

Experimental diabetes drugs offer patients hope

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Some experimental diabetes treatments in late testing offer patients hope of better controlling their blood sugar and weight and preventing dangerously low blood sugar, all big challenges for millions of diabetics.

Results from studies of several new diabetes medicines and insulin products, just announced at the premiere U.S. conference for diabetes specialists, likewise hold the promise of billions in annual revenue for drugmakers that have dominated the diabetes market and for others breaking into it. They have been presenting their data at the <u>American Diabetes Association</u> conference, held in Philadelphia from last Friday through Monday.

Until the last decade, relatively few companies made treatments for diabetes, a <u>chronic condition</u> in which the body either does not make enough insulin to break down the sugar in foods or uses insulin inefficiently.

Now many more drugmakers have jumped in, as the number of American <u>diabetes patients</u> is about 26 million and growing fast, and there are tens of millions more in <u>Western Europe</u>, China and India.

That's because the global <u>obesity epidemic</u> has caused a similar explosion of diabetes cases. About 95 percent are Type 2 diabetes, usually related to being overweight and sedentary. Type 2, once called adult-onset diabetes, now is also being diagnosed in adolescents, just like insulin-dependent <u>Type 1 diabetes</u>, which used to be called juvenile



diabetes.

Both types can cause early death or devastating complications blindness, amputations, stroke, kidney disease, heart disease and more — when too-high blood sugar steadily damages organs and blood vessels.

Roughly \$200 billion a year is spent on treating diabetes and indirect costs such as missed work and premature death, according to the diabetes association.

Last year, U.S. spending on diabetes medicines among insured patients for the first time exceeded spending on cholesterol drugs, according to Express Scripts, a top prescription benefit manager.

"We expect the key diabetes brands and markets to exhibit sustainable high-single-digit growth," reaching about \$54 billion a year by 2020, Jefferies & Company analyst Jeffrey Holford recently wrote to investors. He cited an aging Western population, more health care use and adoption of Western diets in emerging countries, and increased use of new treatments and combination therapies.

Holford expects Denmark's Novo Nordisk AS to remain the top diabetes company by revenue but Eli Lilly and Co. of Indianapolis to overtake France's Sanofi SA as the No. 2 player by 2017.

Among other research, the conference highlighted promising new treatments likely to be approved in the next few years:

—Novo Nordisk on Friday reported on results of degludec, its ultra-longacting insulin for patients with Type 2 diabetes. Its yearlong, 1,030-patient study compared degludec with Sanofi's Lantus, the world's top-selling insulin. Degludec reduced <u>low blood sugar</u> during the night, when it's most dangerous, by 36 percent and also reduced severe



hypoglycemia significantly, compared to Lantus. Those problems occurred less than once in a year in both groups of patients, though.

Novo also reported on other studies finding that because degludec is active in the body for more than the standard 24 hours for long-acting insulins, patients can maintain good blood sugar control even if they don't take it at the same time every day. The Food and Drug Administration was to decide whether to approve U.S. sales by June 29, but just pushed that back until Oct. 29 to allow more time to review data.

—Johnson & Johnson's Janssen Research unit presented five late-stage studies on its daily <u>Type 2 diabetes</u> pill, canagliflozin, part of a newer class of diabetes drugs called SGLT2 inhibitors. They work primarily by increasing how much glucose is excreted in urine. One yearlong study found it reduced long-term blood sugar levels, called A1C levels, and also helped patients lose much more weight than Merck & Co.'s blockbuster pill Januvia. Januvia is in a class called DPP-4 inhibitors, which increase the body's release of insulin after a meal.

Another study similarly showed canagliflozin decreased A1C levels and body weight significantly more than Sanofi's <u>diabetes</u> pill Amaryl. J&J applied for U.S. approval of its drug on May 29.

—On Sunday afternoon, Eli Lilly and partner Boehringer Ingelheim of Germany released results from two mid-stage studies of their new shortacting insulin, known as LY2605541. In separate studies comparing it to Lantus, it was slightly better at reducing blood sugar levels in Type 1 diabetics and about the same in Type 2 diabetics. In the eight-week Type 1 study, patients getting LY2605541 lost about 2.5 pounds (1.13 kilograms) on average while those on Lantus gained 1.5 pounds (0.68 kilograms). Weight changes were similar, but smaller, in the Type 2 study.



LY2605541 still must go through late-stage testing before approval can be sought.

—Other companies were presenting data on an experimental patch to deliver insulin pain-free and two devices in early development that would work like an artificial pancreas, monitoring <u>blood sugar</u> continuously to help control when an insulin pump releases the hormone into the patient's blood.

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