

## OSE Pharma and Effimune announce the launch of a non-interventional study in hepatocellular carcinoma under a private-public collaborative program

Paris, Nantes - May 19, 2016, 18:15pm - OSE Pharma SA (ISIN: FR0012127173; Ticker: OSE), an immuno-oncology company with a specific immunotherapy activating T lymphocytes, currently in a registration Phase 3 study, and Effimune, a biotech company specialized in immune regulation with clinical applications in autoimmunity, transplantation and immune-oncology, today announce the launch of a non-interventional study in patients with hepatocellular carcinoma (primary liver cancer). This study is a private-public research program supported by the French National Cancer Institute (INCa, Institut National du Cancer) and the Direction Générale de l'Offre de Soins (DGOS, the French access to healthcare services).

This collaborative research program, called MDScan (Myeloid-Derived Suppressor Cells Analysis), was selected by the French National Cancer Institute after a competitive process. It is dedicated to a study in patients with hepatocellular carcinoma (primary liver cancer). The title of the study is: « *Control of suppressive myeloid cells by SIRP-alpha: investigation in hepatocellular carcinoma* » and it aims to measure the SIRP-alpha marker (Signal Regulatory Protein  $\alpha$ ) in these patients and to evaluate the activity of Effi-DEM, the new checkpoint inhibitor targeting suppressor myeloid and macrophage cells.

SIRP-alpha is a receptor strongly expressed by suppressor immune cells which play a key role in tumor growth of inflammatory cancers : these are Tumor Associated Macrophages (TAM) and Myeloid Derived Suppressor Cells (MDSC).

The MDScan program will be funded by the National Cancer Institute and the DGOS under a private-public partnership with Effimune and complementary academic institutions of excellence including the University Hospital Institute of Nantes\*, the « Transgenesis Rat and ImmunoPhenomics » (TRIP) platform of the Research structure François Bonamy/Ouest Genopole and the INSERM/Medical center for transplantation research (UMR 1064 INSERM-CRTI). The project has also been funded by the « Comité de Loire-Atlantique de la Ligue contre le Cancer ».

The collaboration, initiated by Effimune, will be continued by OSE Immunotherapeutics, the new company which will be created at the end of May 2016, subject to and after completion of the merger between OSE Pharma and Effimune.

The MDScan study will be coordinated by Pr. Gilles Blancho, Head of the CESTI (European Center for Transplantation and Immunotherapy Sciences of the University Hospital Institute of Nantes) and ITUN (Institute of Urology and Nephrology Transplantation). The other teams involved are those of Ignacio Anegón, Director of INSERM UMR 10464-CRTI and TRIP, and of Dr Isabelle Archambeaud at the University Hospital Institute of Nantes (Hepato-gastroenterology Department headed by Dr Jérôme Gournay).

*« Based on a scientific rationale and substantial preliminary data, this research program could potentially increase the value and expand the clinical applications for Effi-DEM. We are pleased to collaborate with excellent complementary academic teams to develop this novel product's potential through a therapeutic strategy arising from our knowledge acquired in immunology of transplantation and applied in immuno-oncology », comments Bernard Vanhove, CEO of Effimune.*

*\* The University Hospital Institute of Nantes will be in charge of patient inclusion and of the analysis of bio samples.*

## ABOUT Effi-DEM

Effi-DEM is a second generation checkpoint inhibitor developed by Effimune in immuno-oncology. It blocks SIRP-alpha (Signal Regulatory Protein Alpha) receptor and transforms Myeloid Derived Suppressor Cells (MDSC) and Tumor Associated Macrophages (TAM) into non suppressor cells. The immune system is thus reactivated and tumor growth is blocked. Hepatocellular carcinoma, a type of cancer linked to chronic inflammation that expresses key cells of tumor progression, is one of the potential indications targeted by Effi-DEM.

## ABOUT THE MERGER BETWEEN OSE PHARMA AND EFFIMUNE

**On February 24, 2016, OSE Pharma and Effimune announced a proposed merger to create OSE Immunotherapeutics, a significant immunotherapy player. The terms of the merger will be submitted for approval to the shareholders of the two companies during the next General Meetings: on May 30, 2016 for Effimune and on May 31, 2016 for OSE Pharma.**

The objective of the merger is to create a new international enterprise that offers innovative immunotherapies based on the activation or regulation of the immune system. This new generation of products is optimized to better target key receptors of the activation or regulation of immune response and allow a durable therapeutic effect. The new company will benefit from a balanced portfolio that would open up major avenues to growth and have a financial visibility of about two years to advance its projects toward greater attractiveness.

**OSE PHARMA** is a biotechnology company that designs and develops cancer immunotherapy treatments aimed at re-educating the immune system to fight cancer while preserving patients' quality of life. The Company is conducting a Phase 3 registration trial in Europe and the U.S. for its lead product, Tedopi<sup>®</sup>, in the treatment of NSCLC.

OSE Pharma is listed on Euronext Paris (ISIN: FR0012127173; Mnemo: OSE).

For more information, please visit [www.osepharma.com](http://www.osepharma.com)

**EFFIMUNE** is a biotech company specialized in immune regulation for applications in transplantation, autoimmunity and cancer immunotherapy. The originality of Effimune's therapeutic strategy, compared to conventional immunosuppression, is the modification in the balance between effector and regulatory immune cells. The biological drugs Effimune develops are aimed at restoring the natural balance of these cells by targeting the molecular checkpoint.

The expertise of the company lies in its ability to identify new therapeutic targets and develop effective biomolecules for the pharmaceutical industry by guaranteeing the manufacture of pilot and clinical batches and by validating preclinical and clinical proofs of concept.

For more information, please visit: [www.effimune.com](http://www.effimune.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 PHARMA. They do not constitute historical facts. These information and statements include financial projections that are based upon certain assumptions and assessments made by OSE PHARMA's 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.

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 PHARMA's management believes that the forward-looking statements and information are reasonable, the OSE PHARMA's 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 PHARMA. 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 PHARMA 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 PHARMA Reference Document filed with the AMF on 12 June 2015 under the number R.15-051, the consolidated financial statements and the management report for the fiscal year 2015, as well as the Merger Document registered with the AMF on 26 April 2016 under number E.16-026, all available on the OSE PHARMA website.

OSE PHARMA undertakes no obligation to update any forward-looking statements except what would be required by applicable laws and regulations