HYBRIGENICS

Press Release

# Hybrigenics gets approval and funding for a Phase II clinical trial of inecalcitol in psoriasis

## The French drug agency approves an IMPD application extending the study of oral inecalcitol to psoriasis, a non-cancerous proliferative skin disease

## OSEO grants a zero interest loan of €650,000

**Paris, 06 September 2011** – Hybrigenics (ALHYG), a bio-pharmaceutical company listed on Alternext (NYSE-Euronext) in Paris, with a focus on research and development of new treatments of proliferative diseases, announces today that AFSSAPS, the French drug agency, has granted authorization for a Phase II clinical trial with oral inecalcitol in patients with moderate-to-severe psoriasis under an Investigational Medicinal Product Dossier (IMPD) procedure. Hybrigenics also announces it has received a zero interest loan of €650,000 from OSEO, the French financial institution supporting innovation, to cover 45% of the overall costs of the study.

The study will be conducted by Professor Jean-Paul Ortonne in the Dermatology Department of the University Hospital of Nice, France. It will be a double-blinded and placebo-controlled trial comparing inecalcitol in 40 patients *vs.* placebo in 20 patients. Inecalcitol will be given orally at 4 milligrams per day during 16 weeks. Current plans are for the trial to start in the last quarter 2011, and to last about one year.

"*We are delighted to investigate the full anti-proliferative potential of inecalcitol in psoriasis, a second indication in addition to prostate cancer. This study could extend the therapeutic potential of inecalcitol to non-cancerous proliferative diseases,"* said Dr. Jean-François Dufour-Lamartinie, Head of Clinical R&D.

"W*e are also grateful to OSEO for its support to finance nearly half the cost of this Phase II trial. Oral treatment of moderate-to-severe psoriasis by inecalcitol would be a major breakthrough as compared with older oral drugs such as cyclosporin, methotrexate or retinoids which are immunosuppressant or teratogenic. The convenience of oral administration of inecalcitol would also represent an alternative of choice to more recent but injectable biological treatments*."

**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 tumor-necrosis factor alpha or interleukins 12 and 23, and older oral chemical drugs: cyclosporin, methotrexate and retinoids.

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**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 castrate-resistant prostate cancer patients, in combination with Taxotere®. A phase IIb clinical trial is being prepared for the same indication pending financing and/or partnering.

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.

**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 metastastic 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' 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, 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

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

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