



OSE Immunotherapeutics Receives Approval in Europe to Resume Patient Accrual for Phase 3 Tedopi® Clinical Trial in Advanced Non-Small Cell Lung Cancer Patients Following Immune Checkpoint Inhibitor Treatment

Phase 3 Trial received Approval to be Initiated in Israel

Patient Accrual Already Resumed in the U.S.

NANTES, France, March 15, 2018, 18:00 p.m. CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnémo: OSE), today announces that the Company has received a positive opinion in Europe through the Voluntary Harmonisation Procedure (VHP) to resume patient accrual in the global Tedopi® Phase 3 trial, based on the revised protocol already approved in the U.S.

The approval from Israeli competent authorities to initiate the trial adds Israel to the U.S. and to seven European countries for the redeployment of the international Phase 3 Tedopi® trial.

The Tedopi® Phase 3 trial is being conducted in patients with Non-Small Cell Lung Cancer (NSCLC) who have failed a previous treatment with PD-1/PD-L1 immune checkpoint inhibitors. The new strategy addresses a specific patient population in immune escape, where there are currently no approved therapies and a significant unmet medical need.

The trial is being conducted in two steps:

1. Global enrolment of approximately 100 patients and a performance analysis of the survival data, with results expected in approximately two years.
2. Based on this analysis, the observed clinical benefit of Tedopi® will determine the registration strategy to be implemented in a second step.

"We are very pleased about resuming patient accrual in the Tedopi® Phase 3 trial, now possible in all countries involved," said Dominique Costantini, CEO of OSE Immunotherapeutics. "By specifically reactivating T lymphocytes, our Tedopi® neoepitope product is particularly interesting in immune escape after checkpoint inhibitors, now considered as standard treatments for advanced lung cancer."

The Tedopi® Phase 3 trial, 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. The primary endpoint of the trial is overall survival.

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, autoimmune diseases and transplantation. The company has several scientific and technological platforms: neoepitopes, agonist or antagonist monoclonal antibodies, ideally positioned to fight cancer and autoimmune diseases. Its first-in-class clinical portfolio offers a diversified risk profile.

In immuno-oncology:

- **Tedopi®**, 10 combined neo-epitopes to induce a specific T lymphocyte activation. Phase III trial in advanced NSCLC: after temporary pause of new patient accrual end of June 2017, new recruitment strategy in December 2017, following the recommendation of the trial's Independent Data Monitoring Committee, to focus the trial on patients who failed a previous treatment with a PD-1/PD-L1 immune checkpoint inhibitor. In Q1 2018, after approvals from the competent authorities, resume of patient accrual in the US and in Europe, and initiation of the trial in Israel.

Phase II with Tedopi® in combination with an immune checkpoint inhibitor planned in advanced pancreatic cancer, in collaboration with GERCOR, a cooperative group of clinical research.

- **OSE-172**, new generation checkpoint inhibitor targeting myeloid cells via the SIRP- α receptor - In preclinical development for several cancer models. Clinical program planned end of 2018.
- **OSE-703**, cytotoxic monoclonal antibody against the alpha chain of IL-7R - Under a 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**, interleukin receptor-7 antagonist - In preclinical development for inflammatory bowel diseases and other autoimmune diseases. Clinical phase planned end of 2018. 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, cancer Immunotherapy could represent nearly 60% of treatments compared to less than 3% of treatments currently*. The projected market is estimated to be 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.