

OSE Immunotherapeutics Announces Publication on Anti-IL-7 Receptor Antagonist, OSE-127, in The Journal of Clinical Investigation

- Data further support OSE-127's potential in chronic inflammatory bowel diseases
- Confirm novel and differentiated mechanism of action of OSE-127, currently being investigated in an ongoing Phase 1 trial

Nantes, April 11, 2019 – 6:00PM CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnémo: OSE), today announced the publication of data on OSE -127, its full-antagonist monoclonal antibody targeting the interleukin-7 receptor (IL-7R), in the prestigious Journal of Clinical Investigation (JCI). The article reports on research led by the OSE Immunotherapeutics team, in collaboration with multiple international expert partners, that further supports the product's potential for the treatment of chronic inflammatory bowel diseases.

The article, entitled "IL-7 receptor influences anti-TNF responsiveness and T cell gut homing in inflammatory bowel disease", concluded that:

- In patients with active mucosal lesions, the overexpression of IL-7R, the target of OSE-127, is significantly increased and is predictive for non-response to anti-TNF α treatment. Moreover, this non-response is strongly correlated to a mucosal defect in regulatory T-lymphocytes.
- In preclinical humanized models reconstituted with human T lymphocytes, OSE-127 significantly blocked pathological homing of human T lymphocytes to the inflamed colon thereby preventing destruction of gut mucosa by the T lymphocytes.
- OSE-127 significantly reduced production of gamma interferon expressed by proinflammatory mucosal T lymphocytes *ex vivo* in colon biopsies from patients with inflammatory bowel disease.

"These findings confirm a novel and differentiated mechanism of action of full-antagonist of IL-7R OSE-127. They support the potential of this compound to be a relevant therapy in chronic inflammatory bowel diseases where there is a high unmet medical need. OSE-127 is currently being evaluated in a Phase 1 clinical trial and we look forward to further exploring the product's potential through our ongoing partnership with Servier¹," commented Nicolas Poirier, chief scientific officer of OSE Immunotherapeutics. "We would like to warmly thank our team, the network of renowned experts and clinicians and all international and French institutions for their commitment to this work (Center for Research in Transplantation and Immunology, Nantes University Hospital: Pr. Gilles Blancho, Pr. Jean-Paul Soulillou, Dr. Sophie Brouard; Bpifrance; The London School of Medicine and Dentistry: Pr. Thomas T. MacDonald; The Institute of Digestive Diseases (IMAD), Nantes; Icahn School of Medicine at Mount Sinai, New York: Pr. Miriam Merad)."

OSE-127 is being developed in partnership with Servier under an option agreement up to the completion of a Phase 2 clinical trial planned in autoimmune bowel diseases and in parallel, Servier plans a development in Sjögren's syndrome. The product is currently under a Phase 1 clinical trial in which the first healthy volunteers were enrolled and dosed in December 2018. 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.

¹ Servier is an international pharmaceutical company governed by a non-profit foundation, with its headquarters in France (Suresnes).

IL-7 receptor influences anti-TNF responsiveness and T cell gut homing in inflammatory bowel disease

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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. BI 765063 (OSE-172) (anti-SIRPa monoclonal antibody) is under a license and collaboration agreement with Boehringer Ingelheim; this checkpoint inhibitor has received CTA from French and Belgian health authorities for a Phase 1 clinical trial in multiple cancer indications. BiCKI[®] is a bispecific fusion protein platform built on the key backbone component anti-PD-1 (OSE-279) and targeting innovative targets. 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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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.