

## Fifth country opens recruitment in the global pivotal Phase 3 Trial of the immunotherapy Tedopi® with initiation in Hungary

Paris, April 11, 2016 – 8:00AM – OSE Pharma SA (Euronext Paris: OSE), an immuno-oncology company developing a T-specific immunotherapy for late-stage cancer patients, today announced the initiation of its Phase 3 registration clinical trial, Atalante 1, in Hungary. This latest initiation represents an expansion of the study into a fifth country. The goal of the trial is to evaluate the benefits of Tedopi®, the company's lead product, for advanced non-small cell lung cancer in HLA-A2 positive patients.

The formal authorization from the regulatory agency and the positive opinion from national ethics committee in Hungary have enabled the initiation of Atalante 1 in this new European country where first patient enrolment can now begin.

To date, the Phase 3 pivotal trial has begun in three European countries – France, Italy and Czech Republic – and in the United States. This latest expansion into Hungary is on schedule and in line with the company's planned timetable. Approval from national regulatory agencies and ethics committees from other European countries are expected to finalize the geographic implementation of the study.

Atalante 1 is the last step before the registration of Tedopi® and it has been open to recruitment in Europe and in the United States since early 2016. Recruitment is now underway and the first patients were treated in February. The study's results are expected in 2018.

**ABOUT ATALANTE 1 – For additional information about the Atalante 1 trial and to learn more about eligibility, patients can visit:** <https://clinicaltrials.gov/ct2/show/NCT02654587>

This international Phase 3 registration study is aimed at evaluating the benefits of Tedopi® as compared to current standard chemotherapies (docetaxel or pemetrexed, both approved second line therapies). Tedopi® is administered as second-line (after failure of platinum based therapy) or third-line (after failure of immune checkpoint inhibitors) of treatment in HLA-A2 positive patients ; HLA-A2 is a key receptor for the cytotoxic T-immune response in those patients diagnosed with stage IIIB (locally advanced) or IV (metastatic) NSCLC. The primary endpoint of Atalante1 is overall survival. The study will include 500 patients enrolled at 70 European and U.S. investigational clinical sites. The trial 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 study. Phase 2 results with Tedopi® showed highly promising efficacy and an increase in survival duration alongside a good safety profile.

### ABOUT NON-SMALL CELL LUNG CANCER (NSCLC)

NSCLC represents 88% of all lung cancers. Its overall relative five-year survival rate is 15.6%. For most patients, this cancer is diagnosed at an advanced stage, which makes it difficult to treat. NSCLC is considered to be a major public health issue, in large part due to its poor prognosis.

The products developed by OSE Pharma target patients who express HLA-A2 markers. The presence of these markers is considered to be an aggravating risk factor at an advanced stage. Approximately 45% of the global

population (and of patients with NSCLC) express HLA-A2 markers (and are so-called “HLA-A2+”). OSE Pharma’s treatments could thus target nearly 84,000 patients in the U.S., 134,000 in Europe and 258,000 in China.

Despite the different treatments available today (surgery, radiotherapy, chemotherapy, targeted therapy), the overall 5-year survival rate of NSCLC metastatic patients is only about 1%.

## ABOUT OSE PHARMA

OSE Pharma is a biotechnology company that designs and develops cancer immunotherapy treatments aimed at re-educating the immune system to fight cancer while preserving patients’ quality of life.

***On February 24, 2016, OSE Pharma and Effimune announced proposed merger to create significant immunotherapy player. The objective of the merger is to create a new international enterprise that offers innovative immunotherapies based on the activation or regulation of the immune system. This new generation of products is optimized to better target key receptors of the activation or regulation of immune response and allow a durable therapeutic effect. The new company will benefit from a balanced portfolio that would open up major avenues to growth and have a financial visibility of about two years to advance its projects toward greater attractiveness.***

The Company is conducting a Phase 3 registration trial in Europe and the U.S. for its lead product, Tedopi®, in the treatment of NSCLC.

Tedopi® (OSE-2101) is a new “off-the-shelf” cancer immunotherapy approach based on OSE Pharma’s proprietary Memopi® technology. This technology is based on “neo-epitopes” (small synthetic peptides chemically modified to increase the binding the HLA A2 or TCR receptors) which trigger 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.

Tedopi® 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 “neo-epitopes” have been selected and modified to enhance their binding to HLA-A2 and TCR receptors, and trigger a stronger cytotoxic T-cell response and lead the immune system to destroy cancer cells expressing the HLA-A2 antigen or one of the targeted cancer antigens.

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, breast) for HLA-A2 positive patients.

OSE Pharma is listed on Euronext Paris (ISIN: FR0012127173; Mnémon: OSE).

For more information, please visit [www.osepharma.com](http://www.osepharma.com)



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Forward-looking statements include statements typically using conditional and containing verbs such as "expect", "anticipate", "believe", "target", "plan", or "estimate", their declensions and conjugations and words of similar import.

Although the OSE PHARMA's management believes that the forward-looking statements and information are reasonable, the OSE PHARMA's shareholders and other investors are cautioned that the completion of such expectations is by nature subject to various risks, known or not, and uncertainties which are difficult to predict and generally beyond the control of OSE PHARMA. These risks could cause actual results and developments to differ materially from those expressed in or implied or projected by the forward-looking statements. These risks include those discussed or identified in the public filings made by OSE PHARMA with the AMF. Such forward-looking statements are not guarantees of future performance.

This press release includes only summary information and should be read with the OSE PHARMA Reference Document filed with the AMF on 12 June 2015 under the number R.15-051 as well as the consolidated financial statements and the management report for the fiscal year 2015, available on the OSE PHARMA website.

OSE PHARMA undertakes no obligation to update any forward-looking statements except what would be required by applicable laws and regulations.