OSE Immunotherapeutics Invited to Present Mechanistic Data on Clinical Stage Anti-Interleukin-7 Receptor Antagonist OSE-127 at Two International Scientific Conferences

Data presented at the Annual World Congress of Digestive Disease in Rome, Nov. 30 - Dec. 2, and at the Antigen-Specific Immune Tolerance Europe Summit in London, Dec. 10 - 12

- ***Presentations highlight OSE-127's differentiated mechanism of action and significant therapeutic potential for treatment of autoimmune diseases and chronic inflammation.***
- ***Clinical Trial Application Approval to initiate a Phase 1 dose-escalation study with OSE-127 recently received.***

NANTES, France, December 10, 2018, 6 p.m. CET - **OSE Immunotherapeutics SA** (ISIN: FR0012127173; Mnémo: OSE) was invited to present data on OSE-127, its anti-interleukin-7 receptor (IL-7R) antibody, including preclinical results from inflammatory and autoimmune chronic disease models and *ex-vivo* human biopsies, at the *Annual World Congress of Digestive Disease* in Rome, Nov. 30 - Dec. 2, and at the *Antigen-Specific Immune Tolerance Europe Summit* in London, Dec. 10 - 12.

The data presented, partially described in OSE's recent publication in *Nature Communications*[(1)], highlight the differentiated mechanism of action of OSE-127, currently in a first-in-human Phase 1 study, and confirm the potential therapeutic value of its further clinical development in inflammatory bowel diseases:

- IL-7R, expressed on T effector cells and target of OSE-127, is strongly overexpressed in colon biopsies from patients with inflammatory bowel diseases who are in therapeutic failure following treatment with corticosteroids, immunosuppressors or anti-TNFα compounds.
- In patients with active mucosal lesions IL-7R expression is significantly increased and is predictive for non-response to anti-TNFα treatment. Moreover, this non-response is strongly correlated to a mucosal defect in regulatory T-lymphocytes.
- OSE-127 has shown:
  - A good safety profile in relevant preclinical models by selectively targeting pathogenic effector cells while preserving quiescent T cells and natural T cell regulators.
  - Long-term control of specific memory T cell mediated autoimmunity and chronic inflammation including local decrease in colon inflammation and a role in restoring a favorable immune balance between regulatory T cells and effector T cells.
  - Full antagonist properties *in vivo* via blocking two sites of IL-7R ("Sites 1 and 2b"). Two other mAbs against IL-7R that only target Site 1 were tested in parallel and presented paradoxical agonist and antagonist properties, thereby limiting their efficacy[(1)].

"OSE-127 is highly differentiated by its mechanism of action, which makes it a true antagonist of IL-7R and more likely to deliver therapeutic benefits and we look forward to initiating Phase 1 clinical trial," said Alexis Peyroles, CEO of OSE Immunotherapeutics.

On Nov. 26, 2018, OSE Immunotherapeutics received authorization from the Belgian health authorities to initiate a Phase 1 clinical trial of OSE-127. 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.

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) 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

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.

(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 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. 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) to develop the product up to the completion of a Phase 2 clinical trial planned in autoimmune bowel disease and Sjogren's syndrome. In November 2018, OSE received CTA approval to initiate a Phase 1 clinical trial of OSE-127.

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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.