



OSE Immunotherapeutics Partners with Oncology Physician Network GERCOR to Conduct a Combination Phase 2 Trial of Tedopi® for Pancreatic Cancer

Clinical Collaboration Advances Potential of Tedopi® in Additional Oncology Indications

NANTES, France, 6 Sept., 7:30 a.m. CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnémo: OSE) today announced an agreement with GERCOR, an independent non-profit French network of cancer specialists, to study Tedopi® in locally advanced or metastatic pancreatic cancer. GERCOR is finalizing the design of this Phase 2 trial of maintenance therapy with Tedopi® alone or combined with a PD-1 checkpoint inhibitor versus Folfiri*, in patients with stable disease after 4 months of standard chemotherapy with Folfirinnox**.

“We are pleased to have joined forces with such a prestigious oncology group as GERCOR to conduct the first study of Tedopi® in combination with a checkpoint inhibitor,” said Dominique Costantini, CEO of OSE. *“We believe that Tedopi® may potentiate the activity of checkpoint inhibitors, enlarging the patient population who may benefit from them. We look forward to conducting this first combination study.”*

Professor Christophe Louvet, President of GERCOR, added: *“Tedopi®’s effects on the tumor micro-environment could make checkpoint inhibitors relevant for a larger percentage of patients. Our network is excited to have the opportunity to explore this new immuno-oncology pathway addressing a particularly aggressive cancer, and for which new therapeutic options are strongly needed.”*

* Folfiri: combination chemotherapy with folinic acid, fluorouracil and irinotecan

** Folfirinnox: combination chemotherapy with folinic acid, fluorouracil, irinotecan and oxaliplatin

FOLFIRINOX versus Gemcitabine for Metastatic Pancreatic Cancer; Conroy T, Desseigne F, Ychou M, Bouché O, Guimbaud R, Becouarn Y, et al. Folfirinnox versus Gemcitabine for metastatic pancreatic cancer. N Engl J Med 2011;364:1817-25

ABOUT PANCREATIC CANCER

Pancreatic ductal adenocarcinoma (PDAC) incidence is increasing regularly in Western countries and projections have reported that it should become the second leading cause of cancer-related mortality in 2020^{1,2}. Worldwide, pancreatic cancer incidence is of 337 000 cases and the mortality of 330 000 cases³. In France, pancreatic adenocarcinoma is the second most frequent digestive cancer, after colorectal cancers, with an annual incidence of more than 12 000 new cases. The prognosis of this disease remains very poor with a prevalence roughly equivalent to the incidence and a 5-year overall survival rate inferior to 5%.⁴ At diagnosis, most of the patients have a metastatic (more than 50%) or a locally advanced disease (one third). In case of resectable disease, surgical resection followed by an adjuvant

chemotherapy allow to cure only a minority of patients, a relapse occurring during the follow-up in most of them (> 80%)⁵.

1. Ehemam C, Henley SJ, Ballard-Barbash R, et al: Annual Report to the Nation on the status of cancer, 1975-2008, featuring cancers associated with excess weight and lack of sufficient physical activity. *Cancer* 118:2338-2366, 2012
2. Rahib L, Smith BD, Aizenberg R, et al: Projecting cancer incidence and deaths to 2030: the unexpected burden of thyroid, liver, and pancreas cancers in the United States. *Cancer Res* 2014, 74:2913-2921.
3. *Globocan 2012* (World Health Organization).
4. Carpelan-Holmstrom M, Nordling S, Pukkala E, et al: Does anyone survive pancreatic ductal adenocarcinoma? A nationwide study re-evaluating the data of the Finnish Cancer Registry. *Gut* 2005, 54:385-387.
5. Neoptolemos JP, Stocken DD, Bassi C, et al: Adjuvant chemotherapy with fluorouracil plus folinic acid vs gemcitabine following pancreatic cancer resection: a randomized controlled trial. *JAMA* 2010, 304:1073-1081.

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

Our ambition is to become a world leader in activation and regulation immunotherapies.

OSE Immunotherapeutics is a biotechnology company focused on the development of innovative immunotherapies for immune activation and regulation in the fields of immuno-oncology, autoimmune diseases and transplantation. The company has a balanced portfolio of first-in-class products with a diversified risk profile ranging from clinical phase trials to R&D:

In immuno-oncology:

- **Tedopi®**, a combination of 10 optimized neo-epitopes to induce specific T activation in immuno-oncology – Registration Phase 3 trial in advanced NSCLC in EU/US in HLA A2+ patients; follow-up of patients already included ongoing after temporary pause of new patient accrual end of June 2017 - Orphan Status in the US. A Phase 2 with Tedopi® in combination with an immune checkpoint inhibitor is planned in locally advanced and metastatic pancreatic cancer, in collaboration with GERCOR, a cooperative group of clinical research.
- **OSE-172** (Effi-DEM), new generation checkpoint inhibitor targeting myeloid cells via the SIRP- α receptor - In preclinical development for several cancer models.
- **OSE-703** (Effi-3), cytotoxic monoclonal antibody against the alpha chain of IL-7R - Under a research collaboration with Memorial Sloan Kettering Cancer Center, New York.

In auto-immune diseases and transplantation:

- **FR104**, CD28-antagonist in immunotherapy - Phase 1 trial completed – For the treatment of autoimmune diseases and for use with transplantation - Licensed to Janssen Biotech Inc. to pursue clinical development.
- **OSE-127** (Effi-7), interleukin receptor-7 antagonist - In preclinical development for inflammatory bowel diseases and other autoimmune diseases. License option agreement with Servier for the development and commercialization.

The portfolio's blockbuster potential gives OSE Immunotherapeutics the ability to enter global agreements at different stages of development with major pharmaceutical players.

Immunotherapy is a highly promising and growing market. By 2023 Immunotherapy of cancer could represent nearly 60% of treatments against less than 3% at present * and the projected market is estimated at \$67 billion in 2018 **.



There are more than 80 autoimmune diseases that represent a significant market including major players in the pharmaceutical industry with sales towards \$10 billion for the main products. The medical need is largely unmet and requires the provision of new innovative products involved in the regulation of the immune system.

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Contacts

OSE Immunotherapeutics

Sylvie Détry

Sylvie.detry@ose-immuno.com

+33 143 297 857

French Media: FP2COM

Florence Portejoie

fportejoie@fp2com.fr

+33 607 768 283

U.S. Media: LifeSci Public Relations

Matt Middleman, M.D.

matt@lifescipublicrelations.com

+1 646 627 8384

U.S. and European Investors

Chris Maggos

chris@lifesciadvisors.com

+41 79 367 6254

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 28 April 2017 under the number R.17-038, including the annual financial report for the fiscal year 2016, 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.