

## **Hybrigenics receives authorization to dose prostate cancer patients twice daily with oral inecalcitol**

### **French drug agency grants permission for higher and more frequent dosing of inecalcitol in its current clinical tolerance Phase IIa study**

**Paris, January 06, 2009** -- Hybrigenics, a bio-pharmaceutical company with a focus on research and development of new cancer treatments and specialized in protein interactions, announced today that the French drug agency, AFSSAPS ("Agence Française de Sécurité Sanitaire des Produits de Santé"), approved an amendment to the current clinical tolerance Phase IIa study in hormone-refractory prostate cancer patients. The amendment allows the 4 milligram oral dose of inecalcitol to be tested once- and twice-a-day.

Excellent tolerance has been observed at the dose of 2 mg per day for 18 weeks in 6 additional patients since August 2009 with no sign of hypercalcemia, the usual dose-limiting toxicity of vitamin D analogues. As a result, the dose can now be increased to 4 mg per day. In addition, based on the favorable pharmacokinetics of inecalcitol, which does not accumulate in the body, the twice-daily regimen (every 12 hours) will be tested for a more frequent exposure of the tumour to the cytostatic activity of inecalcitol.

*"A twice-daily regimen is very innovative for a vitamin D agonist such as inecalcitol," said Dr. Jean-François Dufour-Lamartinie, Hybrigenics' Head of Clinical R&D. "It will increase the probability that it will prove efficacious in cancer indications where tumour drug exposure is key to therapeutic success."*

#### **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.

# HYBRIGENICS

## Press release

### About Hybrigenics

Hybrigenics ([www.hybrigenics.com](http://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.

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**HYBRIGENICS is listed on the Alternext by NYSE Euronext Paris**

**ISIN: FR0004153930**

**Ticker: ALHYG**



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