OSE Immunotherapeutics Announces First Healthy Volunteers Dosed in Phase 1 Clinical Trial of OSE-127

Entry into clinical phase of this anti-IL-7 receptor antagonist

A breakthrough approach for the treatment of inflammatory autoimmune diseases

NANTES, France, December 20, 2018, 6 p.m. CET - **OSE Immunotherapeutics SA** (ISIN: FR0012127173; Mnémo: OSE) today announces that the first healthy volunteers have been dosed in the Phase 1 clinical trial evaluating OSE-127, a monoclonal antibody with a diffentiated mechanism of action targeting the interleukin-7 receptor (IL-7R)[(1)], for the treatment of autoimmune diseases and chronic inflammation.

Alexis Peyroles, CEO of OSE Immunotherapeutics, said: *"Entering the clinic is an important milestone for OSE-127 which has already demonstrated a novel mechanism of action in recently peer-reviewed preclinical studies. As the only full-antagonist at the IL-7R, this compound has the potential to be a best-in-class therapy for a number of autoimmune conditions, such as Sjögren disease or inflammatory bowel diseases, with strong medical need and presenting blockbuster market opportunities."*

The first healthy subjects have been enrolled soon after having received approval at the end of November 2018 from the Belgian health authorities. This first-in-human dose-escalation, randomized, double-blind, placebo-controlled Phase 1 trial, aims to evaluate the safety and tolerability of single- and multiple-ascending intravenous and subcutaneous doses of OSE-127 in 63 healthy volunteers.

Secondary endpoints include measures of pharmacokinetics, pharmacodynamics and immunogenicity to help assess and understand how the drug is absorbed and metabolized. In addition, exploratory biomarkers will be used to assess OSE-127's potential for the treatment of inflammatory autoimmune diseases.

The effectiveness of current therapies for autoimmune and chronic inflammatory diseases is hindered by both primary and acquired resistance to treatments. This resistance is governed by re-activation and proliferation of pathogenic memory T cells[(2)]. Best-in-class full-antagonistic properties[(1)] of OSE-127 was shown to prevent long-term deleterious memory T cell-mediated inflammation *in vivo*. Blocking IL-7R with OSE-127 abrogated the response of pathogenic antigen-specific memory T lymphocytes while preserving quiescent T cells and natural T cell regulators.

ABOUT OSE-127

OSE-127 is a monoclonal immunomodulatory antibody targeting the CD127 receptor, the alpha chain of the interleukin-7 receptor (IL-7R) that induces a powerful antagonist effect on effector T lymphocytes. Interleukin-7 is a cytokine which specifically regulates the tissue migration of human effector T lymphocytes, especially in the gut. The blockage of IL-7R prevents the migration of pathogenic T lymphocytes while preserving regulator T lymphocytes [(1,2,3,4)] which have a positive impact in autoimmune diseases.

OSE-127 is being developed under an option license agreement with Servier* up to the completion of a Phase 2 clinical trial, planned in ulcerative colitis, a bowel autoimmune disease, and in parallel in Sjögren's syndrome.

*Servier is an independent international pharmaceutical company governed by a foundation with Headquarters based in France.

(1) *Belarif, L. et al.IL-7 receptor blockade blunts antigen-specific memory T cell responses and chronic inflammation. Nature communications, 26 October 2018*

(2) *Belarif, L. et al;Full antagonist of the IL-7 receptor suppresses chronic inflammation in non-human primate models by controlling antigen-specific memory T cells; Microreview Cell Stress, December 2018*

(3) *Powell, N. et al. The transcription factor T-bet regulates intestinal inflammation mediated by interleukin-7 receptor+ innate lymphoid cells. Immunity 37, 674–684 (2012)*

(4) *Yamazaki, M. et al. Mucosal T cells expressing high levels of IL-7 receptor are potential targets for treatment of chronic colitis. J. Immunol. 171, 1556–1563 (2003)*

ABOUT OSE Immunotherapeutics

OSE Immunotherapeutics is a clinical-stage biotechnology company focused on developing and partnering therapies to control the immune system for immuno-oncology and autoimmmune diseases. The company has a diversified first-in-class clinical portfolio consisting of several scientific and technological platforms including neoepitopes and agonist or antagonist monoclonal antibodies, all ideally positioned to fight cancer and autoimmune diseases. The most advanced therapeutic-candidate, Tedopi®, is a proprietary combination of 10 neo-epitopes aimed at stimulating T-lymphocytes and is currently in Phase 3 development in non-small cell lung cancer (NSCLC) after checkpoint inhibitor failure (anti PD-1 and anti PD-L1) and in Phase 2 testing in pancreatic cancer in combination with checkpoint inhibitor Opdivo®. FR104 (an anti-CD28 mAb) has successfully completed Phase 1 testing and has potential to treat autoimmune diseases. In April 2018, Boehringer Ingelheim and OSE signed a global license and collaboration agreement to develop preclinical checkpoint inhibitor OSE-172 (anti-SIRPa monoclonal antibody) in multiple cancer indications. OSE-127 (monoclonal antibody targeting the CD127 receptor, the alpha chain of the interleukin-7 receptor) is partnered with Servier under an option agreement up to the completion of a Phase 2 clinical trial planned in autoimmune bowel diseases; in parallel, Servier plans a development in the Sjögren syndrome. OSE-127 is currently under Phase 1 clinical trial.

Click and follow us on Twitter and Linkedln

Contacts

OSE Immunotherapeutics
Sylvie Détry
Sylvie.detry@ose-immuno.com
+33 143 297 857

U.S. Media: LifeSci Public Relations
Darren Opland, Ph.D.
Darren@lifescipublicrelations.com
+1 646 627-8387

French Media: FP2COM
Florence Portejoie
fportejoie@fp2com.fr
+33 607 768 283

U.S. and European Investors
Chris Maggos
chris@lifesciadvisors.com
+41 79 367 6254

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 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.