

# HYBRIGENICS

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## **Hybrigenics receives authorization to accelerate inecalcitol dose escalation in Phase II trial for hormone-refractory prostate cancer**

**Paris, June 17, 2008** - Hybrigenics, a bio-pharmaceutical company with a focus on research and development of new cancer treatments and specialized in protein interactions, announced today that France's regulatory agency AFSSAPS has authorized the company to increase inecalcitol dosage in Hybrigenics' Phase II clinical trial currently underway for patients suffering from hormone-refractory prostate cancer.

Inecalcitol is a chemical analogue of vitamin D and is being administered in the trial via daily oral doses in combination with Taxotere® (Sanofi-Aventis), the gold-standard intravenous chemotherapy for this indication. The trial started six months ago in six cancer centers in France; so far, a total of 18 patients have been enrolled. At 40, 80 and 160 micrograms per day for several weeks, no increases in calcium levels have been observed in blood or urine, the dose-limiting side effect of the natural derivatives of vitamin D.

As a result, Hybrigenics submitted an application to amend the Investigational Medicinal Product Dossier (IMPD) to AFSSAPS to allow it to continue to double the dosage. Now AFFSAPS has accepted this application, Hybrigenics will test the doses of 300 micrograms per day between June and September – and 600 micrograms per day from October until the end of 2008. The objective of this Phase II study is to determine the maximum tolerated daily oral dose of inecalcitol over an 18 week period.

"We are delighted at the confidence AFSSAPS has displayed in Hybrigenics by granting our initial IMPD and now its amendment in a faster time than required," said Jean-François Dufour-Lamartinie, Hybrigenics' director of clinical R&D. "We now expect inecalcitol to demonstrate its full tolerance potential at higher doses in the same timeframe as originally planned," said Rémi Delansorne, CEO at Hybrigenics.

### **About Hybrigenics**

Hybrigenics is a bio-pharmaceutical company focusing its internal R&D programs on innovative targets and therapies for the treatment of cancer through its Hybrigenics Pharma unit. Hybrigenics Pharma's development program is based on inecalcitol, a vitamin D analogue more powerful and less toxic than calcitriol, the naturally active form of vitamin D. Inecalcitol is being developed for the treatment of hormone-resistant

prostate cancer in combination with Sanofi-Aventis' Taxotere(R), which is the current gold-standard chemotherapeutic treatment for this indication. Hybrigenics Pharma's research program explores the role of enzymes known as ubiquitin-specific proteases (USP) in the degradation of oncoproteins, 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.