OSE Pharma Announces U.S. Initiation of Atalante 1, the Company's Global, Pivotal Phase 3 Trial for Tedopi® Immunotherapy in Non-Small Cell Lung Cancer

Paris, February 4, 2016 - 18:00 PM – OSE Pharma SA (Euronext Paris: OSE), an immuno-oncology company developing a T-specific immunotherapy for late-stage cancer patients, today announced initiation in the United States of its Phase 3 clinical trial, Atalante 1. This global, pivotal trial will evaluate Tedopi®, the company's lead product, for advanced non-small cell lung cancer (NSCLC).

The company's approval of a first clinical site triggers the initiation in the United States of the global Phase 3 trial Atalante 1. The study was initiated in Europe in early 2016, and so the screening of eligible HLA-A2 positive patients diagnosed with NSCLC is now actively ongoing in both territories.

"The initiation of Atalante 1 in the U.S., where 20 per cent. of the total number of patients is expected to be included, marks a new critical milestone for the registration trial of Tedopi®. Atalante 1 is now open in both Europe and the U.S. We are very proud of all of the work that has been achieved in order to reach this key milestone, and we thank all the teams involved in reaching this developmental stage", commented Dominique Costantini, Chief Executive Officer of OSE Pharma.

Atalante 1 is designed to evaluate the benefits of Tedopi® compared to current standard chemotherapies (docetaxel or premetrexed, both approved second line treatments) in positive HLA-A2 patients with stage IIIB (locally advanced) or IV (metastatic) NSCLC who have failed at least one first-line treatment. This Phase 3 trial is based on the Phase 2 results showing an immune T-cell response significantly correlated with a survival increase, as well as on the long term survival benefit observed in highly pretreated patients with a poor prognosis. The trial will include 500 total patients and results are expected to be reported in 2018.

Tedopi® is a new "off-the-shelf" cancer immunotherapy approach which leverages the company's proprietary Memopi® technology and uses synthetic neo-epitopes to trigger a cytotoxic ("killer") T-cell response, leading the immune system to destroy cancer cells.

ABOUT ATALANTE 1 – For additional information about the Atalante 1 trial and to learn more about eligibility, patients can visit: https://clinicaltrials.gov/ct2/show/NCT02654587

This international Phase 3 registration study is aimed at evaluating the benefits of Tedopi® as compared to current standard chemotherapies (docetaxel or pemetrexed, both approved second line therapies). Tedopi® is administered as second-line (after failure of platinium based therapy) or third-line (after failure of immune checkpoint inhibitors) of treatment in HLA-A2 positive patients ; HLA-A2 is a key receptor for the cytotoxic T-immune response in those patients diagnosed with stage IIIB (locally advanced) or IV (metastatic) NSCLC. The primary endpoint of Atalante1 is overall survival. The study will include 500 patients enrolled at 70 European and U.S. investigational clinical sites. The trial is expected to be completed in 2018, provided that the recruitment of patients, their observed survival and the safety of the product meet the strict criteria set for this study. Phase 2 results with Tedopi® showed highly promising efficacy and an increase in survival duration alongside a good safety profile.

ABOUT NON-SMALL CELL LUNG CANCER (NSCLC)

NSCLC represents 88% of all lung cancers. Its overall relative five-year survival rate is 15.6%. For most patients, this cancer is diagnosed at an advanced stage, which makes it difficult to treat. NSCLC is considered to be a major public health issue, in large part due to its poor prognosis.

The products developed by OSE Pharma target patients who express HLA-A2 markers. The presence of these markers is considered to be an aggravating risk factor at an advanced stage. Approximately 45% of the global population (and of patients with NSCLC) express HLA-A2 markers (and are so-called "HLA-A2+"). OSE Pharma's treatments could thus target nearly 84,000 patients in the U.S., 134,000 in Europe and 258,000 in China.

Despite the different treatments available today (surgery, radiotherapy, chemotherapy, targeted therapy), the overall 5-year survival rate of NSCLC metastatic patients is only about 1%.

ABOUT OSE PHARMA

OSE Pharma is a biotechnology company that designs and develops cancer immunotherapy treatments aimed at re-educating the immune system to fight cancer while preserving patients' quality of life. The Company is conducting a Phase 3 registration trial in Europe and the U.S. for its lead product, Tedopi®, in the treatment of NSCLC.

Tedopi® (OSE-2101) is a new "off-the-shelf" cancer immunotherapy approach based on OSE Pharma's proprietary Memopi® technology. This technology is based on "neo-epitopes" (small synthetic peptides chemically modified to increase the binding the HLA A2 or TCR receptors) which trigger a cytotoxic T-cell response and leads the immune system to destroy cancer cells. More than 10,000 epitopes were selected to obtain a therapeutic universal T vaccine.

Tedopi® combines 10 optimized "neo-epitopes" simultaneously acting against 5 tumor-associated antigens (TAAs). These 5 antigens have been selected because they are a factor of poor prognosis in several types of cancers. The 10 "neo-epitopes" have been selected and modified to enhance their binding to HLA-A2 and TCR receptors, and trigger a stronger cytotoxic T-cell response and lead the immune system to destroy cancer cells expressing the HLA-A2 antigen or one of the targeted cancer antigens.

Tedopi® can also be developed in Phase 2 in combination with other immunotherapeutic products or targeted therapies. It is also considered for other oncology indications (ovary, colon, breast) for HLA-A2 positive patients.

OSE Pharma is listed on Euronext Paris (ISIN: FR0012127173; Mnémo: OSE).

For more information, please visit www.osepharma.com

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