

OSE Immunotherapeutics and GERCOR Announce Positive Topline Phase 2 Result for Clinical Trial TEDOPaM Evaluating OSE2101 (Tedopi®) in Advanced Pancreatic Cancer

- Primary endpoint met in randomized Phase 2 trial evaluating OSE2101 (Tedopi®) with FOLFIRI in Advanced Pancreatic Cancer
- Detailed results to be presented at upcoming medical congresses

NANTES, France – March 11, 6:00pm CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) and the GERCOR Group today announced that the primary endpoint has been reached in TEDOPaM (GERCOR D17-01 PRODIGE 63 trial), a Phase 2 clinical trial sponsored and conducted by the French GERCOR Oncology Clinician Group, evaluating OSE2101 (Tedopi®), the ‘off-the-shelf’ neoepitope-based therapeutic cancer vaccine, in advanced or metastatic Pancreatic Ductal Adenocarcinoma (PDAC).

TEDOPaM is a randomized, non-comparative, Phase 2 trial evaluating FOLFIRI¹ (Arm A) and cancer vaccine OSE2101 (Tedopi®) plus FOLFIRI chemotherapy (Arm B) as maintenance treatment in HLA-A2 positive patients with PDAC with no progression after eight cycles of FOLFIRINOX induction chemotherapy². The primary endpoint of the trial was the one-year overall survival (OS) rate in the experimental Arm B (Fleming 2-stage design, H0: 25%; H1: 50%, 1-sided alpha: 2.5%, power: 90%). 107 patients were enrolled with a 1:1 ratio.

The TEDOPaM trial met its primary objective, showing positive outcomes according to the predefined statistical hypothesis, with minimal toxicity for OSE2101 (Tedopi®) combined with FOLFIRI as maintenance treatment. Further follow-up and translational analyses are ongoing, with detailed results to be presented at upcoming medical congresses.

Prof. Cindy Neuzillet, MD, PhD (Curie cancer research Institute, Saint-Cloud), Principal Investigator of the TEDOPaM study: *“These are positive results in a non-comparative trial. That said, we need to better understand the contribution of Tedopi® in the context of this combination. A large translational program on tumor tissue, blood, and imaging is ongoing. Additional analysis at a longer time point will also be necessary for more mature survival data. These results underscore the critical need for ongoing research and the development of more effective therapies, especially given the low long-term survival rates in pancreatic cancer. Every step we take brings us closer to making a meaningful impact in the fight against this challenging disease.”*

Nicolas Poirier, CEO of OSE Immunotherapeutics: *“The initial results provide a glimmer of hope in the fight against advanced or metastatic pancreatic cancer. This disease is notoriously difficult to treat, and the need for effective therapies is urgent. These early results show potential promising benefit in some subsets of patients; further research and analysis are needed to confirm their impact. These additional*

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

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

positive results in a randomized clinical trial represent another step forward for the development of Tedopi® and more broadly, these data provide more evidence for the therapeutic cancer vaccine modality.”

ABOUT PANCREATIC DUCTAL ADENOCARCINOMA (PDAC)

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. The overall five-year survival rate for pancreatic cancer is 10% worldwide, showing only a modest improvement over the past decade³. More than 67,000 Americans will be diagnosed with pancreatic cancer in 2025, which is the equivalent of 184 people being diagnosed every day. Pancreatic cancer is now the 10th most found cancer in the US⁴ and represents about 3.5% of all new cancer diagnoses, and 7.1% of all cancer deaths in the EU⁵.

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 the disease⁶. Even with successful surgery and neoadjuvant therapies, the prognosis remains poor, with a high likelihood of recurrence, underscoring the need for continued research and development of more effective systemic therapies to improve outcomes for patients with pancreatic cancer⁷.

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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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](#)

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, 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.