OSE Immunotherapeutics Provides Clinical Updates on Neo-Epitope Based Cancer Vaccine Tedopi® in Pancreatic Cancer and Non-Small Cell Lung Cancer

- **Two presentations at the American Society of Clinical Oncology (ASCO) 2025:**
  - **TEDOPaM - Phase 2 first positive results in advanced pancreatic cancer: Oral communication presented by the French GERCOR Oncology Group, trial sponsor.**
  - **ARTEMIA - International pivotal Phase 3 study in Non-Small Lung Cancer (NSCLC): Trial in Progress.**

NANTES, France – June 2, 2025, 6:00pm CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE), today provided clinical updates on Tedopi®, the "off-the-shelf" neo-epitope-based therapeutic cancer vaccine under evaluation in both monotherapy and combination therapy across five clinical trials in several cancer indications.

Silvia Comis, MD, Chief Clinical and Medical Research Officer OSE Immunotherapeutics, commented: *"We are pleased to share the latest clinical updates on our cancer vaccine Tedopi® at the ASCO Annual Meeting. Tedopi® combines 10 neo-epitopes derived from five tumor antigens, selected for their presence in a range of tumors, offering a multi-target "pipeline in a product" approach for HLA-A2 positive patients to address unmet needs in oncology. The positive results for Tedopi® in pancreatic cancer are promising for this devastating disease with a poor prognosis. We extend our gratitude to the GERCOR Oncology Group and the PRODIGE Intergroup, sponsors of the TEDOPaM study, for presenting these encouraging results at ASCO.*

In lung cancer, patient recruitment is progressing per plan in the Artemia Phase 3 registration study, a key milestone bringing us one step closer to the registration of Tedopi® for NSCLC.

As previously communicated, the readouts of the combination Phase 2 trials, CombiTED for NSCLC and TEDOVA for ovarian cancer, are expected in 2026."

TEDOPaM - An oral communication, titled ***"Maintenance with OSE2101 plus FOLFIRI vs FOLFIRI alone after FOLFIRINOX induction in patients with advanced pancreatic ductal adenocarcinoma (PDAC): Primary endpoint results of a randomized TEDOPAM GERCOR D17-01 PRODIGE 63 trial"*** (abstract 4009) featuring positive topline Phase 2 results for the clinical trial TEDOPaM was presented by the GERCOR Oncology Group at ASCO 2025.

TEDOPaM is a randomized, non-comparative, Phase 2 trial evaluating FOLFIRI[1] (Arm A) and cancer vaccine Tedopi® (OSE2101) plus FOLFIRI chemotherapy (Arm B) as maintenance treatment in HLA-A2 positive patients with advanced or metastatic Pancreatic Ductal Adenocarcinoma (PDAC) with no progression after eight cycles of FOLFIRINOX induction chemotherapy[2]. The primary endpoint of the trial was the one-year overall survival (OS) rate in the experimental Arm B (Fleming 2-stage design, H0:

[1] *FOLFIRI: A combination chemotherapy with folinic acid, fluorouracil and irinotecan*

[2] *FOLFIRINOX: A combination chemotherapy with folinic acid, fluorouracil, irinotecan and oxaliplatin*

25%; H1: 50%, 1-sided alpha: 2.5%, power: 90%). 107 patients (53 patients in Arm A and 54 patients in Arm B) were enrolled *(NCT03806309)*.

The TEDOPaM trial met its primary objective, showing positive outcomes according to the predefined statistical hypothesis, with a 12-month OS of 65% in Arm B, and minimal toxicity for Tedopi® combined with FOLFIRI as maintenance treatment. Two complete responses were observed when adding Tedopi®. No new safety signal was observed.

Prof. Cindy Neuzillet, MD, PhD (Curie Cancer Research Institute, Saint-Cloud), Principal Investigator of the TEDOPaM study stated: *"These results are an encouraging first step towards better understanding the contribution of Tedopi® in combination therapy in advanced pancreatic cancer. We now need more mature data on overall survival over a longer period. A translational and biomarker program is also underway to identify patient profiles likely to benefit from this maintenance treatment involving a neo-epitope-based cancer vaccine. Thanks to the digestive oncology community for their support in this research, which helps us better understand this disease."*

Detailed results: A total of 107 patients were randomized between April 2021 and May 2023. The median age was 64 years, with 53% men and 69% having metastases. The median number of Tedopi® injections was 7.5. At the data cut-off on December 9, 2024, the median follow-up was 21 months.

