



## OSE Immunotherapeutics Announces Temporary Pause of Patient Accrual While Continuing Treatment for Patients Already Enrolled In Phase 3 Clinical Trial of Tedopi® in Advanced Lung Cancer

NANTES, France, June 23, 2017, 9:00 p.m. CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnémo: OSE) today announced that following the recommendation by IDMC (independent experts) on the phase 3 clinical study, Atalante 1, which is evaluating Tedopi® for the treatment of non-small cell lung cancer, the Company is temporarily pausing patient accrual while continuing treatment for patients already enrolled in order to further assess the study's current patient profile in relation to the potential benefit of Tedopi® with more mature data.

*"The Company has decided to halt temporarily patient enrolment, but to continue treatment of patients already enrolled in this clinical trial, due to an emerging benefit/risk balance of the experimental treatment"* said Dominique Costantini, Chief Executive Officer of OSE Immunotherapeutics. *"Patients eligible for inclusion in the Atalante 1 study are cancer patients at an advanced stage who have failed a first-line treatment with chemotherapy or failed second-line therapy with checkpoint inhibitors, and enter the trial at stage of disease progression. This cancer progression may be difficult to control for some patients in the near-term due to the generally longer-term activity observed with a combination of neoepitopes, which differs from chemotherapy's generally near-term activity."*

Following further review of more patients' data and additional information being available, a decision will be made for the trial continuation as such or possible amendment to include specific sub-groups of patients.

The expected safety profile was observed in both treatment groups. The safety profile observed in the experimental treatment group is consistent with the one observed in the previous clinical trials of Tedopi®.

*"While further data analysis occurs here, we remain focused on advancing our other promising product candidates in the Company's robust development pipeline,"* continued Dr. Costantini.

### 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 - **A Phase 2 with Tedopi® in combination with a checkpoint inhibitor** in NSCLC is considered.
- **OSE-172 (Effi-DEM)**, new generation checkpoint inhibitor targeting the **SIRP- $\alpha$**  receptor - **In preclinical development** for several cancer models.
- **OSE-703 (Effi-3)**, cytotoxic monoclonal antibody against the alpha chain of IL-7R - Under a **multi-year strategic research collaboration with Memorial Sloan Kettering Cancer Center**, New York



**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.

\*Citi Research Equity  
\*\*BCC Research

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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 28 April 2017 under the number R.17-038, including the annual financial report for the fiscal year 2016, 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.