# OSE Immunotherapeutics and Servier Announce First Option Within Global License Agreement Exercised for Further Clinical Development and Potential Commercialisation of OSE-127 in Autoimmune Diseases

*Servier exercised first of two steps under OSE-127 global licensing option agreement*
*OSE-127, an IL-7R antagonist, is currently in Phase 1 clinical testing*

**Nantes and Paris, France**, Feb. 7, 2019, 18:00 p.m. CET – **OSE Immunotherapeutics** (ISIN: FR0012127173; Mnémo: OSE), today announced that Servier, an independent international pharmaceutical company, has exercised the first step under a two-step option agreement for exclusive global rights to OSE-127, a differentiated monoclonal antibody antagonist targeting the interleukin-7 receptor (IL-7R), discovered by OSE.

Under the license agreement, exercising the first step of the option triggered a €10 million* milestone payment to OSE from Servier, who made the decision following the achievement of prespecified data-based developmental achievements. OSE-127, which has potential to treat both autoimmune disease and chronic inflammation, is currently being evaluated in a Phase 1 clinical trial in which the first healthy volunteers were enrolled and dosed in December 2018.

Alexis Peyroles, CEO of OSE Immunotherapeutics, said: *"This demonstrates Servier's commitment and strong belief in the potential of OSE-127 as a potential best-in-class treatment for autoimmune conditions. We look forward to continuing our partnership to develop and deliver this innovative therapy to patients suffering from debilitating autoimmune diseases, including inflammatory bowel diseases and Sjögren's syndrome. More broadly, the progress on OSE-127, together with continued progress in our expanding pipeline, further demonstrates the potential of OSE's discovery and development capabilities in autoimmune diseases and immuno-oncology. The milestone payment reinforces the Company's cash position, providing financial viability until 2020."*

Under the terms of the agreement, signed in December 2016, OSE Immunotherapeutics granted Servier a two-step option agreement to acquire the exclusive worldwide license to develop and commercialize OSE-127 until the completion of a Phase 2 clinical trial planned in ulcerative colitis, an autoimmune bowel disease. OSE is eligible to receive up to a total of €272 million in development, regulatory and sales milestones. The €272 million includes the upfront payment of €10.25 million, received in early 2017, and additional payments of up to €30 million to be paid upon the exercise of the two-step option (including €10 million paid upon exercise of this first option step), linked to undisclosed development milestones.

*"The partnership with OSE Immunotherapeutics illustrates Servier's resolve to provide innovative therapeutic solutions for patients with immune-inflammatory diseases. It fits with Servier's philosophy of focusing its research on diseases with high unmet needs, by relying on partners with complementary knowledge and technologies to accelerate research for the benefit of patients,"* declared Philippe Moingeon, Head of therapeutic area immuno-inflammatory diseases at Servier.

**As both OSE and Servier are French companies, total amount received is of €12 million including the VAT.*

**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 agreement with Servier, which has the option to license global rights to develop and market OSE-127 until the completion of Phase 2 clinical trials, planned in ulcerative colitis, an autoimmune bowel disease, and, in parallel, in Sjögren's syndrome.

*(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 antigenspecific 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.

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**About Servier**

Servier is an international pharmaceutical company governed by a non-profit foundation, with its headquarters in France (Suresnes). With a strong international presence in 149 countries and a turnover of 4.2 billion euros in 2018, Servier employs 22 000 people worldwide. Entirely independent, the Group reinvests 25% of its turnover (excluding generics) in research and development and uses all its profits for development. Corporate growth is driven by Servier's constant search for innovation in five areas of excellence: cardiovascular, immune-inflammatory and neurodegenerative diseases, cancer and diabetes, as well as by its activities in high-quality generic drugs. Servier also offers eHealth solutions beyond drug development.
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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.