

Bristol-Myers gets EU approval for diabetes drug

October 5 2009, By LINDA A. JOHNSON , AP Business Writer

(AP) -- Drugmaker Bristol-Myers Squibb Co. said Monday that its new diabetes drug, Onglyza, has been approved for sale in the European Union's 27 countries.

That means Onglyza will compete with [Merck](#) & Co.'s blockbuster [diabetes drug](#) Januvia both in the EU and in the United States, where the Bristol Myers drug was approved on July 31.

Onglyza is the first diabetes drug to be launched in Europe by a partnership of New York-based Bristol-Myers and British drugmaker AstraZeneca PLC to develop drugs for type 2 diabetes. It was approved for use with three other standard diabetes drugs, based on six late-stage studies including more than 4,100 patients.

Onglyza and Januvia both are in a newer class of diabetes medicines called DPP-4 inhibitors. They work by increasing insulin production and lowering the production of glucose.

Whitehouse Station, N.J.-based Merck's Januvia and a related drug called Janumet, which includes metformin, constitute Merck's fastest-growing product line, third in overall sales with a total of \$1.75 billion in revenue last year.

Onglyza is to be launched in the European Union by year's end; it's already on sale in the U.S.

Analysts have forecast that Onglyza sales could hit as high as \$1 billion a year, given the alarming increase in the number of people in developed countries with diabetes. The U.S. market for diabetes medicines alone already exceeds \$5 billion annually.

Meanwhile, Bristol and AstraZeneca are in late-stage testing of another potential diabetes drug, dapagliflozin, that works by helping the kidneys eliminate excess glucose.

Onglyza was approved to be used with metformin or another drug from one of two different classes that are often prescribed, along with diet and exercise, when patients are first diagnosed with type 2 diabetes. People with the disorder, most often caused by obesity and inadequate exercise, do not use the insulin made by their body efficiently and may eventually need injected insulin as well as pills to control the disease.

Also Monday, Bristol and AstraZeneca released results of a new study showing that Onglyza with metformin works roughly the same as Januvia with metformin, reducing a key measure of long-term blood sugar level by 0.52 percent, compared with a 0.62 percent reduction for the patients in the Januvia group.

In New York trading, Bristol-Myers shares were down 4 cents at \$22.22 while AstraZeneca shares were up 64 cents, or 1.5 percent, at \$44.28.

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