FDA Approves Nubeqa for Nonmetastatic Prostate Cancer

The androgen receptor inhibitor delayed cancer metastasis in a late-stage clinical trial.

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The Food and Drug Administration (FDA) has approved Nubeqa (darolutamide) for the treatment of prostate cancer that has progressed despite a low testosterone level but has not yet spread elsewhere in the body.

Nubeqa, from Bayer, is an androgen receptor inhibitor that interferes with the activity of male hormones in the body, including their ability to trigger prostate cancer growth. The Phase III ARAMIS trial showed that the new medication more than doubled the time before cancer metastasized, or spread beyond the prostate.

Nubeqa is taken as a tablet twice daily with food. It should be combined with medications that stop testosterone production, known as androgen deprivation therapy (ADT).

Testosterone and other androgens—known as male hormones, although females produce small amounts too—can stimulate prostate cancer growth. To do so, they must bind to androgen receptors in prostate cells. Nubeqa blocks chemical signals from androgen receptors, preventing them from triggering cancer cell proliferation.

Prostate cancer is usually initially treated with surgery or radiation therapy, often followed by ADT. But the cancer can develop the ability to grow despite low testosterone levels, which is known as being castration-resistant.

The ARAMIS trial evaluated whether Nubeqa would delay metastasis and death in men with nonmetastatic, castration-resistant prostate cancer. About 40% of people with prostate cancer have disease that has not yet spread but is associated with a rising prostate-specific antigen (PSA) level, despite low testosterone.

ARAMIS enrolled 1,509 men with a median age of 74. They had a rapid PSA doubling time—usually six months or less—indicating high-risk disease. Three fourths had used two or more prior hormone therapies. Participants were randomly assigned to receive twice-daily Nubeqa or placebo tablets along with ADT. Scans were done every 16 weeks to look for disease progression.

Study results were presented at the American Society of Clinical Oncology Genitourinary Cancers

Symposium in February and published in The New England Journal of Medicine.

Men who used Nubeqa had a median metastasis-free survival time, meaning they were still alive without cancer spreading beyond the prostate, of 40.4 months, compared with 18.4 months in the placebo group—a 59% reduction in the risk of metastasis or death. Those in the Nubeqa group also went longer before they experienced worsening pain, developed skeletal problems such as bone fractures or started chemotherapy. Overall survival data were not yet mature, but interim data showed a 29% reduction in the risk of death.

Nubeqa was generally safe and well tolerated. Most side effects were mild or moderate. A quarter of Nubeqa recipients and 20% of placebo recipients experienced serious adverse events. In both groups, 9% stopped treatment because of adverse events. The most common adverse events associated with Nubeqa are fatigue, back pain, joint pain and skin rash.

Nubeqa was approved under the FDA's priority review designation, indicating that it may provide significant improvements in the safety or effectiveness of treatment for a serious condition.

"Patients at this stage of prostate cancer typically don't have symptoms of the disease. The overarching goals of treatment in this setting are to delay the spread of prostate cancer and limit the burdensome side effects of therapy," Matthew Smith, MD, PhD, of Massachusetts General Hospital Cancer Center, said in a Bayer press release. "This approval marks an important new option for the prostate cancer community."

Click here to see the full prescribing information for Nubeqa.

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