



## **OSE Immunotherapeutics and Oncology Physician Network GERCOR Announce Submission of a Clinical Trial Application to Evaluate Tedopi® in Combination with Nivolumab in Pancreatic Cancer**

- **The Phase 2 clinical trial of Tedopi® in pancreatic cancer will be sponsored by the oncology group GERCOR**
- **The study will explore Tedopi®'s potential in an additional oncology indication**

**NANTES, France, October 10, 2018, 6:00 p.m. CET - OSE Immunotherapeutics SA** (ISIN: FR0012127173; Mnémo: OSE) today announced the submission of a clinical trial application to initiate a Phase 2 clinical trial of Tedopi® in advanced or metastatic pancreatic cancer. The trial will compare Tedopi®, 10 neoepitopes associated to activate cytotoxic T-lymphocytes, in combination with nivolumab, an immune checkpoint inhibitor releasing the brakes that prevent optimal T lymphocyte activation versus maintenance standard of care treatment with Folfiri.

The clinical trial application has been submitted in France to the ANSM (the French National Agency for Medicines and Health Products Safety) and to the central Ethics Committee by the oncology cooperative group GERCOR, who is sponsoring the clinical trial as part of PRODIGE intergroup. The Company expects activation of the trial and opening of clinical centers in early 2019.

The Phase 2 clinical trial, named TEDOPaM, aims to evaluate Tedopi® as a maintenance therapy, alone or in combination with immune checkpoint inhibitor nivolumab, and evaluated versus Folfiri, a combination chemotherapy with folinic acid, fluorouracil and irinotecan and the standard of care. The study will be completed in HLA-A2 positive patients with stable disease who have received four months of first line standard-of-care chemotherapy Folfirinox, a combination chemotherapy with folinic acid, fluorouracil, irinotecan and oxaliplatin.

*"This new step marks the expansion of the development of Tedopi, already under evaluation in a Phase 3 study in advanced lung cancer, to an additional oncology indication, a particularly aggressive cancer for which new therapeutic options are strongly needed. With this new clinical development program evaluating Tedopi in combination with the PD-1 inhibitor nivolumab, a checkpoint inhibitor, in advanced pancreatic cancer, we are broadening our exploration of new pathways in immuno-oncology,"* commented Alexis Peyroles, chief executive officer of OSE Immunotherapeutics.

*"The study's rationale is based on the interest of a combination of immunotherapies that stimulate cytotoxic T-cells with Tedopi, whose antigens are overexpressed in pancreatic tumor, and a PD-1 checkpoint*



*inhibitor nivolumab, whose preclinical data available to date in this cancer plead in favor of a combination with a neoepitope-type immunotherapy, likely to potentiate its activity. Our network of clinicians is now mobilizing to start this Phase 2 trial,"* concluded Professor Christophe Louvet, president of GERCOR.

Tedopi is a combination of 10 neoepitopes selected and optimized from five tumor associated antigens able to generate a specific response against cytotoxic T-cells expressing at least one of these tumor associated antigens and an associated helper T-cell response.

#### **ABOUT GERCOR**

GERCOR is an association of physicians 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 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 stimulates the inclusion into its network of the greatest number of physicians involved in the treatments it is conducting, offers vital logistical assistance to research physicians whose job is to direct and monitor the application of the treatments to patients.

#### **ABOUT OSE Immunotherapeutics**

OSE Immunotherapeutics is a clinical-stage biotechnology company focused on developing and partnering therapies to control the immune system for immuno-oncology and autoimmune diseases. The company has a diversified first-in-class clinical portfolio consisting of several scientific and technological platforms including neoepitopes and agonist or antagonist monoclonal antibodies, all ideally positioned to fight cancer and autoimmune diseases. Our most advanced asset, Tedopi<sup>®</sup>, is a proprietary combination of 10 neo-epitopes aimed at stimulating T-lymphocytes and is currently in Phase 3 development in non-small cell lung cancer (NSCLC) after checkpoint inhibitor failure (anti PD-1 and anti PD-L1). In April 2018, Boehringer Ingelheim and OSE signed a global license and collaboration agreement to develop checkpoint inhibitor OSE-172 (anti-SIRPα monoclonal antibody) in multiple cancer indications. In July 2016, Janssen Biotech exercised a licensing option to continue clinical development of FR104 (an anti-CD28 mAb) in auto-immune diseases after positive Phase 1 results. In 2016, Servier Laboratories signed a two-step license option to develop OSE-127 (monoclonal antibody targeting the CD127 receptor, the alpha chain of the interleukin-7 receptor) to develop the product up to the completion of a Phase 2 clinical trial planned in autoimmune bowel disease and Sjogren's syndrome.

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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 Reference Document filed with the AMF on 26 April 2018, including the annual financial report for the fiscal year 2017, 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.