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FDA approves 3 new drugs for type 2 diabetes

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Nesina, Kazano and Oseni each contain a new active ingredient aimed at boosting insulin production.

(HealthDay)—The U.S. Food and Drug Administration late Friday approved three new medications to help people battle type 2 diabetes.

All three drugs contain a new active ingredient, alogliptin, either alone or in combination with other, previously approved medications. The newly approved drugs include Nesina (alogliptin), Kazano (alogliptin plus metformin) and Oseni (alogliptin plus pioglitazone), the FDA said in a news release.

"Controlling blood sugar levels is very important in the overall treatment and care of diabetes," Dr. Mary Parks, director of the Division of Metabolism and Endocrinology Products in the FDA's Center for Drug

Evaluation and Research, said in the statement. "Alogliptin helps stimulate the release of insulin after a meal, which leads to better blood sugar control."

More than 24 million people in the United States are currently affected by type 2 diabetes, which is closely linked with obesity. In the type 2 form of the disease, people gradually develop resistance to insulin or fail to produce enough of the hormone, resulting in rising blood sugar levels. That can lead to other health problems, such as heart disease, vision problems and neural or kidney dysfunction.

The FDA urges that the new medications be used in combination with a healthy diet and exercise to help bring diabetes under control. All of the drugs underwent study either as stand-alone products or used alongside standard diabetes medications such as sulfonyureas or insulin.

In the case of Nesina, the drug showed safety and effectiveness across 14 clinical trials, involving more than 8,500 patients, according to the FDA. The most common side effects included stuffy or runny nose, headache, and upper respiratory tract infections.

Kazano's safety and effectiveness were tested in four clinical trials involving more than 2,500 patients. Side effects included those seen with Nesina, as well as diarrhea, high blood pressure and back pain, the FDA said. The agency is also requesting that a "boxed warning" be included on Kazano's labeling, highlighting the potential risk of lactic acidosis (lactic acid buildup in the blood), which can occur in products containing metformin.

Oseni was studied in four clinical trials involving more than 1,500 patients, the FDA noted. Side effects were similar to those seen with Nesina, as well as back pain. Oseni's labeling will also carry a boxed warning, this time cautioning users about the risk for heart failure that

accompanies drugs containing pioglitazone.

The drugs will also be subject to what are known as "post-marketing studies," aimed at spotting any emerging risks. For example, studies looking at heart and liver issues are mandated for Nesina, while studies focused on potential liver and pancreas problems are mandated for both Kazano and Oseni, the FDA said.

All three drugs are distributed by Takeda Pharmaceuticals America Inc., of Deerfield, Ill.

More information: Find out more about type 2 diabetes at the American Diabetes Association.