Hormonal Drug Approved for Prostate Cancer

BY BETSY BATES

Los Angeles Bureau

The Food and Drug Administration has approved an injectable gonadotropin-releasing hormone (GnRH) antagonist for the treatment of advanced prostate cancer. It is the first new agent cleared to treat the disease since 2004.

Degarelix, which will launch in Europe in early 2009 under the name Firmagon, was shown in phase III trials to outpace leuprolide (Lupron) in rapidly suppressing testosterone, without the androgen flare associated with Lupron and other luteinizing hormone-releasing hormone (LH-RH) agonists.

Potential trade names for the new drug in the United States are still being reviewed with the FDA, according to a statement issued by Parsippany, N.J.-based Ferring Pharmaceuticals USA following the approval late last year. After those discussions are complete, an immediate commercial release of the drug is planned.

The drug offers a new spin on hormone treatment for advanced prostate cancer, directly binding to GnRH receptors on pituitary cells, rather than working more circuitously, through hypothalamic downregulation of LH secretion, like LH-RH agonists.

The more direct route achieves very rapid and sustained testosterone suppression, clinical trial data confirmed. In a 12-month, randomized, open-label phase III study of 610 patients, testosterone was suppressed to 0.5 ng/mL or less within 3 days in 96.1% and 95.5% of patients receiving either of two dosing regimens of degarelix and no patients in the comparative leuprolide group (BJU Int. 2008;102:1531-8).

By day 14 of the study, castrate levels of testosterone were demonstrated in 99% of degarelix patients compared with 18% receiving leuprolide.

"Use of a GnRH receptor antagonist is a highly efficient way to stop the production of testosterone," Dr. Neal Shore, medical director of the Carolina Urologic Research Center, Myrtle Beach, S.C., said in the statement.

"The approval of degarelix offers the medical community an effective alternative in the treatment of hormonally sensitive prostate cancer."

Other adverse events commonly associated with insulin therapy may include injection site reactions (an average, 3% to 4% of patients in clinical trials) such as hypoglycemia, redness, pain, itching, hives, swelling, and inflammation.

Other than these observed differences represent true differences in the effects of Levemir®, insulin, and insulin analogs is not known, since these trials were not blinded and the protocols (diet and exercise instructions and monitoring) were not specifically directed at exploring hypotheses related to weight effects of the treatments compared. The clinical significance of the observed differences in weight has not been established.

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