

OSE Pharma to partner Tedopi® with RAFA laboratories for long term licensing and distribution agreement in Israel

Paris, May 11th 2015 - 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 that it has signed an exclusive long term agreement with RAFA laboratories in Israël for the registration, marketing, distribution and sale of Tedopi®, today in phase 3 status in lung cancer.

“This collaboration represents a significant step as first licensing and distribution agreement in the business development strategy for OSE Pharma with pharmaceutical companies well established in specific countries. RAFA has obtained a leading position, long history in the pharmaceutical sector particularly in orphan respiratory diseases and in oncology/supportive care. The long-standing relationships with Israeli key opinion leaders made them an ideal partner for Israel and this substantial agreement has been facilitated by our advanced clinical stage in NSCLC ” said Dominique Costantini, Chief Executive Officer.

OSE Pharma is launching its phase 3 in Non-small cell lung cancer in 2015 in the USA (Orphan status obtained in NSCLC patients HLA-A2 Positive) and in Europe (product considered as personalized medicine) and plan to have the results in 2018. The company plans other phase 2 clinical trial for other cancers alone or in combination with other immunotherapy or targeted therapy.

“We are delighted of this first licensing and distribution agreement with a renowned pharmaceutical company, validating the potential of Tedopi® in NSCLC and other cancer indications”, adds Alexis Peyroles, OSE Pharma’s Chief Financial Officer.

Under the terms of the distribution agreement, RAFA will submit the drug for approval in Israel, market and distribute it in the territory for a long term period. RAFA will pay an upfront and milestone payments based on the future development of the product in addition to equally sharing the profit of Tedopi®’s sales in Israel.

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.

ABOUT RAFA Laboratories

RAFA Laboratories, Ltd. is a pharmaceutical company specializing in the manufacture and marketing of medicines in the Israeli market since 1937. The company strives to supply Israeli patients and physicians with state of the art quality medicines and medical devices for the improved treatment of medical conditions and a better quality of life for patients.

The company manufactures and/or markets a wide variety of medication from Over-the-Counter medicines (OTC) to treatments for rare pulmonary diseases like pulmonary arterial hypertension, treatment of pain especially chronic and cancer pain and supportive care treatment through international pharma corporation agreements.

RAFA markets its products to the entire Israeli health market including the health funds (health maintenance organizations), hospitals, the government and private pharmacies.

RAFA is proud to be a pharmaceutical manufacturer operating in a competitive market that includes other local manufacturers and multinational corporations.

Today RAFA Laboratories, Ltd. employs about 260 employees, more than half of whom are academically qualified.

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 cancer¹ (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

¹ NSCLC– 88% of lung cancers

with the 33% one year survival rate in patients treated with currently approved second line treatments². 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 tumours³.

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.

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 globally⁴. Despite the different treatments available today (surgery, radiotherapy, chemotherapy, targeted therapy), the relative survival rates of these patients at metastatic stage remains very low³.

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 billion⁴.

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Other than as required by applicable law (article 223-1 *et seq* of the General Regulation of the AMF), OSE Pharma issues this press release at the date hereof and does not undertake any obligation to update or revise any forward-looking information or statements.

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,

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

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

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).