FIRST EUROPEAN PATENT FOR OSE PHARMA

FOR ITS TARGETED IMMUNE THERAPY FOR LUNG CANCER

OSE Pharma SA, dedicated to severe orphan lung diseases announces the allowance of its first patent in Europe related to OSE2101, its targeted cancer immune therapy product in phase 3 for lung cancer.

Paris, France, January 31, 2013: the product OSE2101 developed by OSE Pharma targets 5 tumor antigens with 10 epitopes -an epitope is a small peptide or a fragment of tumor antigen. The patent covers a composition comprising these epitopes. They produce a response of particular cells named T cytotoxic, able to destroy the tumor cells expressing these tumor antigens.

The 5 tumor associated antigens (HER2/neu; P53; CEA; MAGE2; MAGE3) were selected due to the poor prognosis established when overexpressed in particular in lung cancer named Non-Small Cell Lung Cancer (NSCLC) and for the increasing risk when these Tumor antigens are associated.

The lung cancer is the leading cause of cancer death in the world and the Non Small Cell Lung cancers (NSCLC 88% of lung cancer) amounted to 1,41 million new cases each year with a high level of mortality: 1.21 million deaths. The HLA A2 positive patients (HLA A2 is a requirement for the immune T cytotoxic response) are the target population of OSE2101 and are representing 45% of the NSCLC population. This HLA A2 biomarker is a poor prognosis factor associated with an increasing invasive risk. This population of HLA A2 positive patients is the basis of the demand of an orphan drug status filed by OSE Pharma. The need of innovative drug is critically needed due to this aggressive NSCLC disease often discovered at late stage. Despite aggressive treatments, the 5-year relative survival rates are about 24% for patients with regional disease and less than 4% for patients with metastatic disease.

The European patent obtained describes the original epitopes selected: the innovation is to associate epitopes designed and modified in order to increase the HLA A2 binding with other modified epitopes able to increase the T cell receptor affinity. This specific epitopes combination acting on the two key receptors of the immune response overcomes the immune self -tolerance, avoids any immune dominant response limited to one epitope and provides a strong and sustainable response to all epitopes. During the clinical phase II b trial a positive response was achieved in more than 90% of patients, the study being performed with two third of metastatic patients (stage 4). This multi-epitopes concept targeting various tumor antigens whatever the level of expression is particularly promising in clinical setting, despite the heterogeneity of tumor antigens and the multiples tumor cells immune escape mechanisms.

« *This European patent is related to our OSE Pharma European assets and will protect the invention until 2024. OSE Pharma has also secured the technical know-how and has a team in place in San Diego who initiated this technology of modification and combination of peptides* » says Dominique Costantini, CEO of the company « *The phase IIb trial results are particulary innovative due to the severity of patients (high risk HLA A2 positive NSCLC patients, invasive or metastatic cancer - at least first line previous therapy failure) and the remarkable median of survival (17 months) achieved also significantly correlated to the immune response. The long term survival rate (25% at 4 years) observed is another important item considering two third metastatic patients included and could be*

one of the major attribute of this targeted cancer immune therapy. The phase IIb calls for a phase III in which the same type of high-risk patients will be included » added Dominique Costantini.

COMPANY PROFILE: OSE Pharma an innovative clinical late stage (Phase III status) Biopharmaceutical Company is established in Paris Hospital Cochin France. The company is founded in 2012 by Emile Loria and Dominique Costantini both experienced Biotech entrepreneurs. OSE Pharma is focused on targeting severe and orphan pulmonary diseases, this medico-economic model is based on protection and acceleration of development for drugs significantly improving treatment options for patients with unmet medical needs. OSE lead product OSE2101 has completed a Phase II clinical trial in severe non-small cell lung cancer HLA A2 positive patients. This HLA A2 biomarker is expressed in 45% of this population and is considered as a poor prognosis factor in various cancers including the NSCLC. The 10 epitopes combined are providing T cytotoxic responses (able to kill cells) versus the tumor cells expressing the tumor antigens. The 5 Tumor associated antigens targeted (HER2/neu; P53; CEA; MAGE2; MAGE3) signed the poor prognosis when overexpressed alone and even more severe when associated. The OSE epitopes platform benefits also of two clinical phase I/II results in colon cancer and in NSCLC allowing to define the tolerance, the level of response (>90%) and the rhythm of administration (subcutaneous injection every 3 weeks for 6 injections then every 3 months).

The targeted cancer immune therapy could be also applied for other cancers with the same TAA.

The company is preparing a separate clinical project in Cystic fibrosis, an orphan genetic disorder with progressive lung damages, a molecule with new anti-inflammatory properties. This "reprofiling" molecule has an established safety profile allowing the design of a clinical phase II program.

Lung cancer

Lung cancer is the leading cause of cancer death in the world. More people die of lung cancer than of colon, breast and prostate cancers combined. According to the epidemiology site of Globocan (IARC 2008), lung cancer (non-small cell, NSCLC, and small cell type) affects more than 1.6 million patients a year, with around 1.37 million deaths annually and around 600,000 in Europe (27) (288 000) the U.S (214 000), and Japan (141 000). About 85 to 88 percent of all lung cancers are the non-small cell type. The majority of patients are at advanced stage disease at diagnosis: stage IIIB invasive or Stage IV metastatic.

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