

HYBRIGENICS

Press release

Hybrigenics receives positive answers from EMEA

EMEA gives official scientific advice on clinical Phase IIb efficacy study of inecalcitol in hormone-refractory prostate cancer

Paris, February 03, 2010--Hybrigenics, a bio-pharmaceutical company with a focus on research and development of new cancer treatments and specialized in protein interactions, announced today that it has received the official scientific advice from the European Medicines Agency (EMA) on Hybrigenics' clinical development plan for inecalcitol in hormone-refractory prostate cancer patients.

EMA's recommendations back the protocol proposed by Hybrigenics and will facilitate authorizations by national health agencies in each European country where the Phase IIb clinical trial of high doses of oral inecalcitol in addition to intravenous cycles of Taxotere[®] will be implemented. It will be a double-blind placebo-controlled study on a minimum of 80 patients. The dose and frequency of administrations of inecalcitol are currently being determined in an open label dose-escalation Phase IIa trial now reaching 4 milligrams once- and twice-a-day.

The objective of the Phase IIb study is to achieve clinical "proof-of-concept" (PoC) based on the proportion of patients who will experience a decline in prostate specific antigen (PSA) under treatment. The high response rate currently observed among patients in the ongoing Phase IIa tolerance study of inecalcitol provided the foundation for the proposed PoC.

The answers from the EMA arrived well within the fixed three months timeframe and did not require any additional meetings. *"The scientific advice procedure with the EMA went very smoothly,"* commented Dr. Jean-Francois Dufour-Lamartinie, Hybrigenics' Head of Clinical R&D. *"This is further proof that our clinical development plan for inecalcitol in prostate cancer is sound and straightforward."*

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About prostate cancer

Prostate cancer is the most common type of cancer in men. The latest documented figures are forecasts of 192,300 new cases and 27,400 deaths from prostate cancer for 2009 in the United States of America, and estimates of 345,900 new cases and 87,400 deaths in 2006 for all of Europe.

At the time of diagnosis, if the cancer is localized to the prostate, it can be definitively cured by surgery and/or radiotherapy. If the cancer has already spread beyond the prostate gland, treatments with anti-hormonal drugs initially manage to keep it under control, in a so-called "hormone-dependent" stage. However, after several months or years, tumor growth resumes despite anti-hormonal treatment: the prostate cancer has then escaped into a "hormone-refractory" stage, for which Taxotere®-based chemotherapy is the standard of care. The worldwide drug market for prostate cancer is more than \$ 3 billion per year, with an estimated 75/25 per cent split between hormone dependent/refractory stages, respectively.

About inecalcitol

Inecalcitol is an orally active agonist targeting the vitamin D receptor. The therapeutic rationale behind its development is to add its cytostatic potential to the established efficacy of the reference treatments of the two stages of prostate cancer: anti-hormonals (LH-RH agonists and anti-androgens) for the hormone-dependent stage and Taxotere®-based chemotherapy for the hormone-refractory stage.

About Hybrigenics

Hybrigenics (www.hybrigenics.com) is a bio-pharmaceutical company listed (ALHYG) on Alternext (NYSE-Euronext) in 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 analogue, for the treatment of hormone-refractory prostate cancer in combination with Sanofi-Aventis' Taxotere®, which is the current gold-standard chemotherapeutic treatment for this indication. Hybrigenics' research program explores the role of enzymes known as ubiquitin-specific proteases (USP) in the degradation of onco-proteins, and the effectiveness of proprietary USP inhibitors in treating various types of cancer.

Hybrigenics is also the market leader in Yeast-Two Hybrid (Y2H) and related services to identify, validate and inhibit protein interactions for researchers in all areas of life sciences, using its ISO 9001-certified high-throughput Y2H screening platform, its sophisticated bioinformatics tools and extensive database, along with its chemical library and chemical screening platform.

HYBRIGENICS is listed on the Alternext by NYSE Euronext Paris

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