

## Abbott Didn't Show Cancer Drug Works, FDA Staff Says (Update1)

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By Kerry Dooley Young

Sept. 12 (Bloomberg) -- Abbott Laboratories failed to show its Xinlay pill fights prostate cancer, U.S. regulators said in a report that also noted "serious" heart risks from the drug.

Xinlay, also called atrasentan, caused fluid retention and heart failure in studies, the FDA staff said in a review posted today on its Web site. The report also said more people taking the drug, to be reviewed tomorrow by FDA advisors, had irregular heart rhythms, known as arrhythmias, than those given placebo.

"There are some serious cardiovascular safety issues observed in" two large studies, the staff report said. It also noted the drug "does not demonstrate any clear evidence of clinical efficacy."

Abbott is asking the U.S. Food and Drug Administration to approve Xinlay based on studies showing that while the drug didn't slow cancer in a significant way, it may have helped some patients. The FDA agreed to review the application based on other potential benefits, such as slowing onset of bone pain.

The FDA report questioned how Abbott assessed whether cancer was getting worse. Men could be counted as having pain severe enough to need narcotics, even if the cause was unrelated to the cancer, including from arthritis, the FDA staff said.

"Consequently, a single dose of drugs like Codeine or Demerol could be counted as disease progression, even if not related to prostate cancer," the FDA staff said.

### Bone Pain

Abbott has said Xinlay reduced risk of bone pain by 23 percent in its research in a briefing document, also posted on the FDA's Web site today. If approved, Xinlay sales may reach \$150 million next year, said Glenn Reicin, a Morgan Stanley analyst in New York, in a Sept. 8 report.

The FDA often accepts the advice of its panels. In this case, the agency may decide to delay Xinlay until it sees the results of a study still under way, said Le Anne Zhao, a Caris & Co. analyst in New York, in a Sept. 9 telephone interview.

"There is not a history for approvals" based on examining secondary evidence from failed medical studies, Zhao said.

Shares of Abbott Park, Illinois-based Abbott fell 26 cents as of 9:48 a.m. to \$45.31 in New York Stock Exchange composite trading. Abbott's second-quarter drug sales surged 20 percent to \$1.87 billion, helped by for products gained by an acquisition and sold through a licensing agreement.

### 30,000 Deaths

Prostate cancer kills about 30,000 men a year in the U.S., according to the National

Institutes of Health's Web site. About 16 percent of men in the U.S. will have prostate cancer, with about half of these cases having serious symptoms, according to the National Cancer Institute's Web site. Slow-growing tumors in older men often are left untreated. Aggressive forms of the cancer spread through the body.

Xinlay targets a protein that appears to help cancer cells spread, endothelin.

About 3 percent of American men die from the disease, the site said. Cancer that invades bones can cause pain so severe that even morphine can't stop it, doctors say. Abbott said it wants to offer Xinlay to men with severe prostate cancer, even as it continues research to try to prove the drug's efficacy.

``There are 30,000 prostate cancer related deaths a year. That is about 100 a day" in the U.S., said Eugene Sun, Abbott's vice president for global pharmaceutical clinical development, in a Sept. 9 interview. ``You could wait for even more studies, some of which are in progress. But, I have a drug that does something for patients who have very few options, and for whom there is not a lot of time before their disease marches on."

### **More Options**

Men with prostate cancer want to have more options if their disease progresses, said Thomas Kirk, president of Us TOO International, a non-profit group for patients. The Downers Grove, Illinois-based group, which accepts funding from Abbott, said it does not endorse products. Us TOO members will attend tomorrow's meeting to ask the FDA panelist to keep patients in mind, Kirk said.

``These men have battled this disease for 10 or 15 years in many cases," Kirk said in a Sept. 9 telephone interview. ``When they get to the later stages of their disease, they have very few options, or the option of powerful chemotherapy with side effects that would dramatically impact on their quality of life."

--Editors: Simison, Gale.

Story illustration: For a chart of Abbott's earnings, see {ABT US <Equity> CH2 <GO>} . To graph the company's shares, see {ABT US <Equity> GP D <GO>} . To find the Web site of the prostate cancer group Us TOO: <http://www.ustoo.org>. To learn more about enrolling in tests for prostate cancer, <http://www.clinicaltrials.gov> and enter prostate cancer in the search field.