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FDA panel unanimously backs Onyx cancer drug

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(AP) — A federal panel of cancer specialists on Wednesday unanimously recommended approval of an experimental drug from Onyx Pharmaceuticals Inc. for patients with advanced blood cancer.

The U.S. Food and Drug Administration panel voted 11-0, with one abstention, in favor of carfilzomib as a treatment for patients with advanced forms of multiple myeloma that hasn't responded to other drugs.

The FDA is not required to follow the group's advice but often does. A final decision is expected by July 27.

In documents posted earlier this week, FDA scientists raised safety concerns about carfilzomib, including toxic side effects on the heart and lungs. They also questioned the injectable drug's effectiveness.

Onyx studied the drug in 266 patients who had already been treated with two other cancer drugs. About 22 percent of patients studied responded to the drug, with the typical patient surviving slightly less than eight months after beginning treatment. In its briefing, the FDA panel commented that the response rate was so low "it may not provide an advantage over available therapy."

But FDA's panelists said the drug could still be an important treatment for patients with few other options. The FDA has approved seven drugs for multiple myeloma. Doctors use different therapies depending on a

patient's age and health and stage of disease.

Over 50,000 people have multiple myeloma in the U.S., and about 20,000 new cases are diagnosed annually.

If approved, Onyx would market the drug under the brand name Kyprolis.

South San Francisco-based Onyx said in a statement that the vote "is an important regulatory milestone in the review of Kyprolis, and we are committed to working with the FDA to bring this treatment to patients as quickly as possible."

Company shares fell 9 cents to $44.49 in afterhours trading Wednesday. Shares rose 32 cents to $44.58 in regular trading before being halted ahead of the panel vote.