Corporate Communications

FERRING PHARMACEUTICALS

Press Release

For Immediate Release.

Committee for Medicinal Products for Human Use (CHMP) recommends granting marketing authorisation for FIRMAGON® (degarelix) for treatment of prostate cancer

New gonadtropin-releasing hormone (GnRH) receptor antagonist demonstrates rapid, long-term suppression of testosterone

Saint Prex, Switzerland, 18 December 2008– Ferring Pharmaceuticals received today notification that the Committee for Medicinal Products for Human Use (CHMP), part of the European Medicines Agency (EMEA), has adopted a positive opinion and is recommending to grant a marketing authorization for FIRMAGON® (degarelix), a new GnRH receptor antagonist indicated for patients with advanced, hormone-dependent prostate cancer. In Phase III studies degarelix produced a significant reduction in levels of testosterone [i,ii] within three days in more than 96% of study patients.[ii] Testosterone plays a major role in the growth and spread of prostate cancer cells.

The data show that degarelix provided an extremely fast effect on testosterone levels, close to the immediate effect achieved with surgery (orchidectomy).[ii,iii]

The Phase III study compared monthly administration of degarelix with monthly luteneising hormone releasing-hormone (LHRH) agonist leuprorelin's 7.5 mg in a 12-month randomised, open-label, parallel-group study in prostate cancer patients. In comparison to leuprorelin, degarelix suppressed serum testosterone and Prostate Specific Antigen (PSA) significantly faster. In addition, degarelix was able to sustain these low levels during the entire 12 month study.[ii]

By day 3 of the study, testosterone levels were suppressed to ≤ 0.5ng/mL in 96.1% of patients in the degarelix arms of the study compared to 0% in the leuprorelin arm. By day 14, 100% of patients in the degarelix arms achieved suppression of testosterone levels at ≤0.5ng/mL compared to 18.2% in the leuprorelin arm.[ii] After 14 days of treatment, PSA levels had declined in the degarelix treated patients by a median of 64%, while patients who were administered leuprorelin saw an 18% decline. Both treatments were well tolerated and showed similar side effect profiles. The most common side effects of degarelix are hot flushes, injection site pain, injection site erythema, increased weight, nasopharyngitis, fatigue and back pain.

"Degarelix was discovered and developed by Ferring Pharmaceuticals and in its pivotal Phase III study demonstrated both an immediate onset of action and a profound long-term suppression of testosterone and PSA" commented Dr Pascal Danglas, Executive Vice President Clinical & Product Development at Ferring Pharmaceuticals. "We will be delighted to deliver a new treatment option for advanced prostate cancer to the medical community. Ferring has a considerable pipeline of urology products in development and we expect to introduce additional innovations in the urology field in the near future."

"Our goal is always to have a fast and sustained reduction in testosterone levels" said Mr John Anderson, Consultant Urological Surgeon, The Royal Hallamshire Hospital, Sheffield, United Kingdom "Degarelix produces an extremely rapid impact, approaching the immediacy of surgery and it is good news that the product should become imminently available."

Ferring Pharmaceuticals plans to launch FIRMAGON® (degarelix) in Europe in the first quarter of 2009 and is also awaiting an imminent FDA decision on approval for commercialisation in the US. It is expected that commercialisation in other key global markets will follow during 2009 and 2010 once approval is received from the relevant local regulatory authorities.

Michel Pettigrew, Chief Operating Officer Ferring Pharmaceuticals, stated: "The recommendation from the CHMP to grant marketing authorisation for FIRMAGON® is a significant milestone for Ferring. It is the first positive opinion we have received from a regulatory authority for FIRMAGON® which, in turn, will be the first product that Ferring will launch on a global basis. We are truly excited to be on the brink of introducing this new therapy to physicians and patients, and we look forward to providing an innovative tool that will add meaningfully to the treatment options for addressing prostate cancer."

Degarelix went through an extensive clinical programme of more than 20 studies. All studies have found degarelix to be well tolerated and with no evidence of systemic allergic reactions.[ii,iv,v]

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Notes to Editors

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 218,890 new cases were estimated for 2007, with a mortality rate of 27,050. In 2005 127,490 new cases were diagnosed in the 5 biggest European countries and 18,310 in Japan.

About degarelix

Degarelix is a GnRH receptor antagonist indicated for advanced prostate cancer.

About Ferring

Ferring is a Swiss-headquartered, research driven, speciality biopharmaceutical group active in global markets. The company identifies, develops and markets innovative products in the areas of urology, endocrinology, gastroenterology, gynaecology, and fertility. In recent years Ferring has expanded beyond its traditional European base and now has offices in over 45 countries. To learn more about Ferring or our products please visit www.ferring.com.

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[i] Van Poppel H, De La Rosette JJ, Persson B.E, Oleson TK, Degarelix Study Group; *Long-term evaluation of degarelix, a gonadotrophin-releasing hormone (GnRH) receptor blocker, investigated in a multicentre randomised study in prostate cancer (CAP) patients.* Abstract (23.) Euro Urol Suppl 2007;6(2):28

[ii] Boccon-Gibod L, Klotz L, Schröder FH, Andreou C, Persson BE, Cantor P, Jensen JK, Olesen TK; *Degarelix compared to leuprolide depot 7.5 mg in a 12-month randomised, open-label, parallel-group phase III study in prostate cancer patients.* Abstract 537 presented at the 23rd EAU Congress, Milan, Italy, 2008.

[iii] Nielsen S, Connolly M, Persson B, *Variation between countries in the perceived use of antiandrogens to prevent flare symptoms: results of a comprehensive survey.* Abstract 539 presented at the 23rd EAU Congress, Milan, Italy, 2008

[iv] Gittelman M, Pommerville P, Persson B, Olesen T, A *1-year, open label, randomised Phase II dose finding study of degarelix for the treatment of prostate cancer in North America.* Journal of Urology, Vol. 180, November 2008.

[v] Tammela T, Iversen P, Johansson J, Persson B, Jensen J, Olesen T. *Degarelix-a phase II multicentre, randomised dose escalating study testing a novel GnRH receptor blocker in prostate cancer patients* (Abstract No. 904) European Urology Supplements 4 (2005) No.3, pp 228.