



## OSE Immunotherapeutics Receives €9.2 million Grant from Bpifrance “Invest in the Future Program” for Development of New Immune Checkpoint Inhibitor OSE-172 (Effi-DEM)



**NANTES, France, July 19, 2017, 6 p.m. CET.** - **OSE Immunotherapeutics SA** (ISIN: FR0012127173; Mnémo: OSE) announces today that the Company will receive €9.2 million grant from the “Projets de R&D Structurants Pour la Compétitivité” (PSPC) of the “Invest in the Future Program” (PIA). This program is overseen by the General commissariat of investment (CGI) and led by Bpifrance.

OSE Immunotherapeutics will lead the consortium collaborating on this project named EFFI-CLIN aiming at developing a new generation of checkpoint inhibitor in cancer immunotherapy. The consortium also includes the European Center for Transplantation and Immunotherapy (CESTI), a public organization based in Nantes (France) and HISTALIM, a SME based in Montpellier (France).

EFFI-CLIN will evaluate the safety and the clinical efficacy of new cancer immunotherapy OSE-172 as a monotherapy and in combination in various indications where myeloid cells represent a poor prognosis factor. The project will include in particular the product manufacturing compliant with pharmaceutical standards, translational studies conducted from tumour tissues to measure the presence of immunological targets including SIRP-alpha, and a clinical program planned until the phase 2.

« *We are very happy to support OSE Immunotherapeutics and its partners in this innovative R&D program to serve the future of unmet medical needs,*” said Catherine Borg-Capra, Director of Industrial Innovation sector at Bpifrance.

Dominique Costantini, Chief Executive Officer of OSE Immunotherapeutics, said: *“We thank the Invest in the Future Program for supporting us with this grant that will allow to accelerate the development of our monoclonal antibody platform based in Nantes, in a high-level scientific environment, and to conduct our product OSE-172 to the clinical phase, a step planned for the end of 2018.”*

Bernard Vanhove, Chief Operating Officer and Head of R&D and International scientific collaborations at OSE Immunotherapeutics, adds: *“We are very pleased to collaborate with the highly-skilled teams of CESTI and HISTALIM to conduct this ambitious project and to provide innovative scientific, diagnostic and therapeutic outcomes in immuno-oncology.”*

Tumours have the particularity of secreting molecules that allow the recruitment and/or generation of suppressor cells that prevent the immune system from eliminating tumour cells. Among the major players in immune dysfunctions promoting tumour growth, pro-tumour and suppressor myeloid cells have been identified (MDSC or Myeloid-Derived Suppressor Cells / TAM or Tumour-Associated Macrophages).

OSE Immunotherapeutics was the first to identify the SIRP-alpha target (Signal Regulatory Protein alpha) as a major checkpoint for myeloid cells. The company has developed a selective SIRP-alpha antagonist antibody that transforms the tumour microenvironment by blocking suppressor cells and activating anti-tumour effector cells.

The exploration of SIRP-alpha in key indications will be carried out jointly with CESTI and its various technological platforms. The European Center for Transplantation and Immunotherapy Sciences (CESTI) is a University Hospital Institute (IHU B Nantes, headed by Professor Gilles Blancho) focused on the control of the immune response. CESTI benefits from a recognized expertise in immunotherapy and relevant experimental and translational platforms ahead of clinical trials and development of therapeutic innovations. The proximity of these research laboratories with clinicians and patients is an asset for conducting preclinical and translational studies from tissues derived from patients.

The company HISTALIM will develop a tool called HISTOPROFILE, for a help in the decision-making in a perspective of personalized medicine. This tool will use multiplex immunohistochemistry techniques (several targets measured at the same time on the same tissue) coupled with image analyses. The objective is to characterize the immune profile and the biomarkers found in a patient. This will make it possible to define the most appropriate treatment using algorithms integrating the multiple information obtained from a clinical biopsy.

#### **OSE-172 addresses unmet medical needs in immuno-oncology**

Current therapeutic strategies in immuno-oncology are largely based on T-lymphocyte checkpoint inhibitors (CKI). The CKIs that target T-lymphocytes have revolutionized oncologic practice, with several products in this class leading to sustained tumour reductions. However, a significant medical need remains because a high percentage of patients do not respond or relapse after an initial response to treatments of this type. The search for new targets is focused on T-lymphocytes, with a significant number of product candidates currently being evaluated. However, research into drugs that target myeloid cells, which are present in large numbers in the tumour microenvironment, is still in the preliminary stages.

**Bpifrance** is the managing operator for research and development projects structuring competitiveness under the 'Investments for the Future' Program led by the General Investment Commission. The goal of these projects is to frame and organize industry sectors or to generate new ones. They aim to strengthen the positions of French businesses in key markets by providing funding for ambitious programs. More broadly they aim to enhance the economic standing of a network of enterprises, by building or consolidating sustainable collaborative relationships between manufacturing, service industries and research organizations.

#### **About the PIA (Programme d'Investissement d'avenir – Investments for the Future Program)**

Steered and coordinated by the CGI (Commissariat Général à l'Investissement), the PIA's budget reaches €47bn including more than €36bn already engaged since 2010 to promote six strategic priorities to prepare France for the challenges of tomorrow:

- Higher education and training
- Research and its valorization
- Modernisation of industrial sectors
- Sustainable development
- Digital economy
- Health and biotechnologies



**Find out about the program « Investing for the Future »**

<http://www.gouvernement.fr/investissements-d-avenir-cgi>

### About Bpifrance

Bpifrance, a subsidiary of Caisse des Dépôts and the French State, is a trusted partner of entrepreneurs which provides companies with credit, collateral and equity financing support from start up through to stock exchange listing. Bpifrance also provides guidance services and enhanced support for innovation, external growth and export, in partnership with Business France. Bpifrance offers companies a continuum of financing for each key stage of their development and an offer adapted to specific regional features.

With 47 regional offices (90% of decisions are made regionally), Bpifrance offers entrepreneurs a tool for economic competitiveness. Bpifrance works in support of the public policies pursued nationally and regionally by the French government, to meet three objectives:

- support the growth of businesses;
- prepare for future competitiveness;
- contribute to the development of a favourable ecosystem for entrepreneurship.

With Bpifrance, companies have a strong and effective local contact to meet all their financial, innovation and investment needs.

For more information, please visit: [www.bpifrance.fr](http://www.bpifrance.fr)–<http://investissementsdavenir.bpifrance.fr>–Twitter: @bpifrance

### 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, auto-immune diseases and transplantation. The company has a balanced portfolio of first-in-class products with a diversified risk profile ranging from clinical phase 3 registration trials to R&D:

#### **In immuno-oncology:**

- **Tedopi®**, a combination of 10 optimized neo-epitopes to induce specific T activation in immuno-oncology – Continuation of the registration Phase 3 trial in advanced NSCLC in already included HLA A2+ patients EU /US - Orphan Status in the US - A Phase 2 with Tedopi® in combination with a checkpoint inhibitor in NSCLC is considered.
- **OSE-172** (Effi-DEM), new generation checkpoint inhibitor targeting the SIRP- $\alpha$  receptor - In preclinical development for several cancer models.
- **OSE-703** (Effi-3), cytotoxic monoclonal antibody against the alpha chain of IL-7R - Under a multi-year strategic 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.

\*Citi Research Equity

\*\*BCC Research

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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 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.