OSE Immunotherapeutics and GERCOR Oncology Clinician Group Announce Completion of Patient Enrollment in TEDOPaM Phase 2 Clinical Trial with Tedopi® in Advanced Pancreatic Cancer (GERCOR D17-01 PRODIGE 63 trial)

- **A total of 136 patients were recruited in the Phase 2 trial sponsored and conducted by the French GERCOR Oncology Clinician Group, with the PRODIGE Intergroup and the supply of Tedopi® by OSE Immunotherapeutics.**
- **A futility analysis will be performed in Q3 2023, and the Phase 2 final results will be available Q3 2024.**
- **Pancreatic cancer is an indication with significant unmet medical need and represents an important opportunity for Tedopi®'s clinical development.**

Nantes, France – May 24, 2023, 6:00 p.m. CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announced completion of patient enrollment in the Phase 2 clinical trial TEDOPaM sponsored and conducted by the GERCOR Group and evaluating Tedopi® in advanced or metastatic pancreatic ductal adenocarcinoma.

This randomized, non-comparative Phase 2 trial is designed to evaluate 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 8 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 [*TEDOPaM GERCOR D17-01 PRODIGE 63 study: Maintenance With OSE2101 Plus FOLFIRI, or FOLFIRI After FOLFIRINOX-based Induction Therapy in Locally Advanced or Metastatic Pancreatic Ductal Adenocarcinoma NCT03806309*].

Prof. Cindy Neuzillet, MD PhD (Curie cancer research Institute, Paris), Principal Investigator of the TEDOPaM study, comments: *"Completing enrollment of this Phase 2 trial represents a major milestone in evaluating an innovative activating immunotherapy-based maintenance strategy for patients with pancreatic cancer. Tumor-associated antigens selected for Tedopi® are found overexpressed in pancreatic tumor, thus giving a rationale for testing this cancer vaccine in a very hard to treat patient population. We now look forward to advancing on the patients' follow-up period and to reporting the research main findings, including survival and predictive biomarkers. We are very grateful to the patients involved and their families, and to the clinical investigators and centers for their trust and participation in this important development program."*

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, concludes: *"We are very pleased with the progress of the TEDOPaM clinical study and are now expecting the final results in Q3 next year as additional source of clinical value of Tedopi® beyond non-small lung cancer, further to the first encouraging interim results shared at the 2022 ASCO meeting. We warmly thank the GERCOR academic*

group, sponsor of the trial, and the PRODIGE Intergroup, for this important milestone in Tedopi®'s development program in pancreatic cancer. This step brings us closer to delivering potential evidence to assess the use of Tedopi® as a potentially maintenance treatment in an aggressive disease with a generally poor prognosis, demanding for novel therapeutic approaches and representing significant unmet medical need."

The interim results from the TEDOPaM Phase 2 trial presented at the 2022 ASCO (American Society of Clinical Oncology) meeting referred to the first 29 randomized HLA-A2 positive patients with no progression after 8 cycles of FOLFIRINOX: 9 patients included in standard arm A (FOLFIRI) with a 1-year OS rate of 44% and one partial response (11%); 10 patients in experimental arm B (Tedopi® monotherapy) with a similar 1-year OS rate of 40% and one partial response (10%); and 10 patients in experimental arm C (nivolumab + Tedopi®) with a 1-year OS rate of 30% and no partial response.

Tedopi® as maintenance monotherapy showed a favorable safety profile and encouraging time to strategy failure warranting further evaluation. Nivolumab + Tedopi® was associated with poorer outcomes leading to the closing of this arm. Following an Independent Data Monitoring Committee (IDMC) recommendation, the study continued with an amended protocol comparing a maintenance treatment Tedopi® in combination with FOLFIRI versus FOLFIRI chemotherapy after treatment with FOLFIRINOX. A total of 107 patients were enrolled in this second part.

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

PDAC is the most common type of pancreatic cancer with approximately 60,000 patients diagnosed in the U.S. each year and nearly 500,000 new cases per year globally[1,2]. Due to lack of initial symptoms at early stage and high invasive potential, PDAC diagnosis is made at an advanced stage in 80% of cases, when patients already have metastases (50%) or locoregional extension (30%) precluding surgical treatment[3, 4, 5]. Advanced PDAC remains a challenging, non-curable disease[6,7]. Currently, fewer than half of patients diagnosed with metastatic PDAC and treated with FOLFIRINOX[8] survive longer than one year and overall, pancreatic cancer has the lowest 5-year OS rate of all cancer types globally and in the U.S, not exceeding 10%[1,2]. The global pancreatic cancer treatment market size was estimated at USD 2.527 billion in 2022 and is projected to reach USD 6.859 billion by 2030[9] .

