

## OSE Immunotherapeutics Receives U.S. Patent Notice of Allowance for Tedopi®

*Further Strengthens Global Intellectual Property Portfolio for Tedopi®  
in Non-Small Cell Lung Cancer until 2035*

**Nantes, France, September 7, 2021 - 7:30 AM CET – OSE Immunotherapeutics** (ISIN: FR0012127173; Mnémo: OSE) announced today that it has received notice of allowance from the United States Patent and Trademark Office for a patent application related to Tedopi®, a combination of neoepitopes, protecting its administration schedule for inducing early T-lymphocyte memory response, used in the treatment of non-small cell lung cancer (NSCLC) in HLA-A2 positive patients. This patent will provide a protection until 2035.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, said: *“This new patent notice of allowance granted in the U.S. further expands the patent protection for Tedopi® and confirms a specific mechanism of action inducing an early T-lymphocyte memory response in HLA-A2 positive patients, which represent 45% of the population. Our neoepitope approach with Tedopi® was validated by positive results from Step-1 of the Atalante 1 Phase 3 study in NSCLC patients after immune checkpoint failure released in 2020, confirming the clinical benefit Tedopi® can provide to patients who need new therapeutic options for this indication. We are very pleased to present the final results of Atalante 1 in an oral presentation at the 2021 European Society for Medical Oncology (ESMO) conference on September 20. In parallel, we continue to develop Tedopi® in NSCLC after failure from Immune Checkpoint Inhibitors (ICI) as well as in other cancer indications, in combination with ICIs or with chemotherapy. Such combinations will further reinforce the therapeutic value of Tedopi® in late stage cancer indications.”*

The Atalante 1 clinical trial aims at evaluating the benefit of Tedopi® in HLA-A2 positive NSCLC patients at invasive stage IIIB or metastatic stage IV, as 2<sup>nd</sup> or 3<sup>rd</sup> line treatment following checkpoint inhibitor failure. The Tedopi® treatment is compared to docetaxel or pemetrexed chemotherapy (CT) treatments, with overall survival as the primary endpoint.

### **ABOUT OSE Immunotherapeutics**

OSE Immunotherapeutics is an integrated biotechnology company focused on developing and partnering therapies to control the immune system for immuno-oncology and autoimmune diseases. The company's immunology research and development platform is focused on three areas: T-cell-based vaccination, Immuno-Oncology (focus on myeloid targets), Auto-immunity & Inflammation. Its balanced first-in-class clinical and preclinical portfolio has a diversified risk profile:

#### **Vaccine platform**

- **Tedopi®** (innovative combination of neoepitopes): the company's most advanced product; positive results for Step-1 of the Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer post checkpoint inhibitor failure.
  - In Phase 2 in pancreatic cancer (TEDOPaM), sponsor GERCOR.
  - In Phase 2 in ovary cancer, in combination with pembrolizumab (TEDOVA), sponsor ARCAGY-GINECO.
  - In Phase 2 in non-small cell lung cancer in combination with nivolumab, sponsor Italian foundation FoRT.

- **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 Phase 1 enrollment suspension on-going (July 2021).

#### **Immuno-oncology platform**

- **BI 765063** (OSE-172, anti-SIRPα mAb on SIRPα/CD47 pathway): developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 results in monotherapy and BI 765063 dose escalation study ongoing in combination with Ezabemimab (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 the key backbone component anti-PD-1 (OSE-279) combined with new immunotherapy targets; 2<sup>nd</sup> generation of PD-(L)1 inhibitors to increase antitumor efficacy.

#### **Auto-immunity and inflammation platform**

- **FR104** (anti-CD28 monoclonal antibody): Licensing partnership agreement with Veloxis in the organ transplant 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 IL-7 receptor): developed in partnership with Servier; positive Phase 1 results; in Phase 2 in ulcerative colitis (OSE sponsor) and an independent Phase 2a is being conducted in Sjögren’s syndrome (Servier sponsor).
- **OSE-230** (ChemR23 agonist mAb): first-in-class therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

For more information: <https://ose-immuno.com/en/>

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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 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.