Two Drug Companies Halt Development Of Glitazars

Two major pharmaceutical companies have dropped their development of products in a potential new class of type 2 drugs called PPAR-inhibitors, or “glitazars.” The drugs were designed to lower blood glucose and regulate HDL (“good”) cholesterol and triglycerides.

First, AstraZeneca dropped development of tesaglitazar (brand name Galida) in early May. Later that month, Bristol-Myers Squibb ended efforts to obtain regulatory approval to market mura-glitzar (brand name Pargluva).

AstraZeneca scrapped Galida after analyzing results from its first four Phase III trials. Participants in these trials experienced a decrease in their glomerular filtration rate, the rate at which tiny capillaries in the kidneys called glomeruli filter blood.

This resulted in higher levels of creatinine in the participants’ blood, which is an indication of decreased kidney function. (Their creatinine levels went back to normal after stopping the drug.) In a statement, the company said: “The overall benefit/risk profile is unlikely to offer patients significant advantage over currently available therapy.” In other words, considering the possible risks involved, this drug wouldn’t be any better than anything that’s already available.

When Bristol-Myers Squibb pulled the plug on Pargluva, the U.S. Food and Drug Administration (FDA) had already looked at the drug. The company had submitted Pargluva for approval in 2005 and, at the time, an advisory committee to the FDA had recommended approval but requested more information about the drug’s cardiovascular risks.

Then a study appearing in the Journal of the American Medical Association revealed cardiovascular risks associated with the drug, and the FDA delayed final approval.

Bristol-Myers Squibb put development of Pargluva on hold, pending further evaluation of the drug’s safety by the company. After reviewing data from existing studies, the company issued a statement saying that a long-term clinical trial would be necessary to obtain approval for the drug.

Then, based on the company’s knowledge of other diabetes drugs that are currently in development, it decided to drop Pargluva.

As Forecast went to press, a third company, GlaxoSmithKline, was still moving forward with development of its yet-unamed glitazar.

—Terri D’Arrigo

Accu-Chek Ultraflex Infusion Sets Recalled

In April, the maker of Accu-Chek Ultraflex infusion sets recalled the devices because they may not deliver insulin properly and could result in patients suffering from high blood glucose levels. Disetronic Medical Systems Inc. issued the recall after complaints from users, although a company spokesperson said, “The incidence [of problems] has been rare.”

“Tubing could fully or partially separate at the luer lock-tubing connection,” according to a statement from Disetronic. If this occurs, insulin may leak from the tubing and interrupt insulin delivery, which can lead to high blood glucose.

People using any standard leur-lock insulin pump may be using Accu-Chek Ultraflex infusion sets. Disetronic is advising users to check the luer lock-tubing connection on these sets for separation at least every 3 hours and before bedtime. If you notice problems, have questions, or need a replacement, call Disetronic Medical Systems at 1-800-688-4578.

—Kate Ruder