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Glaxo's Epzicom Loses Preferred Status as HIV Drug

By John Lauerman

Nov. 3 (Bloomberg) — GlaxoSmithKline Plc's Epzicom was taken off the U.S. government's list of preferred initial HIV treatments after two studies linked the medicine to a higher risk of heart attacks.

The drug should only be used as an alternative to Gilead Sciences Inc.'s Truvada, according to a Health and Human Services Department advisory panel that sets guidelines. The panel posted the revision today on a government Web site. Epzicom combines the antiviral drugs abacavir and lamivudine.

The two studies published earlier this year, analyses of previous investigations, found that taking Epzicom or Glaxo's Ziagen, which also contains abacavir, almost doubled patients' risk of a heart attack. Doctors have been debating how or whether to change their use of the drugs, said Calvin Cohen, an AIDS doctor who says he uses less of them since the studies were published.

“We have two studies with a consistent signal,” he said Nov. 2 in a telephone interview. “The question seems to be, what is the safe use of a drug that has this signal?”

Cohen, research director at Harvard Vanguard Medical Associates in Boston, wasn't involved in the two studies and isn't a member of the panel. Glaxo rose 22 pence, or 1.8 percent, to 1219 pence as of 3:10 p.m. in London, and had lost 6.4 percent this year before today.

Epzicom Sales

Epzicom's sales were \$648 million in 2007, with \$284 million in the U.S., according to Glaxo. Ziagen generated \$218 million in global sales, \$89 million of which came from the U.S.

In February, a study group called the Data Collection on Adverse Events of Anti-HIV Drugs Study Group, or DAD, published an analysis that found the link between abacavir and heart attacks. The panel that issued today's revisions said in April its guidelines wouldn't be changed on the basis of “preliminary” research.

“The panel will continue to review additional data as they become available and will make further recommendations if needed,” the statement said.

Glaxo added a caution to Ziagen's prescribing information in July, citing results from the first DAD study, which the company called “inconclusive.” Patients taking the drug should be counseled to lower blood pressure and cholesterol, quit smoking, and manage diabetes if they have it, according to the revised label.

'Smart' Research

In August, the DAD group reported on another analysis, this time looking at the results of the Strategies for Management of Antiretroviral Therapy trial. The SMART research, a 2006 study that followed 5,472 HIV patients for an average of 16 months, was seeking signs of heart, kidney or liver disease.

The results were almost identical to the first DAD study, showing a near doubling of heart attack risk in people taking Ziagen or Epzicom.

The extra risk of heart disease disappeared almost as soon as people stopped taking Ziagen and Epzicom, said Jens Lundgren, a University of Copenhagen researcher who led the DAD study group, in August. The drug may contribute to rare events, such as the breakup of clots on blood vessel walls, which can lead to heart attacks, he said.

Glaxo said it hasn't found the same effect in an analysis of 54 earlier company studies of about 14,600 people taking either abacavir or alternatives. Those trials weren't designed to look for effects in the heart, said John Pottage, Glaxo's vice president for global clinical development in an August interview at an HIV conference in Mexico City.

The U.S. Food and Drug Administration isn't considering any label changes or updates based on the two DAD studies, said Christopher Kelly, an agency spokesman, in an e-mail Oct. 31. The agency is looking forward to more data from the DAD group next year, Kelly said.

Abacavir can also cause rare, strong allergic reactions in some patients, and Glaxo cautions that patients should be tested for a gene marker linked to the reactions before taking Ziagen or Epzicom.

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