

Clinical study of inecalcitol in acute myeloid leukemia stopped for futility

- The clinical development of inecalcitol is discontinued
- Hybrigenics' Board of Directors will propose to the Shareholders to dissolve the company
- The publication of the half-year 2018 results is postponed
- Cash position of EUR 4.4 million as of June 30th, 2018

Paris, France, on October 23rd, 2018 – Hybrigenics (ALHYG), a bio-pharmaceutical company listed on the Euronext Growth market of Euronext Paris, with a focus on research and development of new anticancer treatments, today announces that an interim futility analysis led to the decision to stop the clinical Phase II study of inecalcitol in acute myeloid leukemia (AML).

Inecalcitol was being tested by the oral route in an international double-blind placebo-controlled Phase II study in AML patients unfit for standard chemotherapy, in combination with monthly cycles of intravenous decitabine. A total of 115 patients have been enrolled in France, the United States, Spain, Germany and Belgium. The primary endpoint is overall survival because of the high mortality rate of AML which is still an unmet medical need.

As specified in the protocol, an interim analysis was performed after 64 events (deaths) and revealed that futility was reached, meaning that a final positive outcome could not be expected. As a consequence, Hybrigenics' Board of Directors has decided to stop the study and to discontinue the clinical development of inecalcitol in any therapeutic indication.

Since inecalcitol was the only Hybrigenics' product in development, the Board of Directors has decided to propose to the shareholders the accelerated winding-up of the company. An Extraordinary Shareholders' Meeting will be called to take place before the end of the year.

The impact of this decision on the half-year 2018 results has to be evaluated; their publication is postponed to a later date and will be available for the Extraordinary Shareholders' Meeting. The cash position of Hybrigenics stood at EUR 4.4 million as of June 30th, 2018.

Hybrigenics has asked Euronext to resume the trading of its shares (FR0004153930).

About Hybrigenics

Hybrigenics (www.hybrigenics.com) is a bio-pharmaceutical company listed (ALHYG) on the Euronext Growth market of Euronext Paris.

Inecalcitol is a vitamin D receptor agonist active by oral administration. Oral inecalcitol had shown excellent tolerance and presumption of efficacy for the first-line treatment of metastatic castrate-resistant prostate cancer in combination with Taxotere[®]. Inecalcitol had also been tested in two pilot clinical Phase II studies in chronic myeloid leukemia and chronic lymphocytic leukemia.

Hybrigenics has collaborated with Servier on one particular USP in oncology. In this R&D program, two milestones have been reached and additional milestones may be achieved until registration of a potential drug.



Hybrigenics Pharma Inc., based in Cambridge, Mass., is the U.S. subsidiary of Hybrigenics.

Hybrigenics is listed on the Euronext Growth market of Euronext Paris

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