after an oral presentation at the ESMO 2026 Annual Meeting. The study was sponsored by FoRT and evaluated Tedopi® (OSE2101), in combination with either chemotherapy or anti-PD1, as a 2nd line treatment in 106 patients with metastatic Non-Small Cell Lung Cancer (NSCLC).

Federico Cappuzzo, MD, PhD, Director of Medical Oncology at the National Cancer Institute Regina Elena (Rome, Italy) and Lead Investigator of the trial, commented: *"I am very excited with the results of the Combi-TED phase 2 study, in which Italy, France and Spain participated actively. The overall survival observed when combining Tedopi® with docetaxel or nivolumab is a strong signal suggesting that outperforming docetaxel in this hard-to-treat population, with an acceptable safety profile, may finally be achieved. We are now eager to see what Tedopi® will do as a monotherapy versus docetaxel in the ongoing ARTEMIA phase 3 trial."*

Combi-TED is an open label, randomized, three-arm Phase 2 study evaluating Tedopi® in combination with docetaxel (n = 36) or the anti-PD1 immune checkpoint inhibitor nivolumab (Opdivo®; n = 35), or docetaxel alone (reference arm; n = 35) as second-line treatment in 106 HLA-A2 positive patients with metastatic NSCLC and no evidence of EGFR mutations or ALK or ROS1 rearrangement, after first-line chemo-immunotherapy.

In each study arm, patients were treated every 3 weeks for up to 6 cycles. Docetaxel was dosed at 60mg/m² when combined with Tedopi® and 75mg/m² in the reference arm. From cycle 7 onward, Tedopi® was administered every 6 weeks until 12 months, then every 12 weeks. Nivolumab continued every 3 weeks in the combination arm with Tedopi®. Treatment continued according to protocol until progression, unacceptable toxicity, patient refusal or a maximum of 6 cycles for docetaxel alone.

The primary endpoint was 1-year Overall Survival (OS) rate. As per protocol, each study arm was tested against a predefined 20% survival benchmark using a one-sided exact binomial test at a 5% significance level. The P values therefore refer to comparisons against the 20% benchmark, rather than direct comparisons between treatment arms. Secondary endpoints included median OS, Progression-Free Survival (PFS), Objective Response Rate (ORR) and safety. The trial was conducted in 19 sites in France, Italy and Spain.
(NCT04884282)

As reported on October 19, **the primary endpoint was met and results showed a statistically significant 1-year OS rate for both combinations of Tedopi®** with docetaxel (OS = 47%; n = 17/36 subjects; 90% CI 33-62; p < 0.001) and Tedopi® with nivolumab (OS = 46%; n = 16/35 subjects; 90% CI 31-61; p < 0.001) but not for docetaxel alone (OS = 29%; n = 10/35 subjects; 90% CI 16-44; p = 0.15).[1]

In exploratory Phase 2 studies with limited sample size, Bayesian analyses can be used as decision-support tools, with Go/No-Go criteria defined using different levels of stringency. In Combi-TED, a particularly challenging threshold of 95% was selected to classify a combination as "promising" (in order to mimic the p value of 5% of frequentist analysis) for initiating a Phase 3 study. Bayesian analyses suggest a posterior probability of 94.6% and 92.8% of improved 1-year OS versus docetaxel alone for Tedopi® combined with docetaxel and nivolumab, respectively. Both analyses clearly favored combinations with Tedopi®, and although neither reached the predefined 95% threshold, both were very close to this highly demanding benchmark.

Median OS reached 11.9 months (90% CI 8.9-15.3) for Tedopi® + docetaxel, 11.3 months (90% CI 6.1-13.3) for Tedopi® + nivolumab and 6.4 months (90% CI 5.2-9.0) for docetaxel alone.

Median PFS reached 4.8 months (90% CI 2.4-5.7) for Tedopi® + docetaxel, 2.7 months (90% CI 2.1-4.1) for Tedopi® + nivolumab and 2.3 months (90% CI 1.9-4.1) for docetaxel alone.

ORR was 20% for Tedopi® + docetaxel and 10% for docetaxel alone. No responses were reported for the combination with nivolumab.
Treatment-related adverse events occurred in 89% (Tedopi® + docetaxel), 82% (Tedopi® + nivolumab), and 79% (docetaxel alone) of patients. Drug-related serious adverse events were reported in 17% (Tedopi® + docetaxel), 24% (Tedopi® + nivolumab), and 17% (docetaxel alone) of patients. No unexpected safety signals were observed.

OSE will be hosting a KOL webcast on November 4, 2026, to discuss these results and better understand what could Tedopi® bring to NSCLC patients having progressed after a 1st line chemo-immunotherapy in the context of a high medical need, with international experts **Stephen Liu, MD** (MedStar Georgetown University Hospital) and **Federico Cappuzzo, MD, PhD** (National Cancer Institute Regina Elena, Rome).

[1] P values slightly differ from the initial abstract as reported on October 19, 2026, as data were still preliminary at time of submission. Results are now final. The difference is marginal and does not modify the statistical analysis.

"Combi-TED successfully achieved its predefined primary endpoint in both experimental arms, demonstrating 12-month overall survival rates significantly above the 20% threshold. The complementary exploratory Bayesian analysis provides a positive quantitative assessment of the chances of achieving a survival benefit versus the control arm in future studies", commented **Silvia Comis, MD**, Chief Clinical and Medical Research Officer. *"These data, together with those presented at ASCO in 2025 and 2026, suggest that Tedopi® may be used in combination with various chemotherapies (such as docetaxel, 5-FU, irinotecan, oxaliplatin) and with anti-PD1/anti-PDL1 agents, leading to increased efficacy without compromising patient safety. Tedopi® may therefore become a key partner for many other compounds, such as ADCs, TKIs or bispecific antibodies, across various tumour types and lines of treatment."*

KOL Webcast on Wednesday, November 4, 2026
5pm CET / 11am ET

Live in English with optional French subtitles
Link to Webcast: https://bit.ly/3UpDfL8

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 FORT

FoRT (*Fondazione Ricerca Traslazionale*) aims to support oncology research by optimizing available treatments and striving to improve patient life expectancy. Numerous anti-cancer drugs are available in oncology; unfortunately, only a few patients benefit from these treatments, while many experience their side effects. Translational research makes it possible to identify which patients will benefit from a treatment and which will not. Translational research also helps determine the prognostic value of various biological factors, allowing physicians to better predict the progression of the disease. FoRT's activities include promoting clinical and preclinical studies, supporting scientific initiatives, and disseminating and publishing the resulting scientific data. Furthermore, FoRT seeks to provide concrete assistance to patients in navigating the management of their disease and accessing the best available therapeutic options. More information on www.fondazionefort.org.

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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 June 4, 2026, including the annual financial report for the fiscal year 2025, 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.