- **The TEDOPaM study met its primary endpoint**: M12-OS was 65% in Arm B (FOLFIRI + Tedopi®).
- **With a median follow-up of 21 months**, around 35% of death events were observed.
- **An unexpectedly long OS was observed in these PDAC patients with disease control after induction FOLFIRINOX**: median OS of 17 months in control Arm A (versus 10-12 months expected).
- **Two complete responses** were observed when adding Tedopi® in Arm B, and none in control Arm A with chemotherapy alone.
- **Safety**: 26% in Arm B reported serious adverse events (SAEs). 6% related to Tedopi®. No new safety signal was reported.
- **Further follow-up for OS and safety data** is ongoing.
- **A comprehensive translational analysis** (IMMUNOPANC-Sign program) is ongoing.

ARTEMIA - A "Trial in Progress" poster titled: ***"Phase 3 trial of the therapeutic cancer vaccine OSE2101 versus docetaxel in patients with metastatic non-small cell lung cancer and secondary resistance to immunotherapy"*** was also presented at ASCO 2025. The Phase 3 pivotal clinical trial aims to support the registration of Tedopi® as a second-line treatment in HLA-A2 positive NSCLC patients with secondary resistance to anti-PD-(L)1 immunotherapy. This pivotal trial is conducted in 14 countries across the United States, Canada, Europe, and United Kingdom. ARTEMIA will include 363 patients and enrolment is progressing according to the study program *(NCT06472245)*.

ABOUT RESECTED PANCREATIC DUCTAL ADENOCARCINOMA (PDAC).

Resected pancreatic ductal adenocarcinoma (PDAC) is a highly aggressive form of cancer originating in the ducts of the pancreas. It represents about 95% of all pancreatic cancers. The global burden of pancreatic cancer has

more than doubled in recent decades. It is now the sixth leading cause of cancer-related death worldwide, with an estimated 510,922 new cases and 467,409 deaths in 2022. The incidence of the disease continues to rise annually, with projections indicating a 95.4% increase in new cases by 2050, potentially reaching a total of 998,663 new cases globally. The overall five-year survival rate for pancreatic cancer is 10% worldwide, with only modest improvement in the past decade[3]. Pancreatic cancer is now the 10th most found cancer in the US[4] and represents about 3.5% of all new cancer diagnoses, and 7.1% of all cancer deaths in the EU[5].

Surgical resection is the only potential curative treatment for PDAC, but it's feasible for only 15-20% of patients at diagnosis due to the advanced stage of their disease[6]. Even with successful surgery, the prognosis remains poor, with a high likelihood of recurrence. Advances in neoadjuvant therapies, which are treatments given before surgery, have improved the chances of achieving a margin-negative resection, meaning no cancer cells are found at the outer edge of the removed tissue. However, long-term survival rates remain low, underscoring the need for continued research and development of more effective systemic therapies to improve outcomes for patients with resected PDAC[7].

ABOUT GERCOR

GERCOR is a multidisciplinary association dedicated to clinical research in oncology whose purpose is to improve the care of patients affected by cancer by developing clinical research in the scope of an independent, multidisciplinary and multi-focused cooperative group. GERCOR concentrates its efforts on only one mission: clinical research. Thanks to its network, GERCOR offers patients easy access to its up-to-date treatments. To achieve this goal, GERCOR has all the logistical structure needed to carry out the trials it promotes.

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.

[3] Trends in the Global Incidence of Pancreatic Cancer and a Brief Review of its Histologic and Molecular Subtypes | Journal of Gastrointestinal Cancer
[4] American Cancer Society: Annual Cancer Facts & Figures | American Cancer Society | American Cancer Society
[5] European Network of Cancer Registries: Pancreatic_Cancer_2022_ENG.pdf
[6] A neoadjuvant therapy compatible prognostic staging for resected pancreatic ductal adenocarcinoma | BMC Cancer | Full Text
[7] A neoadjuvant therapy compatible prognostic staging for resected pancreatic ductal adenocarcinoma | BMC Cancer | Full Text

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.