



OSE Immunotherapeutics and Oncology Physician Network GERCOR Announce Initiation of Phase 2 Clinical Trial to Evaluate Tedopi® in Combination with Opdivo® (nivolumab) in Pancreatic Cancer

- **The trial, sponsored and conducted by oncology group GERCOR, will be supported by Bristol-Myers Squibb and OSE Immunotherapeutics**
- **Pancreatic cancer is an indication with significant unmet need and represents an important new opportunity for Tedopi® clinical development**
- **Opening of Phase 2 trial sites scheduled for early 2019**

NANTES, France, November 20, 2018, 8:00 a.m. CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnémo: OSE) today announced that the French National Agency for Medicines and Health Products Safety (ANSM) and the French Central Ethic Committee (CPP) approved the initiation of a new Phase 2 trial evaluating Tedopi®, a combination of neoepitopes, in combination with Bristol-Myers Squibb's Opdivo® (nivolumab), an immune checkpoint inhibitor, versus Folfiri (a combination chemotherapy with folinic acid, fluorouracil and irinotecan) in advanced or metastatic pancreatic cancer.

The clinical trial application was submitted to ANSM and CPP by GERCOR, which is sponsoring the clinical trial as part of PRODIGE intergroup.

The trial, named TEDOPaM, will be supported by Bristol-Myers Squibb, which will provide Opdivo® (nivolumab) for use in the study. OSE Immunotherapeutics will provide Tedopi®, its wholly-owned therapeutic-candidate, and a partial financial support.

Tedopi® is currently in Phase 3 development in non-small cell lung cancer (NSCLC) after checkpoint inhibitor failure (anti PD-1 and anti PD-L1). Tedopi® is a proprietary combination of 10 neo-epitopes selected and optimized from five tumor associated antigens and has been shown to generate a specific response of cytotoxic T cells versus cancer cells expressing at least one of these tumor associated antigens and an associated T-helper cell response.

"Exploring the potential of Tedopi® in additional oncology indications has been an important goal for us. We are particularly excited to be entering pancreatic cancer, an aggressive disease with a generally poor prognosis, demanding for novel therapeutic approaches and representing significant unmet medical need. We hope TEDOPaM will validate that combining Tedopi® with a PD-1 checkpoint inhibitor has potential as a successful new therapeutic strategy for patients suffering from this devastating form of cancer," commented Alexis Peyroles, chief executive officer of OSE Immunotherapeutics.

"Pancreatic cancer is an indication where we feel that a neoepitope-based therapy in combination with a PD-1 checkpoint inhibitor has great potential," said professor Christophe Louvet, MD, president of GERCOR. *"We hypothesize combining Tedopi® and Opdivo® will help stimulate cytotoxic T-cells and*

potentiate overall anti-tumor effects. We are beginning to activate our extensive network of expert clinical oncologists to rapidly initiate this exciting new Phase 2 trial for pancreatic cancer patients."

The three arm TEDOPaM study will evaluate Tedopi® as a maintenance therapy, alone or in combination with Opdivo® compared to Folfiri* alone, in HLA-A2 positive patients with stable disease after 4 months of standard chemotherapy with Folfirin, a combination chemotherapy with folinic acid, fluorouracil, irinotecan and oxaliplatin.

ABOUT GERCOR AND PRODIGE

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.

PRODIGE Intergroup ("Partenariat de Recherche en Oncologie DIGestive") is an oncology group partnership dedicated to implement national and international clinical trials in digestive oncology.

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®, 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-SIRPa monoclonal antibody) in multiple cancer indications. In July 2016, Janssen Biotech, Inc. exercised a licensing option to continue clinical development of FR104 (an anti-CD28 mAb) in auto-immune diseases after positive Phase 1 results; following termination of licence agreement effective Dec. 31, 2018 due to strategic portfolio prioritization, OSE regains all worldwide rights on this asset. 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.