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Amylin's long-delayed diabetes drug gets FDA nod

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Amylin Pharmaceuticals won approval Friday for its long-delayed diabetes drug Bydureon, a next-generation treatment that requires fewer injections than the company's 7-year old diabetes medicine, Byetta.

Bydureon is a once-a-week version of Byetta, which is taken twice a day to control blood sugar. Amylin executives say the new drug's convenient regimen will give it a competitive advantage in the marketplace. However, after multiple delays it enters a crowded market, including one diabetes treatement in the same class that has shown superior results.

The Food and Drug Administration approval comes after two rejections in 2010, when the agency asked Amylin to conduct a new study of the drug's effects on the heart's rhythm. News of the costly delay sent company shares tumbling more than 50 percent and contributed to the eventual breakup of Amylin's long-standing partnership with Eli Lilly and Co. The companies ended their collaboration in November, with Amylin paying $250 million and agreeing to take over full responsibility for both Byetta and Bydureon.

Analysts generally expect Bydureon to generate $940 million in sales annually by 2016, though Deutsche Bank analyst Robyn Karnauskas says the drug must post $1.2 billion annually to turn a profit.

Karnauskas points out in a note to investors that Amylin currently has $2 billion in long-term debt and only $210 million in cash. She says Bydureon's approval should give the San Diego company greater

flexibility to refinance its debt.

Bydureon is part of the broader GLP-1 class of drugs, which work by increasing the body's insulin production.

People with type 2 diabetes are unable to properly break down carbohydrates, either because their bodies do not produce enough insulin or because they've become resistant to the hormone, which controls blood sugar levels. These patients are at higher risk for heart attacks, kidney problems, blindness and other serious complications. Diabetics often require multiple drugs with different mechanisms of action to control their blood sugar levels.

Diabetes affects more than 25 million people in the U.S., or roughly 8 percent of the population.

Amylin executives say the convenience of the Bydureon's weekly regimen should give it a competitive advantage, but Amylin reported disappointing results last year for it against Novo Nordisk's Victoza, a daily injection approved in January 2010. On average, Bydureon reduced blood sugar levels in diabetics less than Victoza, which uses a different mechanism of action.

A monthly series of Bydureon injections is expected to cost $323, compared with $291 for the older Byetta.

Bydureon was co-developed with Indianapolis-based Eli Lilly, which also helped co-market Byetta. Both drugs are scheduled to transfer to Amylin by the end of 2013. Alkermes, based in Waltham, Mass., created Bydureon's formulation technology, which gradually releases the drug over the course of a week.

Shares of Amylin Pharmaceuticals Inc. leaped $1.85, or 15.2 percent, to

$13.99 after hours; the approval was announced just before the markets closed, and the shares ended regular trading up 20 cents at $12.14.

After hours, shares of Alkermes PLC rose 90 cents, or 4.7 percent, to $20. They had ended regular trading down 18 cents.