

OSE Immunotherapeutics Regains Worldwide Rights to its CD28 antagonist FR104 from Janssen Biotech

*OSE to pursue clinical development of FR104 to treat autoimmune diseases
FR104's good phase 1 clinical safety profile and first efficacy signal support phase 2 testing*

NANTES, France, November 2, 2018, 8:00 a.m. CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnémo: OSE) today announced that it will regain the worldwide rights to FR104, its first-in-class CD28 antagonist, from Janssen Biotech, Inc., effective December 31, 2018. Following the termination of the license agreement, OSE Immunotherapeutics will recover its FR104 intellectual property rights that had been licensed to Janssen. The agreement also provides that OSE Immunotherapeutics will for its continued development of FR104 have exclusive access to all intellectual property, data, filings and materials developed by Janssen relating to the FR104 program.

Janssen has been pursuing the development of FR104 pursuant to an exclusive license from OSE Immunotherapeutics*. Janssen's decision to return the program to OSE Immunotherapeutics is based on its own internal strategic review and prioritization of its portfolio.

Alexis Peyroles, chief executive officer of OSE Immunotherapeutics, said: *"FR104 is a valuable asset, phase 2-ready for autoimmune diseases, as we have all the necessary preclinical and clinical data required to conduct phase 2 trials. As such, regaining the rights to FR104 opens new opportunities for OSE Immunotherapeutics to create shareholder value. FR104 has already demonstrated a strong clinical and biological safety profile as well as shown initial signals of clinical efficacy. OSE is currently evaluating the best options for continuing a sustainable development of FR104 including worldwide partnering opportunities."*

CD28 blockade by FR104 controls T effector functions while potentiating regulatory T cells. This novel means of controlling immune synapses potentially offers new therapeutic options in multiple inflammatory and autoimmune diseases where T cells are involved and there are important unmet medical needs. Positive safety and biological activity results from FR104's Phase 1 proof of clinical concept study taken together with the preclinical safety profile and efficacy data in multiple preclinical models of autoimmune/inflammatory diseases further support continued clinical development.

Recent publications on FR104 can be found on the OSE Immunotherapeutics website: <https://ose-immuno.com/en/publications-scientifiques/> and below :

- Poirier et al, *Science Transl Med* 2010
Inducing CTLA-4-Dependent Immune Regulation by Selective CD28 Blockade Promotes Regulatory T Cells in Organ transplantation
- Poirier et al, *J Immunol* 2016,
First-in-Man Study in Healthy Subjects with FR104, a pegylated monoclonal antibody fragment antagonist of CD28

- *Vierboom et al, Clin Exp Immunol. 2016*
Clinical efficacy of a new CD28-targeting antagonist of T cell co-stimulation in a non-human primate model of collagen-induced arthritis
- *Ville et al, J Am Soc Nephrol 2016*
Anti-CD28 Antibody and Belatacept Exert Differential Effects on Mechanisms of Renal Allograft Rejection
- *Zaitsev et al, JCI Insight 2017*
Selective blockade of CD28 on human T cells facilitates regulation of alloimmune responses
- *Watkins et al, JCI 2018*
CD28 blockade controls T cell activation to prevent graft-versus-host disease in primates

* Cf. OSE Immunotherapeutics press release issued on 5 July 2016

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-SIRPα monoclonal antibody) in multiple cancer indications. In July 2016, Janssen Biotech, Inc. 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 Laboratories 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.

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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.