HYBRIGENICS

Press Release

Hybrigenics enrolls a first patient in the United States in the clinical study of inecalcitol in acute myeloid leukemia patients unfit for chemotherapy

Paris, France, 28 November 2016 – Hybrigenics (FR0004153930 - ALHYG), a bio-pharmaceutical company listed on the Alternext market of Euronext Paris, with a focus on research and development of new treatments of proliferative diseases, today announces the enrolment of the first patient in the United States in the Phase II clinical trial of inecalcitol in acute myeloid leukemia (AML) patients unfit for chemotherapy. This double-blind placebo-controlled study is conducted in France and in the US on a population of elderly or frail AML patients who have the most severe prognosis and the highest unmet medical need. The first patient has been enrolled in France in September 2016 (see Hybrigenics' press release of September 13, 2016) and, as of today, 14 patients are under treatment in France.

The objective of the study is to focus on the elderly or frail AML patients who are unfit to standard chemotherapy and who can only receive monthly cycles of intravenous perfusions of decitabine (Dacogen®, Johnson & Johnson). In addition to this treatment, they will receive oral inecalcitol or placebo. The primary endpoint is overall survival. The total number of 110 patients to be included in the study is designed to be sufficiently powered to evidence potential efficacy on mortality.

"*The enrolment and treatment of the first American patient are an important step forward in the Phase II clinical trial of inecalcitol in acute myeloid leukemia patients unfit for chemotheray. It results from the combination of successful efforts in terms of clinical operations and regulatory compliance, together with the positive perception of the relevance of the project by American investigators and by this category of patients whose therapeutic options are extremely limited,"* said Jean-François Dufour-Lamartinie, Hybrigenics' Head of Clinical R&D.

About Acute Myeloid Leukemia

Acute myeloid leukemia (AML) has recently become the most frequent form of leukemia and accounts for about 38% of all leukemic patients. Annual estimates of newly diagnosed AML cases amount to 20,830 in the United States (Cancer Facts and Figures 2015), 18,500 in Europe (RARECARE Working Group, 2012) and 110,000 world-wide (Globocan, 2012). AML is designated as an orphan disease in the United States, Europe and Japan.
AML is a type of cancer that affects the blood and bone marrow. AML is characterized by a fast-increasing overproduction of immature white blood cells, called myeloblasts. These cells rapidly crowd the bone marrow, soon preventing it from making normal blood cells. They can also spill out into the blood stream and circulate around the body. Due to their immaturity, they are unable to function properly to prevent or fight infection. Inadequate numbers of red cells and platelets being made by the marrow cause anemia, and easy bleeding and/or bruising. AML is sometimes called acute myelocytic, myelogenous or granulocytic leukemia.
AML can occur at any age but is more common in adults over the age of 60 years. Treatment needs to begin soon after AML is diagnosed, as it progresses very quickly. Chemotherapy is the main form of treatment for AML; occasionally, a stem cell transplant may be prescribed. Despite available treatments, AML shows the lowest 5-year survival rate of all leukemias: 25% in the US and 19% in Europe.

About Hybrigenics

Hybrigenics (www.hybrigenics.com) is a bio-pharmaceutical group listed (ALHYG) on the Alternext market of Euronext Paris, focusing its internal R&D programs on innovative targets and therapies for the treatment of proliferative diseases.
Hybrigenics' development program is based on inecalcitol, a vitamin D receptor agonist active by oral administration. Inecalcitol has been tested in chronic lymphocytic leukemia patients, an indication for which inecalcitol has received orphan drug status in Europe and the United States. Two clinical Phase II studies of inecalcitol are currently ongoing in chronic myeloid leukemia and acute myeloid leukemia. Oral inecalcitol has shown excellent tolerance and strong presumption of efficacy for the first-line treatment of metastatic castrate-resistant prostate cancer in combination with Taxotere®, which is the current gold-standard chemotherapeutic treatment for this indication.
Hybrigenics' research program is exploring the role of enzymes called Ubiquitin-Specific Proteases (USP) in the balance between degradation and recycling of proteins called onco-proteins due to their involvement in various cancers. Hybrigenics is evaluating the interest of inhibitors of USP as anti-cancer drug candidates. Hybrigenics has collaborated with Servier on one particular USP in oncology. In this R&D program, two steps have been reached and additional milestones may be achieved until registration of a potential drug.
Hybrigenics Corp., based in Cambridge, Mass., is the American subsidiary of Hybrigenics.

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HYBRIGENICS is listed on the Alternext market of Euronext Paris

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