

Press Release

The collaboration between Hybrigenics and the MD Anderson Cancer Center is nominated for the final round of the MedStartUp Awards 2016

- The MedStartUp competition is jointly organized by the Galien Foundation and Business France to encourage and reward international partnerships between French and North American innovators in the life sciences industry.
- Hybrigenics and the University of Texas MD Anderson Cancer Center in Houston are nominated in the "Best Collaboration with Academia Leading to a Breakthrough Solution" category. They have collaborated to set up both in France and the United States a Phase II clinical trial of the combination of inecalcitol and decitabine in acute myeloid leukemia patients unfit for standard chemotherapy.

Paris, 07 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 nomination of its collaboration with the University of Texas MD Anderson Cancer Center to the final round of the MedStarUp Awards, which will take place in New York on October 27th, 2016, in the "Best Collaboration with Academia Leading to a Breakthrough Solution" category. This MedStartUp competition is jointly organized by the Galien Foundation and Business France to encourage and reward international partnerships between French and North American innovators in the life sciences industry.

The outcome of the collaboration between Hybrigenics and the MD Anderson Cancer Center is the design and the implementation of a Phase II clinical trial of daily oral inecalcitol in elderly or frail acute myeloid leukemia (AML) patients who are unfit to standard chemotherapy and who can only receive monthly cycles of intravenous perfusions of decitabine (Dacogen®, Johnson & Johnson).

"The nomination of our collaboration with Prof. J. Cortes of MD Anderson Cancer Center among the last three MedStartUp Award contenders for the Best Collaboration with Academia Leading to a Breakthrough Solution is already a form of recognition of the relevance and innovativeness of our approach to add oral inecalcitol to intravenous decitabine for the treatment of elderly or frail acute myeloid leukemia (AML) patients unfit for standard chemotherapy," said Remi Delansorne, Hybrigenics' CEO.

This single double-blind placebo-controlled Phase II clinical study of inecalcitol in AML was granted authorization with the same protocol by the American Food and Drug Administration and by the French Drug Agency. 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. Prof. J. Cortes, Chair of the acute and chronic myeloid leukemia sections, Department of Leukemia, University of Texas MD Anderson Cancer Center, Houston, will be the principal investigator in the United States. Prof. O. Hermine, Chair of the Department of Hematology, Necker Hospital, Paris, will be the principal investigator of the study in France.



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Inecalcitol, a vitamin D receptor agonist, has received Orphan Drug status for AML both in Europe and the Unites States on the basis of encouraging *in vitro* and *in vivo* preclinical results (cf. Hybrigenics' press releases of June 22 and August 08, 2015). The molecular basis of the synergy between decitabine, a hypomethylating agent, and inecalcitol has been established: decitabine "unmasks" the gene coding for vitamin D receptors (by reducing the methylation of its promoter region). As a consequence, more vitamin D receptors are expressed and available to be activated by inecalcitol (cf. Hybrigenics' press releases of June 20, 2014).

For more information: http://medstartup.galienfoundation.org/wp/award-nominees/

About the Galien Foundation

The Galien Foundation fosters, recognizes and rewards excellence in scientific innovation to improve the state of human health. Our vision is to be the catalyst for the development of the next generation of innovative treatment and technologies that will impact human health and save lives.

The Foundation oversees and directs activities in the USA for the Prix Galien, an international award that recognizes outstanding achievements in improving the human condition through the development of innovative therapies. The Prix Galien was created in 1970 in honor of Galien, the father of medical science and modern pharmacology. Worldwide, the Prix Galien is regarded as the equivalent of the Nobel Prize in biopharmaceutical research.

For further information, please visit: www.galienfoundation.org

About Business France

Business France is the national agency supporting the international development of the Economy of France, responsible to foster export growth by French businesses, as well as promoting and facilitating international investment in France. Business France promotes French companies, brand visibility and nationwide attractiveness. Business France has 1,500 personnel, both in France and in 70 countries throughout the world, who work with a network of public- and private-sector partners.

For further information, please visit: www.businessfrance.fr

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 and providing cutting-edge proteomic and genomic scientific services. 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 metastastic 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 is listed on the Alternext market of Euronext Paris

ISIN: FR0004153930 Ticker: ALHYG



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