US focuses on toxic side effects with Onyx drug

June 18 2012, by MATTHEW PERRONE

(AP) — The toxic side effects of an experimental cancer drug from Onyx Pharmaceuticals may outweigh its benefits for patients with a type of blood cancer, federal health regulators said Monday.

The Food and Drug Administration warned that patients in a company study of the drug had a high rate of heart and lung side effects, some which were fatal. The FDA posted its review of carfilzomib online ahead of a meeting Wednesday, where its panel of cancer experts will recommend whether the drug should be approved.

Despite the negative tone of the review, some analysts said they expect the FDA's panel of outside experts to take a more favorable view. FDA panels are mainly comprised of practicing physicians from leading universities and hospitals.

BMO Capital Markets analyst Jim Birchenough said he expects "panel members to be more constructive toward the carfilzomib data package." Birchenough recommended buying the stock, in a note to investors.

Shares of Onyx Pharmaceuticals Inc., based in San Francisco, fell $1.90 to close at $44.08 Monday after rising as high as $46.99 earlier in the session. They are near their 52-week high of $47.80 in late April.

Onyx has asked the FDA to approve carfilzomib as a treatment for patients with advanced forms of multiple myeloma whose disease has spread despite treatment with other drugs.

Multiple myeloma affects plasma cells in bone marrow. Over 50,000 people have the disease in the U.S., and about 20,000 new cases are diagnosed every year.

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, FDA reviewers commented that the response rate was so low "it may not provide an advantage over available therapy."

FDA reviewers said they were also "very concerned with severe toxicities," including heart problems, which affected 23 percent of patients. The agency's scientists said the root cause of those problems "is not understood."

The FDA has already approved seven drugs for multiple myeloma. Doctors use different therapies depending on the patient's age, health and stage of disease.

The FDA will ask its cancer panel to vote on whether the benefits of carfilzomib outweigh the risks. The agency is not required to follow the group's advice, though it often does. A decision on the drug is expected by July 27.

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