Effimune and OSE Pharma announce the online publication of Preclinical efficacy data for FR104 in a renal allograft model in the « Journal of the American Society of Nephrology »

Paris, Nantes - May 11, 2016, 17:45pm - OSE Pharma SA (ISIN: FR0012127173; Ticker: OSE), an immuno-oncology company developing a T-specific immunotherapy, 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 online publication of a paper on the effects and efficacy of FR104, CD28 antagonist, on mechanisms of renal allograft (kidney transplant) rejection.

The online paper : *« Anti-CD28 Antibody and Belatacept Exert Differential Effects on Mechanisms of Renal Allograft Rejection »* was published in the « Journal of the American Society of Nephrology » (http://jasn.asnjournals.org/content/early/2016/05/07/ASN.2015070774.abstract).

Based on a one-year long therapeutic protocol, these results demonstrate the long term efficacy of FR104, an immuno-modulator composed of a humanized monovalent Fab' antibody targeting CD28 in a preclinical model of renal allograft showing a control of graft rejection and the induction of regulatory mechanisms. These data result from a strong collaboration involving Effimune and Professor Gilles Blancho, Head of the CESTI (the European Center for Transplantation and Immunotherapy Sciences of the University Hospital Institute of Nantes).

These preclinical efficacy results are very promising for the future development of FR104, a product that promotes immune tolerance in transplantation and autoimmune diseases by modulating the action of T lymphocytes.

There is a major medical need for new approaches to decrease the rate of graft failure due to a chronic rejection and to nephrotoxicity of immunosuppressors, especially for those requiring a kidney transplant.

ABOUT FR104

FR104 is an immuno-modulator composed of a humanized monovalent anti-CD28 antibody, a key receptor blocking the destructive function of effector T lymphocytes. These effector T lymphocytes are harmful in the case of autoimmune diseases and transplantation.
FR104 specifically blocks the destructive function of effector T lymphocytes without blocking the regulation function of regulator T lymphocytes, thus fostering immuno-tolerance.

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®, in the treatment of NSCLC.

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

For more information, please visit 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

Contacts

OSE Pharma SA
Dominique Costantini, CEO
dominique.costantini@osepharma.com
Mob : +33 6 13 20 77 49

Alexis Peyroles, CFO & BD
Alexis.peyroles@osepharma.com
Mob : +33 6 11 51 19 77

Effimune
Maryvonne Hiance, Chairman
Tel : +33 (0) 240 412 834
Mobile : 33 (0) 680 060 183
mhiance@effimune.com

Media contacts
Citigate Dewe Rogerson
Laurence Bault
laurence.bault@citigate.fr
+33 1 53 32 84 78

Alize RP
Florence Portejoie & Caroline Carmagnol
osepharma@alizerp.com
+33 6 47 38 90 04

Consilium Strategic Communications
Chris Gardner / Matthew Neal / Hendrik Thys
OSEPharma@consilium-comms.com
+44 (0) 20 3709 5700

Rx Communications Group, LLC
Melody Carey
mcarey@rxir.com
+ 1 917-322-2571

Acorelis
Gilles Petitot
gilles.petitot@acorelis.com
+33 (0) 620 27 65 94

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