

## Servier and OSE Immunotherapeutics announce completion of patient enrollment in the Phase 2a clinical trial of OSE-127/S95011 in primary Sjögren's syndrome

**Paris and Nantes (France), November 3, 2022, 7:30AM CET** - Global pharmaceutical group Servier and French biotechnology company OSE Immunotherapeutics SA today announced the completion of patient enrollment in the Phase 2a clinical trial evaluating the efficacy and safety of monoclonal antibody OSE-127/S95011 in primary Sjögren's syndrome.

This international, randomized, double-blind, placebo-controlled, Phase 2a study is designed to evaluate the efficacy and tolerance of the monoclonal antibody named OSE-127/S95011 in primary Sjögren's syndrome. The study includes 48 patients across a score of centers located in the United States, Australia and Europe. Results are expected in 2023.

**Patricia Belissa-Mathiot, Servier's Director of clinical development and R&D Chief Medical Officer, said:** "We are humbled with the progress of this clinical study and look forward to announcing the initial results in the coming year. Primary Sjögren's syndrome, one of the most common systemic autoimmune diseases, is a disease with significant unmet need and we are grateful to the patients for their participation in this study."

**Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics said:** "We are thankful for our partnership with Servier as we continue to progress this Phase 2a clinical trial, which represents an important step forward in determining the clinical safety and efficacy of OSE-127/S95011 for patients living with Sjögren's syndrome."

OSE-127/S95011, for which Servier has worldwide rights, is being developed in partnership between OSE Immunotherapeutics and Servier via a collaboration agreement, with the possibility for Servier to exercise a licensing option. Two clinical studies evaluating OSE-127/S95011 are ongoing: a Phase 2a study conducted by Servier in primary Sjögren's syndrome and a Phase 2 study conducted by OSE Immunotherapeutics in ulcerative colitis.

### About Sjögren's syndrome

Primary Sjögren's syndrome is an autoimmune disease characterized by lymphocytic infiltration of salivary and lacrimal glands, causing dryness of mouth and eyes and negatively impacting quality of life. Other organs can be affected. Primary Sjögren's syndrome is one of the most common chronic systemic autoimmune diseases, with a prevalence of 60.82 per 100,000 population<sup>1</sup> according to an epidemiological meta-analysis of primary Sjögren's syndrome.

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<sup>1</sup> Source: <https://ard.bmj.com/content/74/11/1983#>

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**About Servier**

Founded to serve health, Servier is a global group governed by a Foundation that aspires to have a meaningful social impact, both for patients and for a sustainable world. With its unique governance model, it can fully serve its vocation with a long-term vision: being committed to therapeutic progress to serve patient needs. The 21,800 employees of the Group are committed to this shared vocation, source of inspiration every day.

As a world leader in cardiology, Servier's ambition is to become a renowned, focused and innovative player in oncology by targeting hard-to-treat cancers. That is why the Group allocates over 50% of its R&D budget to developing targeted and innovative therapies in oncology.

Neuroscience and immuno-inflammatory diseases are the future growth drivers. In these areas, Servier is focused on a limited number of diseases in which accurate patient profiling makes it possible to offer a targeted therapeutic response through precision medicine.

To promote access to quality care for all at a lower cost, the Group also offers a range of quality generic drugs covering most pathologies, relying on strong brands in France, Eastern Europe, Brazil and Nigeria.

In all these areas, the Group includes the patient voice at each stage of the life cycle of a medicine.

Headquartered in France, Servier relies on a strong geographical footprint in over 150 countries and achieved a revenue of €4.7 billion in 2021.

More information on the new Group website: [servier.com](http://servier.com)

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**About OSE Immunotherapeutics**

OSE Immunotherapeutics is a biotech company dedicated to developing first-in-class assets in immuno-oncology and immuno-inflammation.

The Company's current well-balanced first-in-class clinical pipeline includes:

- Tedopi® (immunotherapy activating tumor specific T-cells, off-the-shelf, neoepitope-based): this cancer vaccine is the Company's most advanced product; positive results from the Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in secondary resistance after checkpoint inhibitor failure. Other Phase 2 trials, sponsored by clinical oncology groups, of Tedopi® in combination are ongoing in solid tumors.
- OSE-279 (anti-PD1): advanced preclinical stage.
- OSE-127/S95011 (humanized monoclonal antibody antagonist of IL-7 receptor) developed in partnership with Servier; ongoing Phase 2 in ulcerative colitis (sponsor OSE Immunotherapeutics) and ongoing Phase 2a in Sjögren's syndrome (sponsor Servier).
- VEL-101/FR104 (anti-CD28 monoclonal antibody): developed in partnership with Veloxis Pharmaceuticals, Inc. in transplantation; ongoing Phase 1/2 in renal transplant (sponsor Nantes University Hospital); Phase 1 ongoing in the US (sponsor Veloxis Pharmaceuticals, Inc.).
- BI 765063 (anti-SIRPα monoclonal antibody on CD47/SIRPα pathway): developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 dose escalation results of BI 765063 in

monotherapy and in combination, in particular with anti-PD-1 antibody ezabemlimab; BI sponsored international Phase 1b ongoing clinical trial in combination with ezabemlimab alone or with other drugs in patients with recurrent/metastatic head and neck squamous cell carcinoma (HNSCC) and hepatocellular carcinoma (HCC).

OSE Immunotherapeutics expects to generate further significant value from its two proprietary drug discovery platforms, which are central to its ambitious goal to deliver next-generation first-in-class immunotherapeutics:

- BiCKI<sup>®</sup> platform focused on immuno-oncology (IO) is a bispecific fusion protein platform built on the key backbone component of anti-PD1 combined with a new immunotherapy target to increase anti-tumor efficacy. The most advanced BiCKI<sup>®</sup> candidate is targeting anti-PD1xIL-7.
- Myeloid platform focused on optimizing the therapeutic potential of myeloid cells in IO and immuno-inflammation (I&I). OSE-230 (ChemR23 agonist mAb) is the most advanced candidate generated by the platform, with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

Additional information about OSE Immunotherapeutics assets is available on the Company's website: [www.ose-immuno.com](http://www.ose-immuno.com)

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