First patients enrolled and dosed in the pivotal trial of Phase 3 of the immunotherapy Tedopi® for advanced non-small cell lung cancer

Paris, February 22nd, 2016, 6:30pm - OSE Pharma SA (ISIN: FR0012127173 ; Mnémo: OSE), an immuno-oncology company with a specific immunotherapy activating T lymphocytes, currently in a registration Phase 3 study, today announced enrolment and treatment of the first patients in its Atalante 1 Phase 3 trial. This trial is evaluating the benefits of Tedopi®, the company's lead product, for advanced non-small cell lung cancer in HLA-A2 positive patients.

After its initial launch in Europe and the United States, the first patient has been dosed in the pivotal clinical trial of Tedopi®. Further patients have been enrolled and are awaiting treatment, in accordance with the planned timetable. These first patients were enrolled at the Institut Gustave Roussy (Villejuif) and the Hospital Saint-Louis (Paris), healthcare centers highly specialized in the treatment of lung cancer.

The clinical trial Atalante 1 is being conducted internationally by a steering committee co-chaired by two clinical experts specialized in lung cancer treatments, in Europe by Doctor Benjamin Besse, Head of the Thoracic Pathology Committee at the Institut Gustave Roussy (Villejuif), and in the United States by Giuseppe Giaconne, Professor of Oncology, Medicine and Pharmacology at the Georgetown Lombardi Comprehensive Cancer Center in Washington. Of the 500 patients to be included in the clinical trial, around 80% will be recruited by European clinical centers, and the remaining 20% by US American centers.

"*We would like to thank our study investigators who are highly committed to evaluating Tedopi® and to offering a new therapeutic option to their patients needing a new treatment option. These first patients enrolled and dosed highlight the advance of this clinical Phase 3 study. We wish to confirm the promising results of the Phase 2 clinical trial in order to bring patients who have been diagnosed with advanced non-small cell lung cancer a new immunotherapy with significant clinical benefits and a good safety profile,*" says Alain Chatelin, medical director of OSE Pharma.

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 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 activate 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).

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