Corporate Communications

Press Release

New data from a pooled analysis shows improved overall survival for prostate cancer patients treated with FIRMAGON® (degarelix) compared to LHRH agonists

Saint-Prex, Switzerland, 25 November 2014 – New data published in the December issue of the European Journal of Urology indicates improvement in overall survival (OS) and prostate specific antigen progression free survival (PSA PFS) for degarelix (FIRMAGON®), a gonadotropin releasing hormone (GnRH) antagonist, compared to commonly prescribed luteinising hormone-releasing hormone (LHRH) agonists. In addition, the data showed a reduction in the incidence of joint, musculoskeletal and urinary tract adverse events for those men with prostate cancer treated with degarelix rather than LHRH agonists. However, the overall rate of any adverse event (including hot flush and injection-site reactions) was higher in the degarelix group than the LHRH agonist group.

Results showed a 29% improvement in PSA PFS* (p=0.017) and 53% improvement in overall survival (p=0.023) for men with prostate cancer who were treated with degarelix instead of an LHRH agonist.

Lead study author Professor Laurence Klotz, MD, Sunnybrook Health Sciences Centre, University of Toronto, Canada, said, “These pooled data showed degarelix improved overall survival rates compared to LHRH agonists. This is encouraging for physicians making treatment decisions for their prostate cancer patients.”

These findings are based on a pooled analysis of 1,925 men with prostate cancer from five prospective, phase III or IIIb randomised trials.[1] Men requiring androgen deprivation therapy for the treatment of prostate cancer received degarelix (n=1,266) or an existing LHRH agonist (goserelin, n=458; leuprolide, n=201). The full analysis set used for efficacy analysis consisted of 1,920 patients. Of those, 1,263 received degarelix, 456 goserelin and 201 leuprolide. Those patients being treated with degarelix received a 240 mg dose in all trials and most patients received a maintenance dose of 80 mg. The majority of patients (1,458) received treatment for one year, while the remaining patients were treated for three months.

In terms of disease-related adverse events, for those patients taking degarelix, there were significantly fewer musculoskeletal events (p=0.007) and a significantly lower incidence of any urinary tract infections (p=0.023) compared to the LHRH agonist-treated patients. In addition, in the degarelix group there were fewer patients that experienced a fracture (p=0.064) (although this was not statistically significant) and there were significantly less frequent joint-related signs and symptoms (p=0.041) compared to the LHRH agonist treatment arm.

The overall rate of any adverse event was significantly higher in the degarelix group (74%) compared to the LHRH agonist group (68%), (p=0.002). Specifically, hot flush and injection-site reactions, including pain, erythema, swelling and nodules, were more frequent in the degarelix group.

FIRMAGON® (degarelix) was approved for the treatment of advanced hormone-dependent prostate cancer in both the EU and US in 2009. Today it is available in approximately 40 countries around the world, including a growing number in Asia, Latin America and the Middle East.

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About FIRMAGON®

FIRMAGON® has chemical characteristics and a novel mechanism of action, different from traditionally used hormonal therapies. Administered as a deep subcutaneous injection, FIRMAGON® rapidly reduces levels of testosterone by blocking the GnRH receptors in the pituitary gland. Blocking the receptors suppresses the release of the luteinising hormone and follicle-stimulating hormone, resulting in a decrease in production of testosterone by the testicles to castration levels within three days. Prostate cancer is dependent on testosterone for its growth, and reducing testosterone levels slows the growth of cancer cells.

In clinical trials FIRMAGON® was generally well tolerated. Common side effects are hot flushes, injection site pain and erythema, increased weight, nasopharyngitis, fatigue and back pain.[2]

About Prostate Cancer

Prostate cancer is the most common form of male cancer in the western world,[3] and the second leading cause of cancer death in men in some countries.[4] Around 417,000 new cases of prostate cancer are diagnosed in Europe each year. Worldwide this figure rises to 1.1million new cases.[5] For further media information and news alerts on prostate cancer please visit Ferring's information website www.ProstateCancerLiving.com

About Ferring

Headquartered in Switzerland, Ferring Pharmaceuticals is a research-driven, specialty biopharmaceutical group active in global markets. The company identifies, develops and markets innovative products in the areas of reproductive health, urology, gastroenterology, endocrinology and orthopaedics. Ferring has its own operating subsidiaries in nearly 60 countries and markets its products in 110 countries. To learn more about Ferring or its products please visit www.ferring.com.

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[1] Klotz,L. *et al.* Disease Control Outcomes from Analysis of Pooled Individual Patient Data from Five Comparative Randomised Clinical Trials of Degarelix Versus Luteinising Hormone-releasing Hormone Agonists, *European Urology*. 66(6), p. 1101-1108
[2] Van Poppel H, De La Rosette JJ, Persson B.E *et al.* 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 Urology Supplement* 2007;6(2):28
[3] University of Iowa Hospitals and Clinics. Available at: http://www.uihealthcare.org/2column.aspx?id=236746 [Accessed 24 November 2014]
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[5] Publications. Cancer Research UK. Available at http://publications.cancerresearchuk.org/downloads/product/CS_KF_PROSTATE.pdf [Accessed 24 November 2014]