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Studies show sitagliptin does not improve glycemic control in pediatric patients

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The Food and Drug Administration (FDA) approved labeling changes for three type 2 diabetes medications that contain sitagliptin to state that these products are not proven to improve glycemic control in patients ages 10 to 17 years.

The medications — Januvia (sitagliptin), Janumet (sitagliptin and metformin hydrochloride) and Janumet XR (sitagliptin and metformin hydrochloride extended-release) — are approved as adjuncts to diet and exercise to improve glycemic control in adults ages 18 years and older with type 2 diabetes.

The labeling changes describe the results of three double-blind, placebo-controlled studies that evaluated sitagliptin's safety and effectiveness (with and without insulin) over 54 weeks. All three studies enrolled patients ages 10 to 17 years (n=410) with inadequately controlled type 2 diabetes; two studies included patients on metformin therapy.

Results demonstrated that the pediatric patients receiving sitagliptin did not have a significant change from baseline in hemoglobin A1c at week 20 compared to those receiving placebo. In one study, 95 patients treated with sitagliptin had, on average, a 0.06% increase in hemoglobin A1c compared with an average 0.23% increase in 95 patients receiving placebo.

In two studies, 107 patients treated with sitagliptin had an average 0.23% decrease in hemoglobin A1c compared with an average 0.09% increase in hemoglobin A1c among 113 patients treated with placebo. In the first 20 weeks, 5% of patients treated with sitagliptin received rescue glycemic therapy (i.e., metformin, insulin or both) compared to 15% of patients treated with placebo. Between weeks 20 to 54, the two groups had a similar requirement for glycemic rescue therapy. Similar to adults, pediatric patients receiving sitagliptin with insulin had an increased risk of hypoglycemia (blood sugar levels below 54 mg/dL) compared to those receiving a placebo.

These studies were conducted to fulfill a post-marketing requirement under the Pediatric Research Equity Act (PREA). The law gives the FDA authority to require pharmaceutical companies to evaluate the safety and efficacy of certain drug or biological products in pediatric patients when the product may be useful for pediatric patients. Data submitted in response to a PREA study requirement must be described in labeling regardless of whether the findings are positive, negative or inconclusive.

Findings from the sitagliptin studies underscore the importance of conducting clinical trials in pediatric patients and including the study findings — even when negative — in the product labeling.

Having information from pediatric studies available in the product labeling allows pediatric providers to make evidence-based decisions, thereby helping to ensure children are the beneficiaries of informed treatment decisions.

The FDA's Office of the Commissioner, Office of Clinical Policy and Programs, Office of Pediatric Therapeutics and Center for Drug Evaluation and Research, Division of Pediatric and Maternal Health and Division of Diabetes, Lipid Disorders and Obesity contributed to this article.

Resources

- Januvia (sitagliptin) labeling
- Janumet (sitagliptin and metformin hydrochloride) labeling
- Janumet XR (sitagliptin and metformin hydrochloride extended-release) labeling
- Guidance for Industry: How to Comply with the Pediatric Research Equity Act