

New Treatment Apalutamide (Erleada) Approved for Prostate Cancer That Resists Hormone Therapy

WEDNESDAY, Feb. 14, 2018 – Erleada (apalutamide) has been approved by the U.S. Food and Drug Administration to treat non-spreading prostate cancer that continues to grow despite hormone therapy.

Prostate cancer is the second-most-common form of the disease among men in the United States, the National Cancer Institute says. More than 161,000 men were diagnosed in 2017, and nearly 27,000 men were projected to die of prostate cancer last year, the NCI estimates.

Erleada is designed to block the effects of a type of tumor-spurring hormone known as an androgen. An example of an androgen is the male hormone testosterone, the FDA said in a media release.

The drug was evaluated in clinical studies involving more than 1,200 participants with this type of prostate cancer. Average survival before the tumor spread was 40.5 months among men who took Erleada, compared to 16.2 months among those who took a placebo.

The most common side effects of the drug included fatigue, high blood pressure, rash, diarrhea, nausea, weight loss, joint pain, hot flushes and loss of appetite. More serious adverse reactions included falls, bone fractures and seizures, the FDA said.

Erleada is produced by Belgium-based Janssen Pharmaceutical Companies.

More information

Visit the FDA to find out more.



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Posted: February 2018