

Debiopharm Group™ - First patient treated in Phase III study with Subcutaneous administration of Debio 8206 for treatment of advanced prostate cancer

Lausanne, Switzerland – July 24, 2012 – Debiopharm Group™ (Debiopharm), a Swiss-based global biopharmaceutical group of companies with a focus on the development of prescription drugs that target unmet medical needs and companion diagnostics, today announced the treatment of its first patient in a multicentre, open, non-comparative Phase III study to investigate the efficacy, safety, and pharmacokinetics of two subcutaneous (SC) injections of Debio 8206 (triptorelin pamoate 22.5 mg 6-month formulation) in patients with advanced prostate cancer.

The study will be conducted in the Republic of South Africa and will involve 120 patients suffering mainly from advanced prostate cancer. Patients with recurrent lower stage prostate cancer and rising prostate specific antigen (PSA) following local therapy failure who are candidates for androgen deprivation therapy will also take part.

The 6-month formulation is currently commercialised for an administration by the intramuscular (IM) route in several countries.

“We believe that the SC route of administration of Debio 8206 will prove very convenient, in prostate cancer patients also suffering from concomitant diseases requiring anticoagulation treatments. In these patients SC administration is often preferred due to a potential risk of haematomas at the injection site after intramuscular injection,” said Rolland-Yves Mauvernay, President and founder of Debiopharm.

Patient evaluation will be primarily based on the efficacy in achieving castrate levels of testosterone (< 1.735 nmol/L [50 ng/dL]) 28 days after the first injection of Debio 8206 and in maintaining castrate levels of testosterone from Day 57 to Day 337. The safety profile will also be evaluated. Additional efficacy measures will include the assessment of the percentage of patients who show an increase in testosterone levels 48 hours after the second injection of Debio 8206, as well as the absence of gonadotropin (LH) stimulation 2 hours after the second injection of Debio 8206 and the change in PSA from baseline to study end. In addition, Debio 8206 pharmacokinetics and testosterone pharmacodynamics will be assessed in a subset of 15 patients.

About Triptorelin

Triptorelin is a synthetic decapeptide agonist analogue of GnRH that was first registered in France in 1986 and is currently marketed in more than 80 countries in various indications including advanced prostate cancer. Chronic administration of triptorelin causes down regulation of the pituitary GnRH receptors and suppresses gonadotropin (LH and FSH) secretion and finally the release of gonadal sex hormones. Triptorelin shows a safety profile similar to other GnRH agonists. Except for injection site reactions or rare immunoallergic reactions, the side effects of triptorelin are mostly due to the initial increase in testosterone (temporary worsening of the symptoms including bone pain within the first days of treatment) followed by almost complete suppression of testosterone (e.g. hot flushes and headaches).

About Debiopharm Group™

Debiopharm Group™ (Debiopharm) is a Swiss-based global biopharmaceutical group of companies with a focus on the development of prescription drugs that target unmet medical needs. The group in-licenses, develops and/or co-develops promising biological and small molecule drug candidates having reached clinical development phases I, II or III, as well as earlier stage candidates. It develops its products for global registration and maximum commercial potential. The products are out-licensed to pharmaceutical partners for sales and marketing. Debiopharm is also active in the field of companion diagnostics with a view to progressing in the area of personalised medicine. Debiopharm independently funds the worldwide development of all of its products while providing expertise in pre-clinical and clinical trials, manufacturing, drug delivery and formulation, and regulatory affairs.

For more information on Debiopharm Group™, please visit: www.debiopharm.com.

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