OSE Immunotherapeutics Publishes New Efficacy Data on FR104, CD28-Antagonist Immunotherapy

FR104 shown to be efficacious in a preclinical bone marrow transplant model
Research published in the Journal of Clinical Investigation conducted with multiple international expert partners

NANTES, France, August 22, 2018, 6:00 p.m. CET - **OSE Immunotherapeutics SA** (ISIN: FR0012127173; Mnémo: OSE) today announces new efficacy results from a preclinical study evaluating FR104, an antagonist of CD28, a receptor which controls the activity of effector T lymphocytes. This study, led by OSE Immunotherapeutics and international partners, was published in the August 2018 issue of the Journal of Clinical Investigation (JCI) [(1)].

FR104 is a monoclonal antibody and an antagonist of CD28. This pegylated monovalent antibody selectively inhibits the CD28 receptor and has potential clinical applications in autoimmune diseases and transplantation.

This latest publication[(1)] refers to a research conducted in collaboration with Nantes University/Inserm (a French public organization dedicated to human health), Emory University of Atlanta, the University of Minnesota and the Fred Hutchinson Cancer Research Center of Seattle. It focused on the evaluation of selective CD28-antagonist FR104 to determine its impact on T cell activation and graft-versus-host disease (GVHD) when used both as a monotherapy or combined with immunosuppressant rapamycin in a preclinical model of bone marrow transplant. The results demonstrated that FR104 efficiently controlled GVHD, both when used as a monotherapy or in combination and that this control was superior to the one observed with non-selective CD28-antagonist CTLA4-Ig.

Previous studies conducted with FR104 in preclinical models of transplant and other immune-mediated diseases have generated significant immune data related to the product, and in particular demonstrated its ability to promote immunological tolerance[(2)] and to reinforce immunosuppression[(3)]. Additionally, the results from a Phase 1 clinical[(4)] study of FR104 have shown a good clinical and biological safety and also has confirmed its immunosuppressive activity in human.

"The sum total of all preclinical and clinical data now available on our CD28-antagonist FR104 have built a strong basis to open its further development to various potential indications in immune-mediated diseases. This is indicative of the product's interest and confirms it as a valuable asset for the Company", commented Alexis Peyroles, CEO of OSE Immunotherapeutics.

Based on positive Phase 1 clinical results, FR104 is under a licensing agreement with Janssen Biotech to pursue the product's clinical development with a Phase 2 trial planned in rheumatoid arthritis.

[(1)] *CD28 blockade controls T cell activation to prevent graft-versus-host disease in primates*
Benjamin K. Watkins, Victor Tkachev, Scott N. Furlan et al.; J Clin Invest. 2018 Aug 13

[2] *Selective blockade of CD28 on human T cells facilitates regulation of alloimmune responses*
Masaaki Zaitsu, Fadi Issa, Joanna Hester et al.; JCI Insight. 2017

[3] *FR104, an antagonist anti-CD28 monovalent fab' antibody, prevents alloimmunization and allows calcineurin inhibitor minimization in nonhuman primate renal allograft*
Poirier N, Dilek N, Mary C et al.; Am J Transplant. 2015 Jan.

[4] *First-in-Human Study in Healthy Subjects with FR104, a Pegylated Monoclonal Antibody Fragment Antagonist of CD28*
Nicolas Poirier, Gilles Blancho, Maryvonne Hiance et al. ; The Journal of Immunology, Nov. 2016

ABOUT OSE Immunotherapeutics

OSE Immunotherapeutics is a biotechnology company focused on the development of innovative immunotherapies for immune activation and regulation in the fields of immuno-oncology and autoimmune diseases. Neoepitopes innovation (Tedopi®) is today in Phase 3 in advanced lung cancers (NSCLC) after checkpoint inhibitors failure (anti PD-1 and anti PD-L1). A global license and collaboration agreement was signed in April 2018 with Boehringer Ingelheim to develop checkpoint inhibitor OSE-172 (anti-SIRPa monoclonal antibody), for the treatment of advanced solid tumors. An option to license was exercised in July 2016 by Janssen Biotech to continue clinical development of FR104 (an anti CD28 mAb) in auto-immune diseases after positive phase 1 results. A 2-step license option was signed in 2016 with Servier Laboratories to develop OSE-127 (monoclonal antibody targeting the CD127 receptor, the alpha chain of the interleukin-7 receptor) to develop the product up to the completion of a phase 2 clinical trial planned in autoimmune bowel disease and Sjogren's syndrome. The company has several scientific and technological platforms: neoepitopes, agonist or antagonist monoclonal antibodies, ideally positioned to fight cancer and autoimmune diseases. Its first-in-class clinical portfolio offers a diversified risk profile.
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Forward-looking statements

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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 26 April 2018, including the annual financial report for the fiscal year 2017, 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.