

Hybrigenics develops new oral formulations of inecalcitol

Hybrigenics seeks patent protection until 2030 for innovative oral formulations optimized for the delivery of high doses of inecalcitol

Paris, November 2nd, 2010 – Hybrigenics (ALHYG), a bio-pharmaceutical group with a focus on research and development of new cancer treatments and a fully-owned subsidiary specialized in protein interactions services, today announces the filing of a patent application covering new soft gelatin capsules, tablets or drinking solutions optimized for the delivery of high doses of inecalcitol.

This pharmaceutical optimization followed the demonstration of safety and the presumption of efficacy of oral doses as high as 4 milligrams (mg) of inecalcitol per day in a Phase IIa clinical tolerance study in hormone-refractory prostate cancer patients. By contrast, currently marketed vitamin D analogues are prescribed in other indications at doses in the microgram range only. The superior tolerability of inecalcitol allows patient treatment at 1,000-fold higher dose levels. This higher dosing required innovative formulations.

All microdosed vitamin D analogues are currently marketed as oily solutions in soft gelatin capsules. The first formulations of inecalcitol were also soft gel capsules of different increasing concentrations and strengths, up to a maximum of 1 mg unit dose. The patients treated at the highest tolerated dose had to swallow 4 such relatively big capsules. The new capsules are more concentrated in inecalcitol and contain a fixed 2 mg amount. Treatment will therefore be more convenient with a maximum of two small capsules to swallow, favoring compliance.

Even more convenient, and less expensive to manufacture, dry tablets represent a radical innovation for a vitamin D analogue. Inecalcitol has recently been successfully formulated as 2 mg tablets. In addition, these tablets are scored, allowing the flexibility to adjust doses 1 mg by 1 mg. Drinking solutions of inecalcitol in a liquid excipient could provide complete dose proportionality to body weight, for any putative pediatric indications for example.

Pharmaceutical stability and human bioavailability studies in healthy volunteers are ongoing. The objective is to start Phase IIb efficacy clinical trials in hormone-refractory prostate cancer and severe psoriasis with an already optimized formulation suitable for future commercialization.

"We have worked hard to reduce the size of soft gel capsules and to make tablets feasible, against all odds," explained Rémi Delansorne, Hybrigenics' CEO. "The new formulations are smaller, cheaper, more convenient and flexible to use. Moreover, we believe they are novel and inventive for a vitamin D analogue such as inecalcitol, potentially paving the road for patent protection until 2030."

About Hybrigenics

Hybrigenics SA (www.hybrigenics.com) is a bio-pharmaceutical group 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 Services SAS is a fully-owned subsidiary of Hybrigenics SA, and 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 science, 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

Press Release

HYBRIGENICS is listed on the Alternext by NYSE Euronext Paris

ISIN: FR0004153930

Ticker: ALHYG



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