

OSE Immunotherapeutics Receives Belgian Authorization for a Phase 1 Clinical Trial to Evaluate Anti-IL-7 Receptor Antagonist OSE-127

NANTES, France, November 26, 2018, 18:00 p.m. CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnémo: OSE) today announced authorization by Federal Agency for Medicines and Health Products (FAMH) and Belgian Ethics Committee to initiate a Phase 1 clinical trial of OSE-127, a monoclonal antibody targeting the IL-7 Receptor (IL-7R) with a novel mechanism of action⁽¹⁾.

The first-in-human dose-escalation Phase 1 clinical study aims to evaluate the safety and tolerability of single- and multiple-ascending intravenous and subcutaneous doses of OSE-127. A total of 63 healthy volunteers will be enrolled in this randomized, double-blind, placebo-controlled study.

Alexis Peyroles, CEO of OSE Immunotherapeutics, said: *“Initiating this Phase 1 study represents a leap forward for OSE-127. On the heels of publishing the unique mechanism of action of OSE-127 in Nature Communications⁽²⁾, we believe even more strongly that this asset has significant potential therapeutic value for treatment of autoimmune diseases and chronic inflammation.”*

Specifically targeting IL-7R expression, which has previously been shown to be predictive for non-response to inflammatory bowel disease treatments, and by enhancing regulatory T lymphocytes in the mucosa, OSE-127 offers a differentiated mechanistic profile in debilitating autoimmune conditions, such as intestinal bowel 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.

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^(2,3) which have a positive impact in autoimmune diseases.

OSE Immunotherapeutics has signed a license option agreement with Servier in December 2016 for the development and commercialization of OSE-127.

- (1) Cf. Press release of October 26, 2018: Belarif, L. et al. IL-7 receptor blockade blunts antigen-specific memory T cell responses and chronic inflammation. *Nature communications*, 26 October 2018
- (2) 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)
- (3) 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 autoimmune 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. Our most advanced asset, 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). In April 2018, Boehringer Ingelheim and OSE signed a global license and collaboration agreement to develop checkpoint inhibitor OSE-172 (anti-SIRPa monoclonal antibody) in multiple cancer indications. In July 2016, Janssen Biotech exercised a licensing option to continue clinical development of FR104 (an anti-CD28 mAb) in auto-immune diseases after positive Phase 1 results; termination of licence agreement effective Dec. 31, 2018 due to strategic portfolio prioritization and OSE regained all worldwide rights on this asset. In 2016, Servier signed a two-step license option to develop OSE-127 (monoclonal antibody targeting the CD127 receptor, the alpha chain of the interleukin-7 receptor) 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.

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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 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.