Topics: Regulatory

Pfizer, BMS win blockbuster FDA approval for Eliquis

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The FDA saved one of its biggest approvals of the year until the end of 2012. Eliquis, the clot buster from Bristol-Myers Squibb ($BMY) and Pfizer ($PFE), garnered the agency's stamp for use in certain patients with atrial f brillation.

Bristol and Pfizer--which have suffered from generic competition to the big-selling meds Plavix and Lipitor, respectively--have now won approval for the most lucrative use of the drug in the world's top healthcare market. The FDA sanctioned the bloodthinner for reducing risk of stroke and blood clots in patients with non-valvular atrial f brillation, saying that the drug shouldn't be used in patients with artificial heart valves or defective heart valves.

Atrial fibrillation (AF), a common irregular heart beat, afflicts more than 5.8 million Americans, according the Bristol-Myers, and the ailment spikes their risk of stroke. Last year Pfizer and Bristol revealed that in a 18,201-patient study comparing Eliquis or apixaban to decades-old warfarin, the new clot buster lowered stroke risk by 21%, major bleeding by 31% and mortality by 11%.

"Blood clots in the heart can cause a disabling stroke if the clots travel to the brain," said Dr. Norman Stockbridge, director of the Division of Cardiovascular and Renal Products in the FDA's Center for Drug Evaluation and Research, in a statement.

Bristol and Pfizer have a potential mega-blockbuster product on their hands, with analysts estimating peak sales of more than $5 billion. The drug faces competition from similar drugs such as Xarelto from Johnson & Johnson ($JNJ) and Bayer and the bloodthinner Pradaxa from Boehringer Ingelheim. Yet some experts, including those cited by Leerink Swann, believe that Eliquis is the top new warfarin replacement.

Regulators in the European Union, Canada and Japan approved Eliquis before the FDA for the big AF market. The U.S. agency held up approval of the drug in June,

requesting more information on data management and verification from the major Phase III study of more than 18,000 patients known as "Aristotle." Yet today's FDA approval comes almost three months before its March 17, 2013, PDUFA date.

- here's the release
- see *the Wall Street Journal*'s article (sub. req.)
- check out *Bloomberg*'s report
- and the item from *Reuters*

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