1. *https://seer.cancer.gov/statfacts/html/pancreas.html*
2. *https://www.cancer.net/cancer-types/pancreatic-cancer/statistics*
3. *Ryan DP, Hong TS, Bardeesy N. Pancreatic adenocarcinoma.* The New England journal of medicine. *2014;371(22):2140-2141.*
4. *Neuzillet C, Tijeras-Raballand A, Bourget P, et al. State of the art and future directions of pancreatic ductal adenocarcinoma therapy.* Pharmacol Ther. *2015;155:80-104.*
5. *Pancreatic cancer, Mizrahi et al., Lancet 2020*
6. *Rhim AD, Mirek ET, Aiello NM, et al. EMT and dissemination precede pancreatic tumor formation.* Cell. *2012;148(1-2):349-361.*
7. *Pancreatic cancer: French clinical practice guidelines for diagnosis, treatment and follow-up (SNFGE, FFCD, GERCOR, UNICANCER, SFCD, SFED, SFRO, ACHBT, AFC)*
8. *FOLFIRINOX versus gemcitabine for metastatic pancreatic cancer, CONROY T. et al., N Engl J Med, 2011*
9. *Businesswire, January 27, 2023*

ABOUT OSE Immunotherapeutics

OSE Immunotherapeutics is a biotech company dedicated to developing first-in-class assets in immuno-oncology and immuno-inflammation. The Company's current well-balanced first-in-class clinical pipeline includes:

- **Tedopi®** (immunotherapy activating tumor specific T-cells, off-the-shelf, neoepitope-based): this cancer vaccine is the Company's most advanced product; positive results from the Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in secondary resistance after checkpoint inhibitor failure. Other Phase 2 trials, sponsored by clinical oncology groups, of Tedopi® in combination are ongoing in solid tumors.
- **OSE-279** (anti-PD1): ongoing Phase 1/2 in solid tumors or lymphomas (first patient included). OSE-279 is the backbone therapy of the BiCKI® platform.
- **OSE-127** - *lusvertikimab* (humanized monoclonal antibody antagonist of IL-7 receptor); ongoing Phase 2 in Ulcerative Colitis (sponsor OSE Immunotherapeutics); ongoing preclinical research in leukemia (OSE Immunotherapeutics).
- **FR-104/VEL-101** (anti-CD28 monoclonal antibody): developed in partnership with Veloxis Pharmaceuticals, Inc. in transplantation; ongoing Phase 1/2 in renal transplant (sponsor Nantes University Hospital); Phase 1 ongoing in the US (sponsor Veloxis Pharmaceuticals, Inc.).
- **OSE-172/BI 765063** (anti-SIRPα monoclonal antibody on CD47/SIRPα pathway) developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 dose escalation results in monotherapy and in combination, in particular with anti-PD-1 antibody ezabenlimab; international Phase 1b ongoing clinical trial in combination with ezabenlimab alone or with other drugs in patients with recurrent/metastatic head and neck squamous cell carcinoma (HNSCC) and hepatocellular carcinoma (HCC).

OSE Immunotherapeutics expects to generate further significant value from its two proprietary drug discovery platforms, which are central to its ambitious goal to deliver next-generation first-in-class immunotherapeutics:

- **BiCKI® platform** focused on immuno-oncology (IO) is a bispecific fusion protein platform built on the key backbone component of anti-PD1 combined with a new immunotherapy target to increase anti-tumor efficacy. BiCKI-IL-7 is the most advanced BiCKI® candidate targeting anti-PD1xIL-7.
- **Myeloid platform** focused on optimizing the therapeutic potential of myeloid cells in IO and immuno-inflammation (I&I). **OSE-230** (ChemR23 agonist mAb) is the most advanced candidate generated by the platform, with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

Additional information about OSE Immunotherapeutics assets is available on the Company's website: www.ose-immuno.com
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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 in light of 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 May 2, 2023, including the annual financial report for the fiscal year 2022, 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.