
FDA Approves Drug for Patients with Advanced Prostate Cancer

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Washington, DC - The U.S. Food and Drug Administration recently approved the injectable drug degarelix, the first new drug in several years for prostate cancer.

Degarelix is intended to treat patients with advanced prostate cancer. It belongs to a class of agents called gonadotropin releasing hormone (GnRH) receptor inhibitors. These agents slow the growth and progression of prostate cancer by suppressing testosterone, which plays an important role in the continued growth of prostate cancer.

Hormonal treatments for prostate cancer may cause an initial surge in testosterone production before lowering testosterone levels. This initial stimulation of the hormone receptors may temporarily prompt tumor growth rather than inhibiting it. Degarelix doesn't do this.

“Prostate cancer is the second leading cause of cancer death among men in the United States and there is an ongoing need for additional treatment options for these patients,” said Richard Pazdur, M.D., director of the Office of Oncology Drug Products, Center for Drug Evaluation and Research, FDA.

Prostate cancer is one of the most commonly diagnosed cancers in the United States. In 2004, the most recent year for which statistics are currently available, nearly 190,000 men were diagnosed with prostate cancer and 29,000 men died from the cancer.

Several treatment options exist for different stages of prostate cancer including observation, prostatectomy (surgical removal of the prostate gland), radiation therapy, chemotherapy, and hormone therapy with agents that affect GnRH receptors.

The efficacy of degarelix was established in a clinical trial in which patients with prostate cancer received either degarelix or leuprolide, a drug currently used for hormone therapy in treating advanced prostate cancer. Degarelix treatment did not cause the temporary increase in testosterone that is seen with some other drugs that affect GnRH receptors.

In fact, nearly all of the patients on either drug had suppression of testosterone to levels seen with surgical removal of the testes.

The most frequently reported adverse reactions in the clinical study included injection site reactions (pain, redness, and swelling), hot flashes, increased weight, fatigue, and increases in some liver enzymes.

Degarelix is manufactured for Ferring Pharmaceuticals Inc., Parsippany, N.J., by Rentschler Biotechnologie GmbH, Laupheim, Germany.