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DEGARELIX, A NOVEL GnRH BLOCKER FROM FERRING, MOVES INTO PHASE III

Treatment with degarelix results in fast, profound and sustained reductions in testosterone and prostate-specific antigen (PSA) levels without a testosterone surge

Paris, France, April 7, 2006 – Following the presentation today of the results of the Phase IIb programme with degarelix in prostate cancer, which are in line with previous promising studies, Ferring Pharmaceuticals announced the immediate start of Phase III trials[1].

The findings from the international multi-centre trial in 187 men showed that 100% of those treated with an initial dose of 240 mg and a maintenance dose of 160 mg achieved androgen deprivation from day 28 to the full year. Androgen deprivation achieves disease control in prostate cancer patients.

“Degarelix is one of the first drugs in the emerging novel GnRH blocker class of treatments for prostate cancer and represents a new option which builds on many years of experience with effective hormonal therapies,” commented Professor Hein Van Poppel of the Department of Urology at the University of Gasthuisberg. Leuven, Belgium. “The results from this trial indicate that degarelix offers a potentially fast, profound and sustained suppression of testosterone and PSA, the well-known marker for prostate cancer.”

“Prostate cancer is the second leading cause of cancer death among men and there is an ongoing need for better treatments,” explained Dr Bo-Eric Persson, Director, Medical Sciences, Urology / Oncology for Ferring Pharmaceuticals. “These results encourage us further that degarelix has the potential to answer some of these unmet needs in prostate cancer treatment.’’

How degarelix works

Currently used hormonal treatments for prostate cancer include GnRH (gonadotrphin releasing hormone) agonists. Unlike degarelix, these therapies stimulate the natural hormone’s receptor on the pituitary gland. These agents also have a desired clinical effect, but they stimulate testosterone production before shutting it down. This initial stimulation of the receptors stimulates hormone-dependent tumour growth rather than inhibits it, and may lead to a worsening of cancer symptoms or ‘flare’.

Degarelix is designed to target and block the GnRH receptor. This rapidly prevents the production of testosterone and avoids the surge of testosterone and risk of flare.

Degarelix study findings

Degarelix was investigated in one multicentre, one-year study in Europe/South Africa. The study involved the evaluation of initiation doses of 200 mg and 240 mg administered subcutaneously followed by three maintenance doses 80, 120 and 160 mg given every 28 days. The therapeutic effect was assessed by measuring testosterone and prostate-specific antigen (PSA) levels. 187 patients (age 52-93, median 72 years) with histologically confirmed Prostate Cancer and PSA more than or equal to 2 ng/mL received degarelix subcutaneously every 28 days.

Among those initially treated with 240 mg of degarelix, testosterone levels of less than or equal to 0.5 ng/mL were achieved in 92% of patients at Day 3 and 95% of patients at Day 28 compared with 88% at Day 3 and 86% at Day 28 for those administered with a 200 mg dose.

From Day 28 until Day 364, 100% of patients receiving maintenance doses of 160 mg achieved testosterone levels of less than or equal to 0.5 ng/mL at each monthly visit, compared with 96% of those receiving 120 mg and 92% of those receiving maintenance doses of 80 mg.

No evidence of testosterone surge was detected. PSA levels were reduced by 90% 8 weeks after initiation of therapy, by 94% after 12 weeks and by 96% after 24 weeks of treatment.

About Prostate Cancer:
Prostate cancer is the most common form of cancer in men, and the second leading cause of cancer death. In the US 197,800 new cases, 126,900 in the 5 biggest European countries and 30,400 new cases in Japan were estimated in 2003. In 2002 GLOBOCAN cancer database reported 542,909 new cases of prostate cancer diagnosed worldwide and 204,000 deaths due to this disease.

About Current Treatment Options for Prostate Cancer
Current therapeutic options include surgery, radiation therapy, hormonal manipulation therapy or a combination of these. The approach to treatment is influenced by the patient's age, stage of cancer and co-existing medical problems, though no agreed treatment pathway exists and treatment patterns vary in different countries.

Several different hormonal approaches are available for prostate cancer including bilateral orchiectomy (surgical removal of the testicles), GnRH analogues and anti-androgens.

About GnRH blockers versus agonists
Naturally occurring GnRH binds to the GnRH receptor on cells in the pituitary gland, triggering the production of luteinising hormone (LH), which subsequently stimulates the production of testosterone. Both GnRH agonists and blockers bind to this same receptor target.

Agonists, however, work initially by stimulating release of LH and hence testosterone production meaning there is surge in testosterone at the start of treatment leading to characteristic flare responses in symptoms and tumour growth. Meanwhile blockers, like degarelix, directly prevent the release of LH, which means testosterone suppression is fast and profound without a surge. In addition, with blockers there is no need to administer a second hormonal agent, called an anti-androgen, normally used to combat the flare responses that accompany the GnRH agonist usage.

About Degarelix
Degarelix is a GnRH blocker, a synthetic peptide modelled on the body's own gonadotrophin-releasing hormone.

About Ferring:
Ferring is a Swiss-based research driven, speciality biopharmaceutical group active in global markets. The company identifies, develops and markets innovative products in the areas of endocrinology, gastroenterology, gynaecology, infertility and urology. In recent years Ferring has

expanded beyond its traditional European base and now has offices in over 40 countries. To learn more about Ferring or our products please visit www.ferring.com.

Reference

1. Van Poppel, de la Rosette, Persson, Jensen, Olesen, A one year, multicentre, randomised study of degarelix, a gonadotrophin-releasing hormone (GnRH) receptor block in prostate cancer patients. 21st Annual Meeting of the European Association of Urology (EAU), Paris, 5th – 8th April 2006.

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