OSE Immunotherapeutics Announces that the Independent Data Monitoring Committee (IDMC) Recommends Continuation of Pivotal Phase 3 Clinical Trial of Tedopi® in Non-Small Cell Lung Cancer

Nantes, January 24, 2017, 6:15 p.m. - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnémo: OSE) announced today that the Independent Data Monitoring Committee (IDMC) for the Company's international pivotal Phase 3 clinical study (Atalante 1) of Tedopi® for the treatment of non-small cell lung cancer (NSCLC) has unanimously recommended continuation of the trial, without asking for modifications.

As specified in the study protocol of Atalante 1, the IDMC meets on a regular basis to review data from the ongoing trial. The IDMC is a group of independent experts, external to the study, who assess the progress, safety data and critical efficacy endpoints of the clinical trial for safeguarding the interest of study participants. Based on its review, the IDMC provides the sponsor and the Steering committee with recommendations regarding study modification, continuation or termination. IDMCs are customary for large, randomized, multi-site studies, such as Atalante 1.

"We are very pleased with the IDMC's recommendation to continue, without modification, our ongoing Phase 3 trial with the Company's lead program in immuno-oncology, Tedopi®. This positive outcome following the IDMC's initial review is consistent with the safety and significant efficacy observed in Phase 2 trial", said Alain Chatelin, Chief Medical Officer, Immuno-Oncology.

The international Atalante 1 pivotal Phase 3 study is designed to evaluate the benefits of Tedopi® compared to current standard chemotherapies (docetaxel or premetrexed, both approved as 2nd line treatments) in HLA-A2 positive patients with stage IIIB (locally advanced) or IV (metastatic) NSCLC who have failed platinium-based therapy or 2nd line checkpoint inhibitor therapy. As recent clinical evidence has demonstrated positive results with checkpoint inhibitors in 1st line therapy, the study population has been extended to patients who received checkpoint inhibitors either as 1st or 2nd line therapy. This registration trial will include 500 patients and results are expected to be reported in late 2018.

A second IDMC review is expected to occur in the second quarter of 2017.

ABOUT OSE IMMUNOTHERAPEUTICS

Our ambition is to become a world leader in activation and regulation immunotherapies

OSE Immunotherapeutics is a biotechnology company focused on the development of innovative immunotherapies for immune activation and regulation in the fields of immuno-oncology, auto-immune diseases and transplantation. The company has a balanced portfolio of first-in-class products with a diversified risk profile ranging from clinical phase 3 registration trials to R&D:

In immuno-oncology:

- **Tedopi®, a combination of 10 optimized neo-epitopes** to induce specific T activation in immuno-oncology - **Currently in registration Phase 3 trial advanced NSCLC HLA A2+ patients EU /US -** Orphan Status in the US **- Registration**

expected in 2020 - a Phase 2 with Tedopi® in combination with a checkpoint inhibitor in NSCLC is considered in 2017**.**

- **OSE-172 (Effi-DEM), new generation checkpoint inhibitor** targeting the **SIRP-α receptor - In preclinical development** for several cancer models.

In auto-immune diseases and transplantation:

- **FR104,** CD28-antagonist in immunotherapy - **Phase 1 trial completed** – For the treatment of autoimmune diseases and for use with transplantation - **Licensed to Janssen Biotech Inc.** to pursue clinical development.
- **OSE-127 (Effi-7),** interleukin receptor-7 antagonist - **In preclinical development** for inflammatory bowel diseases and other autoimmune diseases. **License option agreement with Servier** for the development and commercialization.

The portfolio's blockbuster potential gives OSE Immunotherapeutics the ability to enter global agreements at different stages of development with major pharmaceutical players.

Immunotherapy is a highly promising and growing market. By 2023 Immunotherapy of cancer could represent nearly 60% of treatments against less than 3% at present * and the projected market is estimated at $67 billion in 2018 **.

There are more than 80 autoimmune diseases that represent a significant market including major players in the pharmaceutical industry with sales towards $10 billion for the main products. The medical need is largely unmet and requires the provision of new innovative products involved in the regulation of the immune system.

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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 8 June 2016 under the number R.16-052, the consolidated financial statements and the management report for the fiscal year 2015, as well as the Merger Document registered with the AMF on 26 April 2016 under number E.16-026, all 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.