OSE Pharma and Simbec-Orion to participate in the 51st annual Meeting of the American Society of Clinical Oncology, May 29th to June 2nd 2015, Chicago

Paris, May 28th May - OSE Pharma SA (ISIN: FR0012127173; Mnémo: OSE), a biotechnology company based in France, developing T specific immunotherapy treatments against invasive and metastatic cancers, is pleased to announce its participation with Simbec-Orion, a leading global clinical research organization (CRO) with specialization in oncology and rare diseases, in the annual congress of ASCO in Chicago from May 29th to June 2nd, 2015.

Simbec-Orion and OSE Pharma have entered in January 2015 into a collaboration agreement to conduct the upcoming Tedopi® Phase 3 pivotal trial in HLA-A2 positive advanced non-small cell lung cancer (NSCLC) patients who have failed at least one first line therapy. Simbec-Orion will manage this multi-centre, multi-country study involving up to 70 sites and 500 patients in the United States and Europe.

At ASCO, premier worldwide congress in oncology, OSE Pharma and Simbec-Orion will meet physicians and clinical investigators for this pivotal Phase 3. At the congress, OSE Pharma will be represented by Dominique Costantini, General Manager. Simbec-Orion's booth number is #2098.

The ASCO meeting in Oncology brings together 30,000 oncology professionals from around the world. Education sessions feature world-renowned faculty discussing state-of-the-art treatment modalities and new therapies.

About Simbec-Orion

Simbec-Orion is full service international contract research organisation with expertise in oncology, rare and orphan diseases, and a number of other therapeutic areas. The Group employs approximately 250 staff and has operations across Europe, Australia and the United States together with capabilities in multiple other territories. With headquarters in the UK based in Merthyr Tydfil, South Wales, Simbec-Orion offers large and mid-cap pharmaceutical and biotech clients a complete service offering from first- in-human exploratory clinical pharmacology studies, through Phase II and Phase III studies. In addition, the Group offers its clients Phase IV Post authorisation studies for marketing, observational and post authorisation safety studies ("PASS"). The studies are complemented by in-house dedicated Central Laboratory Facility (Bioanalytical and Pathology) for rapid, accurate and reliable sample analysis.

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].

Press Contacts

OSE Pharma sa
Dominique Costantini, CEO
dominique.costantini@osepharma.com
Mob +33 6 13 20 77 49

Alexis Peyroles, CFO
Alexis.peyroles@osepharma.com
Mob : +33 6 11 51 19 77

Citigate Dewe Rogerson
Laurence Bault / Lucie Larguier
+33 1 53 32 84 78
laurence.bault@citigate.fr

HB ComCorp
Florence Portejoie / Anne Hardy
+33 6 88 84 81 74 -
fportejoie@comcorp.fr

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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).

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