Hybrigenics completes enrolment of the international Phase II clinical study of inecalcitol in Acute Myeloid Leukemia

115 patients enrolled in France, the United States, Spain, Germany and Belgium

Paris, France, on July 18th, 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 the completion of patient enrolment in the international Phase II clinical study of inecalcitol in Acute Myeloid Leukemia (AML).

Inecalcitol has received Orphan Drug designation for AML in Europe and the United States. It is currently 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 throughout 31 hospital centers, in France (14 centers), the United States (7 centers), Spain (7 centers), Germany (2 centers) and Belgium (1 center). Since the first patient (cf. Hybrigenics' press release of September 13, 2016), enrolment has been completed in a little less than two years, with a marked acceleration in the second year: 36 patients during the first year mostly in France, and 79 patients since September 2017, when the recruitment in the other countries gained momentum.

The primary endpoint is overall survival because of the high mortality rate of AML which is still an unmet medical need. The 5-year survival rate of AML is the lowest of all types of leukemia: only 27% among all AML patients (American Cancer Society, Facts & Figures, 2018) but even lower in elderly patients unfit for standard chemotherapy and not eligible to bone marrow transplantation.

The first optional result planned in the protocol of the study is a futility analysis which could take place once at least 64 deaths will have occurred; the final results are planned to be generated after at least 90 deaths. As of today, 50 patients have died and 65 are still alive. In terms of next steps, the futility analysis could be performed as early as December 2018 and the final results could be announced as early as June 2019, depending on the potential efficacy of the treatment. The more efficacious inecalcitol may prove, the later the final results will be obtained.

"Once fully deployed internationally, our network of participating hospital centers has delivered a speedy enrolment of more than 110 patients in the Phase II clinical trial of inecalcitol in Acute Myeloid Leukemia. We are now looking forward to the outcome of this double-blind placebo-controlled study, first possibly with an optional futility analysis in about six months of time, and with the final results in about 12 to 18 months, depending on the potential efficacy of inecalcitol treatment: the more efficacious, the longer the study," **said Remi Delansorne, Hybrigenics' CEO.**

About Hybrigenics

Hybrigenics (www.hybrigenics.com) is a bio-pharmaceutical group listed (ALHYG) on the Euronext Growth market of Euronext Paris, focusing its internal R&D programs on innovative targets and therapies for the treatment of cancer.

Hybrigenics' 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 metastastic castrate-resistant prostate cancer in combination with Taxotere®, the current gold-standard chemo-therapeutic treatment for this indication. Inecalcitol has also been tested in two pilot clinical Phase II studies in chronic myeloid leukemia and chronic lymphocytic leukemia and an international double-blind placebo-controlled Phase II studies of inecalcitol is currently ongoing in acute myeloid leukemia. Inecalcitol has received orphan drug designation for chronic lymphocytic leukemia and acute myeloid leukemia in Europe and the United States.

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 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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