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FOR IMMEDIATE RELEASE

DEGARELIX (FIRMAGON®) VS LEUPROLIDE (LUPRON DEPOT®) IN PATIENTS WITH ADVANCED PROSTATE CANCER: FURTHER ANALYSIS FROM A PHASE III PIVOTAL TRIAL

Investigators Presented Results at the Society of Urologic Oncology Annual Meeting

BETHESDA, MD – December 4, 2009 – Drs. Neal Shore and E. David Crawford presented results for prostate-specific antigen (PSA) recurrence from the additional analysis of secondary end points of biochemical recurrence rate in a Phase III pivotal study of FIRMAGON® (monthly degarelix for injection) or monthly leuprolide in prostate cancer patients during the first year of treatment. Prostate cancer patients who received FIRMAGON 240/80 mg/month had a recurrence rate of 7.7% during the first year of treatment compared with 12.9% of patients treated with leuprolide 7.5 mg/month (p=0.05). Patients being treated with FIRMAGON also had longer time to recurrence compared with those on leuprolide (p=0.04).

Results of the PSA analysis were presented in a poster at the 10th Annual Meeting of the Society of Urologic Oncology, held in conjunction with the World Urological Oncology Federation, on December 3 in Bethesda, MD.

About the Study

In the Phase III multicenter, randomized, open-label trial comparing degarelix with leuprolide, prostate cancer patients (n=610) were randomized to a starting dose of degarelix 240 mg for one month, followed by monthly maintenance doses of 80 mg (n=207) or 160 mg (n=202), or leuprolide 7.5 mg/month (n=201). Results showed that degarelix is as effective as leuprolide in reducing and sustaining castrate levels of testosterone.[1,2] Suppression of testosterone to castrate levels occurred significantly faster in patients receiving degarelix than in those receiving leuprolide.[1,2] The study also showed that degarelix achieves faster suppression of luteinizing hormone and follicle-stimulating hormone.[1,2]

PSA recurrence was defined as two consecutive increases in PSA of 50% compared with nadir and ≥5 ng/mL on two consecutive measurements at least two weeks apart. PSA

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progression-free survival was analyzed using the Kaplan-Meier method and “time to event” was defined as the number of days from first dosing to the first occurrence of PSA recurrence or death. PSA recurrences were analyzed by baseline PSA level.

PSA recurrence was 12.9% for leuprolide 7.5 mg/month patients compared to 7.7% with the approved degarelix 240/80 regimen. The probability of completing the study without experiencing PSA recurrence by day 364 was 91.1% (95% CI: 85.9-94.5) for degarelix and 85.9% (95% CI: 79.9-90.2) for leuprolide 7.5 mg/mo. The probability of completing the study without dying by day 364 was 97.4% (95% CI: 93.8-98.9) for degarelix versus 95.1% (95% CI: 90.7-97.4) for leuprolide 7.5 mg/mo. In patients with baseline PSA >20 ng/mL, risk of PSA recurrence was lower for patients receiving degarelix compared with leuprolide (p=0.04). The risk of PSA recurrence was comparable in patients with baseline PSA >50 ng/mL (p=0.10).

At Day 3 of treatment, the degarelix group achieved a 90 percent decrease in median testosterone levels compared with the leuprolide group, which experienced a 65 percent increase in median testosterone levels. Degarelix was as effective as leuprolide in suppressing testosterone levels from Day 28 to the end of the study (Day 364), with 97.2% of the degarelix patients maintaining medical castrate levels compared with 96.4% for leuprolide.

About FIRMAGON

FIRMAGON is an injectable gonadotropin-releasing hormone (GnRH) receptor antagonist approved by the U.S. Food and Drug Administration (FDA) for the treatment of advanced prostate cancer. As a receptor antagonist, FIRMAGON reversibly binds to the GnRH receptors in the pituitary gland, immediately suppressing the secretion of the luteinizing hormone (LH), follicle-stimulating hormone (FSH), and subsequently, testosterone levels.[1-4]

FIRMAGON also reduces levels of prostate-specific antigen (PSA). Unlike luteinizing hormone-releasing hormone (LHRH) agonists, such as leuprolide, an established treatment for prostate cancer, FIRMAGON does not induce an initial testosterone surge. FIRMAGON is administered monthly by subcutaneous injection. The starting dose is 240 mg, followed by monthly maintenance doses of 80 mg. FIRMAGON is available for order through traditional and specialty pharmacy distributors. The average monthly cost of one year of FIRMAGON treatment is comparable to other hormone treatments for prostate cancer.

The most commonly observed adverse reactions during FIRMAGON therapy included injection site reactions (e.g. pain, erythema, swelling or induration) and other androgen deprivation therapy (ADT) associated side effects including hot flashes, increased weight and

fatigue. Ninety-nine percent of these observed adverse reactions were Grade 1 or 2 (mild to moderate). Specifically relating to the injection site adverse reactions, most were transient, of mild to moderate intensity, occurred primarily with the starting dose and led to few discontinuations (<1%). Grade 3 (severe) injection site reactions occurred in two percent or less of patients receiving FIRMAGON.

FIRMAGON is contraindicated in patients with known hypersensitivity to degarelix or to any of the product components. FIRMAGON is not indicated in women or pediatric patients. Long-term ADT prolongs the QT interval. Physicians should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, electrolyte abnormalities, or congestive heart failure and in patients taking Class IA (e.g. quinidine, procainamide) or Class III (e.g. amiodarone, sotalol) antiarrhythmic medications.

About Ferring Pharmaceuticals Inc.

Ferring Pharmaceuticals Inc. is a subsidiary of Ferring Pharmaceuticals, a privately owned, international pharmaceutical company. Ferring Pharmaceuticals offers a line of infertility, urology, and orthopaedic products in the U.S. market. They include: BRAVELLE® (urofollitropin for injection, purified), MENOPUR® and REPRONEX® (menotropins for injection, USP), NOVAREL® (chorionic gonadotropin for injection, USP), ENDOMETRIN® (progesterone) Vaginal Insert, 100 mg, FIRMAGON® (degarelix for injection), PROSED® DS (methenamine, phenyl salicylate, methylene blue, benzoic acid, hyoscyamine sulfate), DESMOPRESSIN, and EUFLEXXA® (1% sodium hyaluronate).

Ferring Pharmaceuticals specializes in the research, development and commercialization of compounds in general and pediatric endocrinology, urology, orthopaedics, gastroenterology, obstetrics/gynecology, and infertility. For more information, call 1-888-FERRING (1-888-337-7464) or visit www.FerringUSA.com.

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[1] Degarelix [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; December 2008.
[2] Klotz L, Boccon-Gibod L, Shore ND, et al. The efficacy and safety of degarelix: a 12-month comparative, randomized, open-label, parallel-group phase III study in patients with prostate cancer. *BJU Int.* 2008;102(11):1531-1538.
[3] Van Poppel H, Tombal B, de la Rosette JJ, Persson B-E, Jensen J-K, Olesen TK. Degarelix: a novel gonadotropin-releasing hormone (GnRH) receptor blocker—results from a 1-yr, multicentre, randomised phase 2 dosage-finding study in the treatment of prostate cancer. *Eur Urol.* 2008;54(4):805-813.
[4] Doehn C. Immunotherapy of Prostate Cancer. *Eur Urol*. (2006);53-4:681-683.

*Lupron Depot® (leuprolide acetate for depot suspension) is a registered trademark of TAP Pharmaceuticals Inc.