

Hybrigenics starts Phase II clinical trial of inecalcitol in psoriasis

Twenty patients have already been enrolled in the first two weeks of the study

Paris, 21 November, 2011 – Hybrigenics (ALHYG), a bio-pharmaceutical company listed on Alternext (NYSE-Euronext) in Paris, with a focus on research and development of new treatments against proliferative diseases, today announces the start of Phase II clinical trial with oral inecalcitol in patients with moderate-to-severe psoriasis. Oral inecalcitol represents a potential alternative of choice in this therapeutic indication, more patient-friendly than injectable biologics against tumor-necrosis factor alpha (TNF- α) or interleukins and less toxic than oral cyclosporin, methotrexate or retinoids.

The study is conducted by Professor Jean-Paul Ortonne in the Dermatology Department of the University Hospital of Nice, France. It is a double-blinded and placebo-controlled trial comparing inecalcitol in 40 patients vs. placebo in 20 patients. Inecalcitol is given orally at 4 milligrams per day during 16 weeks. The first 20 patients have been enrolled since November 7th and are currently screened before random assignment to the placebo or inecalcitol-treated groups.

"The clinical trial of oral inecalcitol in moderate-to-severe psoriasis has started as planned. We are very satisfied with the enrollment speed, which could allow the inclusion and treatment of all the 60 patients in due time for a total study duration of less than a year," said Dr. Jean-François Dufour-Lamartinie, Head of Clinical R&D.

About Psoriasis

Psoriasis is a non-cancerous proliferative skin disease, characterized by thickening and squamous peeling of the epidermis, often accompanied by reddening and itching of the dermis underneath. The severity of psoriasis is defined by the proportion of body surface affected by proliferative epidermal plaques: mild for less than 3%, moderate for 3% to 10% and severe for more than 10% of body surface. Ointment and creams containing vitamin D analogues have shown to be effective topical therapeutics for mild psoriasis; however, these are not appropriate to treat moderate-to-severe psoriasis, as their absorption through a large skin surface can trigger hypercalcemia.

Psoriasis is not life-threatening, but durably affects the quality of life of psoriatic patients. Frequent recurrences are the rule and definitive cure an exception. Psoriasis affects up to 2% of the population, with about one third of the psoriatic patients being moderate or severe. Current systemic treatments for moderate-to-severe psoriasis include recent injectable biological drugs targeting TNF- α or interleukins 12 and 23, and older oral chemical drugs: cyclosporin, methotrexate and retinoids.

About inecalcitol

Inecalcitol is an anti-proliferative vitamin D receptor agonist with a non-calcemic activity by oral administration at doses up to 4 milligrams per day, as observed in a completed Phase IIa clinical study in first-line metastatic castrate-resistant prostate cancer patients, in combination with Taxotere®. A phase IIb clinical trial is being prepared for the same indication.

The anti-proliferative activity of oral inecalcitol could be especially useful in patients with moderate-to-severe psoriasis where current vitamin D analogues, although efficacious as local treatments of mild psoriasis, cannot be used on a larger body surface or by oral administration as they can cause hypercalcemia.

HYBRIGENICS

Press Release

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 proliferative cancerous or non-cancerous diseases.

Hybrigenics' current development program is based on inecalcitol, a vitamin D receptor agonist, for the first-line treatment of metastatic castrate-resistant prostate cancer in combination with Taxotere[®], which is the current gold-standard chemotherapeutic treatment for this indication. Inecalcitol is also being developed to treat moderate-to-severe psoriasis by oral administration.

Hybrigenics has a research collaboration with Servier on deubiquitinating enzymes and their inhibitors in oncology, neurology, psychiatry, rheumatology, ophthalmology, diabetes and cardiovascular diseases. Hybrigenics continues to build on its pioneer research position in the field of ubiquitin-specific proteases by exploring their role in other areas of particular relevance, such as inflammation and virology.

Hybrigenics Services SAS, a fully-owned subsidiary, is 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 the Alternext by NYSE Euronext Paris

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