FDA: Bristol-Myers diabetes drug appears safe

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(AP) -- A potential blockbuster diabetes medication from Bristol-Myers Squibb appears free from heart-related side effects that have plagued similar treatments, federal health officials said Monday.

Despite low rates of heart attacks and related problems in testing, the Food and Drug Administration will still ask an outside panel to scrutinize the company's safety data at a meeting Wednesday.

Bristol-Myers and partner AstraZeneca have asked the FDA to approve Onglyza to reduce blood sugar levels in patients with type 2 diabetes. The drug uses a chemical reaction similar to Merck's Januvia and would compete against the blockbuster medication, which had sales of $1.4 billion last year.

The drug is part of a new wave of medications taking aim at the U.S. diabetes market, which has grown to more than $5 billion as the disease becomes more prevalent.

Analyst estimates of Onglyza's market potential vary, given its similarity to a more established drug. Sales estimates range from $300 million per year to more than $1 billion.

Shares of New York-based Bristol-Myers climbed 29 cents to $20.95 in afternoon trading. U.S.-traded shares of London-based AstraZeneca rose $1.56 cents, or 4.8 percent, to $33.94.

Regulators have begun demanding more rigorous safety testing of diabetes drugs since a 2007 analysis suggested GlaxoSmithKline's blockbuster pill Avandia could increase heart risks.

Under guidelines issued last year, FDA requires companies to test diabetes drugs on more high-risk patients, including the elderly, to detect potential heart problems. Detecting heart risks connected with diabetes drugs is challenging because patients with the disease are already at risk of heart problems.

Because Bristol-Myers and AstraZeneca conducted their studies before the guidelines were released, their testing "was not designed to prospectively measure cardiovascular risk," agency reviewers noted. As a result the FDA said there is "insufficient information" to determine if some heart problems were related to the drug, according to briefing documents posted online.

At the agency's request, the companies went back after the fact and tried to analyze reports of heart problems with the drug. Based on that assessment, the level of heart attacks, deaths and other cardiovascular problems appeared well within the new safety limits imposed by the FDA.

The agency will ask its panel of experts on Wednesday whether the company's results are strong enough to make a follow-up safety study unnecessary.

A decision on whether to approve the drug is expected by the end of April. The FDA is not required to follow its panels' advice, though it usually does.

Bristol-Myers and British firm AstraZeneca are just two of the drugmakers looking to capitalize on the U.S. epidemic of Type 2

diabetes, which affects some 23 million adults and teenagers.

People with the disease have trouble breaking down carbohydrates, because their bodies have become resistant to the protein insulin, which is critical to digesting sugars. Over time, diabetics are at higher risk for heart attacks, kidney problems, blindness and other serious complications.

Onglyza, known generically as saxagliptin, belongs to the DPP-4 inhibitor family of the diabetes medications, which also includes Merck's drug Januvia.

The drugs work by blocking the DPP-4 enzyme, which spurs release of insulin-boosting proteins that help control blood sugar levels.

On Thursday FDA's panel will review another proposed diabetes treatment from Novo Nordisk. The Danish drugmakers's liraglutide boosts insulin while restricting the hormone GLP-1 hormone, which drives up blood sugar.

If approved, the once-daily injection would compete with Eli Lilly and Amylin Pharmaceutical's Byetta, a twice-daily injectable drug in the same family of medications. The makers of Byetta are working on their own extended-release version of the drug that would only require one injection per week.