

## Continuation of “Atalante 1” Phase 3 Clinical Trial of Tedopi® in NSCLC Patients Post Checkpoint Inhibitor Failure Following IDMC Recommendation

**Nantes, France, June 20, 2019 - 6:00 p.m. CET - OSE Immunotherapeutics (ISIN: FR0012127173; Mnémo: OSE)** today announced that, after reviewing global study data, the Independent Data Monitoring Committee (IDMC) saw no safety concerns and recommended the continuation of patient recruitment, without any modifications, of its ongoing international pivotal Phase 3 trial, called Atalante 1, evaluating Tedopi® in HLA-A2 positive non-small cell lung cancer (NSCLC) patients post immune checkpoint inhibitor failure (PD-1/PD-L1).

*“This new IDMC review continues to support the development of Tedopi® in NSCLC in patients with unmet medical needs. While checkpoint inhibitors are now considered the standard of care in first- and second-line treatment of advanced NSCLC, many patients still fail to respond or continue to progress on these therapies. Our Phase 3 study with Tedopi® is conducted in a patient population with no currently approved therapeutic option, and the clinical need for patients in immune escape after such treatment is strong,”* said Alexis Peyroles, CEO of OSE Immunotherapeutics.

### **ABOUT Atalante 1**

Atalante 1 is evaluating the benefit of Tedopi® in HLA-A2 positive patients with NSCLC at invasive stage IIIB or metastatic stage IV, in 2nd or 3rd line treatment, following failure of a checkpoint inhibitor, compared to docetaxel or pemetrexed chemotherapy treatments in this patient population. The primary endpoint of the trial is overall survival. Next IDMC is planned in Q1 2020.

### **ABOUT Tedopi®**

Tedopi®, a proprietary combination of 10 neo-epitopes selected and optimized from five tumor associated antigens, has been shown to generate a specific response of cytotoxic T cells versus cancer cells expressing at least one of these tumor associated antigens and an associated T-helper cell response.

It is also being studied in a Phase 2 trial in combination with Bristol-Myers Squibb’s Opdivo® (nivolumab), an immune checkpoint inhibitor, in advanced or metastatic pancreatic cancer.

### **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 is under Phase 1 clinical trial in patients with advanced solid tumors. BiCKI® 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

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 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.