OSE Immunotherapeutics Receives U.S. Patent Notice of Allowance for Use of Tedopi® to Treat Brain Metastasis

Nantes, France, June 11, 2019 - 7:00 a.m. CET - OSE Immunotherapeutics (ISIN: FR0012127173; Mnémo: OSE) today announced that the United States Patent and Trademark Office (USPTO) has issued the notice of allowance for a new patent family related to Tedopi®, for use in the treatment of brain metastasis originating from cancers, including non-small cell lung cancer (NSCLC), in HLA-A2 positive patients. This patent will provide a protection covering the use of Tedopi®, a combination of neoepitopes, in the treatment of brain metastasis until 2034.

Brain metastasis is associated with poor prognosis as well as significant morbidity, creating a large unmet medical need. The U.S. Tedopi® patent originated from Phase 2 results conducted in NSCLC patients. In the study, patients with brain metastasis showed longer than expected overall survival as well as longer time without disease progression(1), considering the advanced stage and the poor prognosis of these brain metastasis patients heavily previously treated. The long overall survival observed was correlated with immune T lymphocyte response to neoepitopes.

“The expansion of this new patent family to the United States gives Tedopi®, first granted in Japan early 2019, significantly consolidated intellectual property and value. Given the devastating nature of both advanced NSCLC and brain metastatic cancer, there is a great need for new treatment options for patients,” said Alexis Peyroles, chief executive officer of OSE Immunotherapeutics. “The two ongoing clinical trials with Tedopi® reflect our commitment to building on strong Phase 2 and preclinical evidence supporting the potential of this developmental therapy.”

Tedopi® is OSE’s most advanced product, currently in Phase 3 in NSCLC patients who have failed previous immune checkpoint inhibitor therapy, a patient population with no currently approved therapeutic option. Tedopi® is also being evaluated in combination with Opdivo®, an anti-PD-1 checkpoint inhibitor, in a Phase 2 trial in pancreatic cancer sponsored by the GERCOR cooperative group in oncology. A recent key opinion leader event (click here for webcast replay) covered the history and current state of treatment for these patient populations.

Tedopi® is a combination of 10 neoepitopes selected and optimized from five tumor associated antigens able to generate a specific response against cytotoxic T-cells expressing at least one of these tumor associated antigens and an associated helper T-cell response.

(1) J. Nemunaitis et al, Denver IASLC 2015

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. 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®. 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. BICIK® is a bispecific fusion protein platform built on the key backbone component anti-PD-1 (OSE-279) and targeting innovative targets. FR104 (an anti-CD28 mAb) has successfully completed Phase 1 testing and has potential to treat autoimmune diseases. 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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Forward-looking statements
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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 2019, including the annual financial report for the fiscal year 2018, 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.