FDA Panel Backs Onyx Cancer Drug

A Food and Drug Administration advisory panel backed the approval of the experimental cancer drug carfilzomib that is being developed by Onyx Pharmaceuticals Inc., ONXX +39.55% saying more options are needed for patients.

The company is seeking FDA approval of the product to treat patients with multiple myeloma, a cancer that affects the bone marrow, who have failed at least two other treatments.

Carfilzomib was reviewed on Wednesday by the FDA's oncologic drugs advisory committee, which is made up of non-FDA medical experts.

The panel voted 11-0 in the positive in response to the question that asked "has a favorable benefit risk profile been shown for the treatment of patients...with multiple myeloma?" One person voted to abstain. The vote amounts to a recommendation that the FDA approve the product under the agency's so-called accelerated approval mechanism.

The FDA isn't required to follow its panels' advice but usually does. The FDA is expected to make a decision by July 27, according to Onyx. The company said it is "committed to working with the FDA to bring this treatment to patients as quickly as possible."

Wyndham Wilson, the chairman of the FDA advisory committee and the chief of the National Cancer Institute's lymphoma therapeutics section, voted to support the drug saying, "This is a group that has run out of options."

Accelerated approval allows drugs to be approved on less clinical data than required for regular approval. Companies are required to keep studying products that receive accelerated approval and then seek full approval. The FDA can revoke an accelerated approval if future studies fail to show benefit.

Earlier this week the FDA released a negative review of carfilzomib, saying it was "very concerned with the severe toxicities including deaths that are associated with the use of this agent." The agency also said the risks of the product might not outweigh the benefits, and cited a number of side effects likely associated with the drug, including heart problems, respiratory problems and liver failure.

However, during Wednesday's panel meeting, an FDA medical reviewer said it wasn't clear what role the disease, previous therapy, or the study drug might have played in the development of cardiac and other side effects.
The main study submitted in support of carfilzomib's approval, which involved 266 patients, showed a response rate of 22%. Each patient in the study received the study drug.

Carfilzomib has a proposed brand name of Kyprolis.