OSE Pharma announces selection of 70 international clinical centers to participate in its pivotal Phase 3 trial of Tedopi® for patients diagnosed with advanced non-small cell lung cancer (NSCLC)

Paris, December 23rd, 2015 5:45 PM – OSE Pharma SA (ISIN: FR0012127173; Mnemo: OSE), an immuno-oncology company developing a T-specific immunotherapy in Phase 3 registration trial, announces that it finalized the selection of the 70 investigator centers, in Europe and the United States, to participate in its pivotal Phase 3 clinical trial of Tedopi®.

Simbec-Orion, specialized in oncology, and OSE Pharma's strategic partner responsible for the management of the study, has selected the 70 expert investigator centers that will lead the multi-center phase 3 trial. These sites were chosen according to criteria of excellence in the field of lung cancer and their recruitment capabilities in this pathology.

For example, among these centers of excellence in lung cancer, OSE Pharma works closely in France with the Gustave Roussy Institute (Paris), in Poland with the Medical University (Gdansk), and in the United States, with the Georgetown Lombardi Comprehensive Cancer Center (Washington).

«Following the European regulatory approvals recently obtained in 7 European countries, the European investigator centers selected to participate in our pivotal Phase 3 trial of Tedopi® are ready to recruit", said Alain Chatelin MD, Chief Medical Officer, OSE Pharma.

About the Tedopi® phase 3 registration study

The Phase 3 clinical trial, which will include 500 patients in Europe and the United States, is expected to be completed in 2018 provided that the recruitment of patients, their observed survival and the safety of the product meet the usual criteria for this kind of trials. The trial will focus on patients diagnosed with stage IIIB (advanced) or IV (metastatic) non-small cell lung cancer (NSCLC) after at least one first line therapy failure. All patients will express HLA-A2 receptor (representing 45% of NSCLC patients). It is a key receptor for the cytotoxic T-immune response and HLA-A2 patients are the responder Tedopi® population. Tedopi® will be compared to current standard chemotherapy (docetaxel or pemetrexed, both approved in second therapy line). The primary endpoint of this trial will be overall survival (the Phase 2 study demonstrated a long survival of patients, considering how advanced their pathology was).

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).