

Hybrigenics' positive meeting with FDA on US clinical development of inecalcitol

**Successful pre-IND meeting with the FDA sets the stage
for the development of inecalcitol for prostate cancer in the United States**

Paris, March 12, 2009--Hybrigenics, a bio-pharmaceutical company with a focus on research and development of new cancer treatments and specialized in protein interactions, announced today the comprehensive review by the American Food and Drug Administration of the pharmaceutical, preclinical and clinical information on inecalcitol. A proposal for a two-step efficacy development plan for hormone-refractory prostate cancer in combination with Taxotere® has been accepted.

First a mid-size clinical trial will be conducted with the response rate based on the sustained decline of prostate specific antigen as "proof-of-concept" endpoint. Then, a large scale pivotal trial with overall survival as primary endpoint would support registration.

"The clear road map drawn with the FDA for development of inecalcitol in the United States is a major achievement for Hybrigenics," said Remi Delansorne, Hybrigenics' CEO, *"It allows a quick access to clinical proof-of-concept. In addition, it will facilitate discussions with potential partners for co-development in the US."*

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.

Inecalcitol is currently undergoing an escalating-dose study in combination with the gold standard regimen of intravenous Taxotere®. A total of 38 patients have been included so far in 5 centres in France and the top dose currently being tested is 1,000 µg/day. Enrolment is going ahead of schedule. No change in blood or urinary calcium, the usual specific toxicity of vitamin D derivatives, has been observed so far, and the clinical tolerance of inecalcitol is excellent.

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Press Release

About prostate cancer in the United States

According to the American Prostate Cancer Foundation, prostate cancer "is the most common non-skin cancer in America, affecting 1 in 6 men. A non-smoking man is more likely to develop prostate cancer than he is to develop colon, bladder, melanoma, lymphoma and kidney cancers combined. In 2008, in the USA, more than 186,000 men were diagnosed with prostate cancer, and more than 28,000 men died from the disease. It is estimated that there are more than 2 million American men currently living with prostate cancer."

About Hybrigenics

Hybrigenics is a bio-pharmaceutical company listed (ALHYG) on Alternext 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 also offers a range of services to identify, validate and inhibit protein interactions to researchers in all areas of life sciences through its Hybrigenics Services unit, using its ISO 9001-certified high-throughput Yeast-Two Hybrid (Y2H) screening platform, its sophisticated bioinformatics tools and extensive database, along with its chemical library and chemical screening platform.

Hybrigenics
Rémi Delansorne
Directeur Général
Tel.: +33 (0)1 58 10 38 00
investors@hybrigenics.com

NewCap.
Communication financière
Axelle Vuillermet / Pierre Laurent
Tel.: +33 (0)1 44 71 94 94
hybrigenics@newcap.fr