



PRESS RELEASE

## Servier and OSE Immunotherapeutics Announce Enrollment of First Patient in OSE-127/S95011 Phase 2 Clinical Trial in Sjögren's Syndrome

**Paris and Nantes (France), August 25, 2021 – 6:00 PM CET:** Servier, an independent global pharmaceutical group, and OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnémo: OSE), a French biotech, have announced enrollment of the first patient in the Phase 2 clinical trial of OSE-127/S95011 in Sjögren's syndrome, with Servier sponsorship.

This international, randomized, double-blind, placebo-controlled Phase 2 study aims to evaluate the efficacy and safety of OSE-127/S95011 in patients with Sjögren's syndrome.

Patricia Belissa-Mathiot, Director of Clinical Development and R&D Chief Medical Officer at Servier: *"The enrollment of the first patient in this study illustrates the momentum initiated with our partner, OSE Immunotherapeutics, to continue the development of OSE-127/S95011. This drug candidate may be a leading treatment in autoimmune diseases and specifically for patients with Sjögren's syndrome for whom the current therapeutic alternatives are still limited."*

*"We are very pleased with this new milestone for OSE-127/S95011 which, through our partnership with Servier, is now advancing into Phase 2 clinical development in two particularly debilitating autoimmune disease indications, Sjögren's syndrome and ulcerative colitis"* says Alexis Peyroles, CEO of OSE Immunotherapeutics.

Sjögren's syndrome is an autoimmune disease characterized by lymphoid infiltration of the salivary and lacrimal glands leading to dry mouth and eyes. Sjögren's syndrome is one of the most common chronic systemic autoimmune diseases, with an incidence of 60.82 per 100,000 people, according to a meta-analysis of epidemiological studies in Sjögren's syndrome<sup>1</sup>.

OSE-127/S95011 is being developed in partnership with OSE Immunotherapeutics as part of a collaboration agreement with license option upon completion of two Phase 2 clinical studies, and exercise of the option by Servier. An initial Phase 2 study under the sponsorship of OSE Immunotherapeutics is currently underway in ulcerative colitis.

As part of the agreement, two milestone payments are planned in favor of OSE Immunotherapeutics: An initial payment of EUR 5 million upon enrollment of the first patient in the Phase 2a clinical study and, if Servier exercises the option, a EUR 15 million payment upon completion of the two Phase 2 clinical studies.

---

<sup>1</sup> Qin et al, 2015

### **About OSE-127/S95011**

OSE-127/S95011 is a humanized monoclonal antibody that targets the CD127 receptor, the alpha chain of the interleukin-7 receptor, facilitating a potent antagonistic effect on effector T cells. IL-7 is a cytokine that specifically regulates tissue migration of human effector T lymphocytes, particularly in the digestive tract. Blocking the IL7 receptor slows down the migration of pathogenic T cells while preserving regulatory T cells that are beneficial in autoimmune diseases.

### **About Servier**

Servier is a global pharmaceutical group governed by a Foundation. With a strong international presence in 150 countries and a total revenue of 4.7 billion euros in 2020, Servier employs 22,500 people worldwide. Servier is an independent group that invests over 20% of its brand-name revenue in Research and Development every year. To accelerate therapeutic innovation for the benefit of patients, the Group is committed to open and collaborative innovation with academic partners, pharmaceutical groups, and biotech companies. It also integrates the patient's voice at the heart of its activities, from research to support beyond the pill.

A leader in cardiology, the ambition of the Servier Group is to become a renowned and innovative player in oncology. Its growth is based on a sustained commitment to cardiovascular and metabolic diseases, oncology, neuroscience and immuno-inflammatory diseases. To promote access to healthcare for all, the Servier Group also offers a range of quality generic drugs covering most pathologies More information: [servier.com](http://servier.com)

Follow us on Social Media:



### **Servier Media Relations contacts:**

Sonia Marques : [presse@servier.com](mailto:presse@servier.com) – Tel. +33 (0)1 55 72 40 21 / + 33 (0)7 84 28 76 13

Jean-Clément Vergeau : [presse@servier.com](mailto:presse@servier.com) – Tel. +33 (0)1 55 72 46 16 / +33 (0)6 79 56 75 96

### **About OSE Immunotherapeutics**

OSE Immunotherapeutics is an integrated biotechnology company focused on the development of innovative immunotherapies, directly or through partnerships, for immune activation and regulation in immuno-oncology and autoimmune diseases. The Company's immunology research and development is based on 3 areas: T cell-based vaccines, Immuno-Oncology (myeloid targets), and Auto-Immunity & Inflammation.

The company has a balanced clinical and preclinical portfolio with a diversified risk profile:

#### **Vaccines**

- Tedopi® (innovative combination of neo-epitopes); the Company's most advanced product:

- Positive Phase 3 (Atalante 1) step-1 results in advanced Non-Small Cell Lung Cancer in patients who have failed to respond to treatment with inhibitory checkpoints.
- In Phase 2 in pancreatic cancer (TEDOPaM), sponsor GERCOR.
- In Phase 2 in ovarian cancer in combination with pembrolizumab (TEDOVA) sponsor ARCAGY-GINECO.
- In Phase 2 in non-small cell lung cancer in combination with nivolumab, sponsor Italian FoRT Foundation.

- CoVepiT: a prophylactic second-generation vaccine against COVID-19, developed using SARS-CoV-2 optimized epitopes against multi variants. Positive preclinical and human ex vivo results. Voluntary and temporary pause in recruitment of the ongoing Phase 1 clinical trial (July 2021).

#### **Immuno-Oncology**

- BI 765063 (OSE-172, anti-SIRPα monoclonal antibody on the SIRPα-CD47): Developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 results in monotherapy and dose escalation study ongoing in combination with ezabenlimab (PD-1 antagonist).

- CLEC-1 (novel myeloid checkpoint target): Identification of mAb antagonists of CLEC-1 blocking the “Don't Eat Me” signal that increase both tumor-cell phagocytosis by macrophages and antigen capture by dendritic cells.
- BiCKI®: Bispecific fusion protein platform built on key backbone component anti-PD-1 (OSE-279) combined with new immunotherapy targets; second generation PD-L1 inhibitors to increase anti-tumor efficacy.

#### **Auto-Immunity & Inflammation**

- FR104 (anti-CD28 monoclonal antibody): Licensing partnership with Veloxis in the organ transplantation market; ongoing Phase 1/2 in renal transplant (sponsored by the Nantes University Hospital); Phase 2-ready asset in an autoimmune disease indication.
- OSE-127/S95011 (humanized monoclonal antibody targeting the IL-7 receptor): Developed in partnership with Servier; positive Phase 1 results; in Phase 2 in ulcerative colitis (OSE Immunotherapeutics sponsorship) and an independent Phase 2a ongoing in Sjögren's syndrome (Servier sponsorship).
- OSE-230 (ChemR23 antagonist antibody): first-in-class therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

More information on <http://ose-immuno.com>

Follow OSE Immunotherapeutics on Twitter and LinkedIn



#### **OSE Immunotherapeutics Press Contact:**

FP2COM - Florence Portejoie: [fportejoie@fp2com.fr](mailto:fportejoie@fp2com.fr) – Tel. +33 (0)6 07 76 82 83

#### **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 Universal Registration Document filed with the AMF on 15 April 2021, including the annual financial report for the fiscal year 2020, 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.

