OSE Pharma Announces Initiation of its Pivotal Phase 3 trial of Tedopi® in Non-Small Cell Lung Cancer

Paris, January 6th, 2015 18:45 PM – OSE Pharma SA (ISIN: FR0012127173; Mnemo: OSE), an immuno-oncology company developing a T-specific immunotherapy for late-stage cancer patients, announces today the initiation of its registration clinical trial named "Atalante 1". This trial evaluates Tedopi®, the company's lead product for advanced non-small cell lung cancer (NSCLC).

The formal authorizations from regulatory agencies in France, Italy and Czech Republic, and the positive opinions from national ethic committees in these three countries enable the initiation of the Phase 3 trial Atalante 1. Patient enrollment is now open in these three countries and the company is expecting the same national authorizations in the remaining four European countries and in the US. Screening of eligible HLA-A2 positive patients begins in the first investigational clinical sites in NSCLC patients after failure of at least a first line therapy, as provided in the study protocol.

"The initiation of the Phase 3 trial of Tedopi® marks an important milestone of the product's development, "Atalante 1" being the pivotal study to support its registration in treatment of non-small cell lung cancer. We warmly thank all investigational centers involved in the study who, together with our teams, are fully committed to conduct the major step of this development program", commented Dominique Costantini, CEO of OSE Pharma.

This trial aims at evaluating the benefits of Tedopi® as compared to current standard chemotherapy (docetaxel or pemetrexed, both approved in second line therapy). Tedopi® is administered in second line or third line in HLA-A2 positive patients diagnosed with stage IIIB (locally advanced) or IV (metastatic) non-small cell lung cancer (NSCLC). The primary endpoint of this trial is overall survival. The phase 3 trial is conducted in 70 investigational clinical sites in Europe and in the US and will include 500 patients. It 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 trial.

ABOUT OSE PHARMA

OSE Pharma is a biotech company that designs and develops cancer immunotherapy treatments. Its Memopi® technology is based on "neo-epitopes" (small synthetic peptides chemically modified to increase the binding the HLA A2 or TCR receptors) which triggers 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.

Its lead product Tedopi® (OSE-2101) 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 optimized "neo-epitopes" have been selected and modified to enhance their binding to HLA-A2 and TCR receptors, and trigger a stronger T-cell response. These strong cytotoxic T-cell responses lead the immune system to destroy tumor cells expressing HLA-A2 antigens and one of the targeted tumor antigens.

The most advanced clinical stage of Tedopi® is a pivotal Phase 3 study put in place in Europe and in the U.S. in patients diagnosed with non-small cell lung cancer (NSCLC).

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, prostate, 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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These risks and uncertainties include among other things, the uncertainties inherent in future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives,
For a description of risks and uncertainties which could lead to discrepancies between actual results, financial condition, performance or achievements and those contained in the forward-looking statements, please refer to Chapter 4 "Risk Factors" of the company's Documents de Base filed with the AMF under number I. 14-056 on September, 17th 2014 and Chapter 2 "Risk Factors related to the Offer" in the prospectus approved by the AMF under number 15-078 on 6th March 2015, which can be found on the websites of the AMF (www.amf-france.org) and of OSE Pharma (www.osepharma.com).