OSE Pharma sets up Scientific Steering Committee and takes a first step in the launch of its Phase 3 trial in lung cancer

Paris, September 1st, 2015, 7:00 PM – OSE Pharma SA (ISIN: FR0012127173; Mnémo: OSE), a biotechnology company based in France that is developing T-specific immunotherapy treatments against invasive and metastatic cancers, is pleased to announce the formation of its International Scientific Steering Committee as a part of the launch of its pivotal Phase 3 trial of Tedopi® by the end of the year.

The objective of this pivotal study is to evaluate the benefits of OSE Pharma's lead product Tedopi® compared to current standard chemotherapy treatments (docetaxel or pemetrexed) in HLA-A2 positive patients diagnosed with stage IIIB (advanced) or IV (metastatic) non-small cell lung cancer (NSCLC). These patients will be eligible to the trial after at least the failure of a first-line therapy. The primary endpoint of this trial will be overall survival. The Phase 2 study demonstrated a long survival of patients, taking into account how advanced their pathology was.

The creation of this Scientific Steering Committee is a key step for OSE Pharma in finalizing its trial's protocol. The Committee will be in charge of making decisions regarding the monitoring of the clinical study, in consultation with an independent monitoring committee.

The International Scientific Steering Committee consists of 4 members:

- **Dr. Benjamin Besse**, Oncologist and Head of the Thoracic Pathology Committee at the Institut Gustave Roussy in Paris, will chair the Scientific Steering Committee,
- **Pr. Giuseppe Giaconne**, Associate Director of Clinical Research at the Georgetown Lombardi Comprehensive Cancer Center**,** will co-chair the Committee in the United States, with
- **Dr. Enriqueta Felip**, Head of the Thoracic Tumors Group at Vall d'Hebron Institute of Oncology in Barcelona, and
- **Dr. Rafal Dziadziuszko**, Assistant Professor in the Department of Oncology and Radiotherapy of the Medical University of Gdansk.

"We are very pleased to announce the formation of this Scientific Steering Committee for our Phase 3 trial of Tedopi®. As a matter of fact, the Committee, which includes leading clinical experts and specialists in lung cancer, has already issued important recommendations for the design of the study," welcomed Dominique Costantini, CEO of Pharma OSE.

About OSE Pharma

OSE Pharma is a European cancer immunotherapy company with a multi-epitope technology named Memopi® that directs the body's immune system to generate a specific cytotoxic T response to prevent cancer cell growth.

OSE Pharma's lead product, Tedopi®, combines 10 "neo-epitopes" directed against five tumour associated antigens. In its most advanced application, it is about to enter a pivotal Phase III study in patients with advanced non-small cell lung cancer (NSCLC) who express HLA-A2 and failed first line therapy. Tedopi® has orphan drug status in the USA and is considered as personalized medicine in Europe in HLA-A2 positive patients.

OSE Pharma is also planning a new Phase II clinical trial in combination with another immunotherapy treatment in NSCLC.

Tedopi® targets five tumour associated antigens (TAA), selected because their presence is linked to a poor prognosis and the severity of various cancers. Tedopi® contains ten optimized epitopes, or "neo- epitopes", designed on the binding of HLA-A2 and TCR. These neo-epitopes generate strong specific T cytotoxic responses that fight cancer and prevent tumour escape.

OSE PHARMA: a new T specific immunotherapy weapon against advanced cancers

- **Immunotherapy in oncology is** becoming a clinical reality and raises hope for patients by mobilizing their own immune defence to fight against cancer.
- **For OSE Pharma's lead product Tedopi®: the Phase 3 clinical programme** is scheduled in 2015 and will be active in Europe and in the USA, in order to obtain registration in non-small cell lung cancer. The study will recruit patients with invasive/metastatic non-small cell lung cancer (NSCLC), expressing the HLA-A2 receptor (45% of the NSCLC population).
- Tedopi® is a patented combination of 10 epitopes. The epitopes *(small peptides triggering immune response)* are optimized. They have been selected and modified for a stronger binding with immune response receptors (HLA-A2 and TCR). These neo-epitopes trigger a stronger immune response and target 5 tumor associated antigens expressed in several cancers.
- Tedopi® will enter in new therapeutic combinations in Phase 2 studies with industrial partnerships (other immunotherapy treatments or targeted therapies) to increase clinical efficacy while maintaining high quality of life with late-stage patients.
- Tedopi® has been granted "orphan drug" status in the USA and is considered a personalised medicine in Europe, enabling accelerated clinical development.

PIVOTAL PHASE 3 STUDY IN LUNG CANCER LAUNCHED IN 2015 IN EUROPE AND IN THE USA

Tedopi® has been tested in a phase 2 study in patients with non-small cell lung cancer[1] (NSCLC- the most common form of lung cancer). These patients were HLA-A2 positive, had an invasive or metastatic disease and had received at least one previous line of treatment. The results of this phase 2 trial showed that Tedopi® generated a significant increase in the survival times of patients with NSCLC, which correlates with immune response.

This study showed a one year survival rate of 59% for the group treated with Tedopi®. This compares favourably with the 33% one year survival rate in patients treated with currently approved second line treatments[2]. The median survival in the group treated was 17 months, compared with 12 months in the group of patients who did not receive the treatment. In addition, 25% of patients treated were still alive after 4 years, with a good quality of life, which is important for patients suffering from principally metastatic tumours[3].

OSE Pharma is currently preparing to start a phase 3 study of Tedopi®. The trial protocol is common to Europe and to the USA. The launch of the Phase 3 study of Tedopi® is planned for the second half of 2015.

It will look to enrol 500 patients with invasive/metastatic non-small cell lung cancer (NSCLC), expressing the HLA-A2 receptor. Tedopi® will be used as a second line treatment for patients for whom first line treatments (such as chemotherapy) have not been able to control their disease. Preparatory works and manufacturing of the clinical supplies have started. An agreement has been signed in January 2015 with Orion-Symbec, CRO based in Great-Britain for this international Phase 3 study.

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[1] *NSCLC– 88% of lung cancers*

[2] *(Cielanu T et al 2012) (Hanna N et al 2004) (Garassino MC et al 2013)*

[3] *Overall survival rate after 5 years: 1% for metastatic cancers – American Cancer Society – 22/05/2013*

ADVANCED LUNG CANCER: A STRONG MEDICAL NEED

Lung cancer is the deadliest cancer in the world. In 2012, there were 1.58 million new diagnosed lung cancer cases and 1.39 million deaths from this disease globally[4]. Despite the different treatments available today (surgery, radiotherapy, chemotherapy, targeted therapy), the relative survival rates of these patients at metastatic stage remains very low[3].

Given the large incidence of NSCLC, OSE Pharma estimates that the potential global sales at peak for Tedopi® for this single indication could be about €2 billion[4].

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[4] *Based on independent studies, source international epidemiologic data, Globocan 2012*