

Hybrigenics enrolls a first patient in France in the clinical study of inecalcitol in acute myeloid leukemia

Paris, 13 September 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 in France of the first patient in the Phase II clinical trial of inecalcitol in acute myeloid leukemia (AML). This double-blind placebo-controlled study has been authorized both in France by the National Drug Safety Agency and in the United States by the Food and Drug Administration, with the same protocol.

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 daily oral inecalcitol (4 milligrams per day) or placebo. The primary endpoint will be 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 treatment of the first French patient is an important operational step, after having obtained regulatory authorizations and set up the logistics of the study both in France and in the United States. The next step will be the enrolment of the first American patient,” 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 used. 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’ current development program is based on inecalcitol, a vitamin D receptor agonist active by oral administration. 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. Inecalcitol has also been tested in chronic lymphocytic leukemia patients, an indication for which inecalcitol has received orphan drug status in Europe and the United States. A clinical Phase II study of inecalcitol is currently ongoing in chronic myeloid leukemia patients.

Hybrigenics has a research collaboration with Servier on deubiquitinating enzymes (DUBs) and their inhibitors in oncology, neurology, psychiatry, rheumatology, ophthalmology, diabetes and cardiovascular diseases. A first milestone has been achieved in a drug discovery program targeting one DUB in oncology.

Hybrigenics Corp., based in Cambridge, Mass., is the American subsidiary of Hybrigenics.

HYBRIGENICS

Press Release

HYBRIGENICS is listed on the Alternext market of Euronext Paris

ISIN: FR0004153930

Ticker: ALHYG



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