OSE Immunotherapeutics announces exercise of option within global license agreement with Janssen for further clinical development of FR104 and potential commercialisation in autoimmune diseases

Paris, Nantes, July 5, 2016 - OSE Immunotherapeutics SA (ISIN : FR0012127173 ; Mnémo : OSE), an immunotherapy company developing activating or regulating immunotherapies in immuno-oncology, autoimmune diseases and transplantation, is pleased to announce the exercise by Janssen Biotech, Inc. (one of the Janssen Pharmaceutical Companies of Johnson & Johnson) of the option within the global license agreement between Janssen and OSE Immunotherapeutics. Under the terms of this agreement, Janssen will be responsible for all clinical development, registration and commercialization activities for FR104, internationally, in the areas of autoimmune diseases and transplantation. The deal was facilitated by Effimune and Johnson & Johnson Innovation's London Innovation Centre in October 2013.

FR104 is a new generation product, a monoclonal antibody fragment and antagonist of CD28, a key receptor in effector T lymphocytes, with preclinical proof of concept demonstrated in autoimmune diseases and transplantation. The product has been developed by Effimune, today OSE Immunotherapeutics.

Positive results from the recently concluded FR104 Phase 1 clinical trial, triggered the exercise of the license option and will enable further clinical development of the product by Janssen. Under the terms of the agreement, OSE Immunotherapeutics is eligible to receive up to a potential total of €155 million ($172 million) which includes an option exercise fee of €10 million ($11 million) and potential development, regulatory and commercial milestone payments as well as a royalty.

"The exercise of this option is a significant achievement which allows continued development of the company's compound in collaboration with Janssen's immunology scientists, thanks to the initial strategic collaboration with Johnson & Johnson Innovation (London Centre)," declared Bernard Vanhove, Chief Operating Officer in charge of R&D and International Scientific Collaborations for OSE Immunotherapeutics, and co-inventor of FR104.

"We are proud of the work performed by our teams and we are very pleased with the commitment of Janssen and Johnson & Johnson Innovation to this clinical research. We also thank our academic and regional supporters, including Inserm, Nantes University hospital / "Région Pays de la Loire" / Atlanpôle Biothérapies, European funds FP7" who accompanied the company during this period," added Maryvonne Hiance, Vice-Chairman and Director of Strategy for OSE Immunotherapeutics.

ABOUT FR104

The first phase 1 clinical trial in healthy volunteer (NCT02800811) is now finalized. The clinical results have shown a good safety profile, have established the pharmacological profile and demonstrated a dose/response relationship. The purely antagonist activity of FR104 has been confirmed.
The targeted indications are autoimmune diseases, organ transplantation and graft-versus-host-disease after hematopoietic stem cell transplant.

- FR104 is an optimized monovalent fragment of monoclonal antibody, CD28-antagonist, a key receptor controlling effector and suppressor T lymphocytes activation. These effector T lymphocytes are harmful in the case of autoimmune diseases and transplantation whereas regulator T lymphocytes play an anti-inflammatory role.
- In September 2013, with FR104 at a preclinical stage, a global option and license agreement was signed with Janssen Biotech, Inc.. This step allowed the development of the product to the end of phase 1. The option license is being exercised by Janssen to pursue further clinical development, with expected payments of milestones and royalties.

ABOUT OSE IMMUNOTHERAPEUTICS

OSE Immunotherapeutics is a biotechnology company specializing in immune regulation with clinical applications in immuno-oncology, autoimmune diseases and transplantation. The company has a balanced portfolio, from R&D to clinical phase 3 registration, with a diversified risk profile. It is composed of advanced immunotherapy products in clinical pivotal phase 3 and in phase 2 with Tedopi® (combined neoepitopes in oncology, developed in advanced lung cancer, NSCLC); and FR104 with phase 1 completed (a CD28-antagonist Immunotherapy licensed to Janssen Biotech Inc.). The company also has promising products in preclinical phase and potential drug candidates in R&D, targeting new receptors of interest in immuno-oncology, autoimmune diseases, and transplantation. This product portfolio is supported by an innovative technology foundation and know-how in selection and optimization of new generation products acting on new immunological targets, notably a new generation check-point inhibitor targeting suppressive myeloid cells and to tumor associated macrophages (Effi-DEM) and an immunomodulator, interleukin-7 antagonist (Effi-7), developed for autoimmune diseases and transplantation.

Contacts

OSE Immunotherapeutics
Dominique Costantini, CEO
dominique.costantini@ose-immuno.com
Mob +33 6 13 20 77 49

Maryvonne Hiance, Vice Chairman
maryvonne.hiance@ose-immuno.com Tél : +33 (0) 240 412 834
Mobile : 33 (0) 680 060 183

Alexis Peyroles,COO, Operations, Finance & BD
alexis.peyroles@ose-immuno.com
Mob : +33 6 11 51 19 77

Bernard Vanhove, COO, R&D, Scientific collaborations
bernard.vanhove@ose-immuno.com
Mob: +33 6 75 41 40 08

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

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

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

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

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

"The collaborative project - R&D Program of immune system regulation in transplantation: development of FR104-TX molecule carried out by Effimune is co-funded by the European Union. Europe is moving in the Pays de la Loire with the European Regional Development Fund"

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 8 June 2016 under the number R.15-052, 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 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.