OSE Pharma successfully completes the manufacturing of the clinical batches for its pivotal Phase 3 clinical trial with Tedopi®

In compliance with GMP, at a manufacturing site certified in Europe and the U.S.

Paris, November 19, 2015, 5:45 PM – OSE P harma SA (ISIN: FR0012127173; Ticker: OSE), an immuno-oncology company developing a T-specific immunotherapy for late-stage cancer patients, announces it has taken further critical steps in its pharmaceutical development by successfully manufacturing its lead product Tedopi® in compliance with Good Manufacturing Practices (GMP) at a dedicated facility, certified both in Europe and the United States. This announcement comes a few weeks after several European regulatory authorities issued a positive opinion so that OSE Pharma may initiate its pivotal Phase 3 clinical trial of Tedopi® in patients with advanced non-small cell lung cancer (NSCLC).

The initial clinical batches of Tedopi® were manufactured by Baccinex, a company that specializes in manufacturing development batches for clinical trials as well as commercial batches. These sterile products will be administered by subcutaneous injection during the pivotal Phase 3 clinical trial of Tedopi® in NSCLC.

"We are very pleased with the collaboration we started a few months ago with Baccinex to manufacture the clinical batches of neo-epitopes that are used in the composition of Tedopi®," explained Jean-Pascal Conduzorgues, Pharmaceutical Director and Qualifed person at OSE Pharma. *"This global manufacturing company, based in Switzerland, is GMP-certified to produce batches of sterile products. We worked closely with Baccinex teams to achieve the manufacturing stage and relied on the experience they've acquired working with peptides to manufacture the products that will be used in our clinical trial. We're particularly grateful for their responsiveness in finalizing these GMP batches, following the positive opinion we recently received from 7 European agencies to start our trial,"* added Jean-Pascal Conduzorgues.

ABOUT BACCINEX

Baccinex is a full-service pharmaceutical contract manufacturing organization (CMO) specializing in fill and finishing of sterile lyophilized or liquid dosage forms. The company is a privately owned Swiss company founded in 1999 and obtained in 2004 its Good Manufacturing Practice (GMP) certificate and its manufacturing license to produce sterile lyophilized and liquid products from Swissmedic (Swiss Regulatory Authorities). Since then, Baccinex releases commercial batches and development batches for clinical trials.

ABOUT OSE PHARMA

OSE Pharma is a biotech company that designs and develops cancer immunotherapy treatments using its Memopi® technology, through "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.

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 (TCR).

The most advanced clinical stage of Tedopi® is a pivotal Phase 3 study to be launched soon in Europe and in the U.S. in patients diagnosed with non-small cell lung cancer (NSCLC). It will target patients whose cells are expressing HLA-A2 antigens, a key receptor for the cytotoxic T-immune response that can be found in nearly 45% of patients with lung cancer. Patients expressing the HLA-A2 positive receptor are those responsive to Tedopi®. The trial will focus on patients with stage IIIb (invasive) or stage IV (metastatic) NSCLC after at least one first line therapy failure. Its objective will be to evaluate the benefits of Tedopi® compared to current standard chemotherapy treatments (docetaxel or pemetrexed) in this patient population. 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). 500 patients will be included in Europe and in the U.S.

Tedopi® can 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; Ticker: OSE).
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Press contacts

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

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

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

Alize RP
Florence Portejoie /Caroline Carmagnol
fportejoie@alizerp.com
+33 6 47 38 90 04