

Promising interim results from Hybrigenics' Inecalcitol Phase II in Combination with Taxotere® for Hormone-Refractory Prostate Cancer

Hybrigenics will present interim results at the 2009 Meeting of the American Society of Clinical Oncology in Orlando, Florida on May 31

Paris, April, 17th 2009 - Hybrigenics (ALHYG), a bio-pharmaceutical company listed on Alternext (NYSE-Euronext) in Paris, with a focus on research and development of new cancer treatments and specialised in protein interactions, today announces preliminary results from its phase II clinical trial of inecalcitol in patients with hormone-refractory prostate cancer to be presented at the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Orlando, Florida, USA, May 29 – June 2, 2009.

Oral daily doses of inecalcitol have been given in combination with the standard Taxotere® chemotherapy. The clinical tolerance of inecalcitol was excellent, and no changes in calcium parameters have been observed in any of the 42 patients enrolled so far, even at the highest dose of 1,000 µg/day currently being tested since January 2009. This safety profile is especially positive for inecalcitol because hypercalcemia is the usual specific toxic effect of most vitamin D analogues, limiting their use at doses as low as 10 µg/day. The excellent tolerance of inecalcitol allowed a fast and effective patient enrolment for an accelerated dose-escalation approved by the French Regulatory Drug Agency, and supported by a 1.4 million euro refundable subsidy from OSEO Innovation.

Out of the 31 evaluable patients having already completed the full 18 weeks of treatment at different doses up to 600 µg/day, 27 showed a decrease in Prostate Specific Antigen (PSA) levels of more than 30% within 3 months of initiation of treatment, which means that the response rate to the combination of inecalcitol and Taxotere® was 87%. As an indication, although not a direct comparison, when Taxotere® was studied as a single agent in previously reported clinical trials, this PSA response rate was around 65%. These numbers would mean that about one third more patients responded to the combination of inecalcitol and Taxotere®: this is the hypothesis to be confirmed in the next Phase IIb efficacy study, according to a development plan recently approved by the American Food and Drug Administration.

"These preliminary results are very encouraging", said Dr. Jean-François Dufour-Lamartinie, Head of Clinical R&D at Hybrigenics, "both in terms of safety with no hypercalcemia, and of presumption of efficacy with a high PSA response rate".

HYBRIGENICS

Press Release

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 Alternext Paris, by NYSE Euronext

Action
ISIN : FR0004153930
Mnemo : ALHYG

BSA
ISIN : FR0010555656
Mnemo : HYGBS

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

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

HYBRiGENiCS