

Industry Spotlight

FDA Spotlight on Dangerous Drugs

The US Food and Drug Administration has issued a safety announcement about potential side effects of a class of diabetes drugs. The SGLT2 inhibitors, which aid excretion of blood sugar through urine, may cause dangerous levels of blood acidity. The drugs noted were: Farxiga (dapagliflozin) and Xigduo XR (dapagliflozin and metformin extended-release; both from AstraZeneca); Invokana (canagliflozin) and Invokamet (canagliflozin and metformin; both from Johnson & Johnson) and Jardiance (empagliflozin) and Glyxambi (empagliflozin and linagliptin; both from Lilly and Boehringer)

Between March 2013 and June 2014, 20 incidents of hospitalizations and emergency room visits for diabetic ketoacidosis, ketoacidosis, or ketosis were reported. Since then, the agency said it continued to receive additional adverse

event reports of diabetic ketoacidosis and ketoacidosis in patients treated with SGLT2 inhibitors.

Among several recommendations, the FDA advised health care workers to:

- Encourage patients to read the Medication Guide or Patient Package Insert they receive with their SGLT2 inhibitor prescriptions.
- Inform patients and caregivers of the signs and symptoms of metabolic acidosis, such as tachypnea or hyperventilation, anorexia, abdominal pain, nausea, vomiting, lethargy, or mental status changes, and tell them to seek medical attention immediately if they experience the signs or symptoms.
- Evaluate for the presence of acidosis, including ketoacidosis, in patients who have signs or symptoms of

acidosis; discontinue SGLT2 inhibitors if acidosis is confirmed; and take appropriate measures to correct the acidosis and to monitor glucose levels.

- Make sure supportive medical care is started to treat and correct factors that may have precipitated or contributed to the metabolic acidosis.

After the safety announcement surfaced, analysts started forecasting which companies might benefit from the news. Reuters reported the announcement “could benefit other oral diabetes drug classes such as the DPP4 inhibitors,” according to Bernstein analyst Tim Anderson. “The biggest of the DPP4s, by a wide margin, is Merck’s Januvia.”

Januvia, Merck’s best-selling drug, reached sales of approximately \$6 billion in 2014. ●

New Personal Dialyzer on Horizon

Outset Medical (San Jose, CA) has eclipsed an initial funding level of \$9.5 million thanks to Warburg Pincus, a private equity investment firm. Warburg Pincus reported recently that it had invested \$60 million in the company.

Outset has plans for a user-friendly at-home dialysis machine that uses a home’s water supply and purifies it for dialy-

sis-level usage. The device also generates dialysate on demand. Warburg was a leading venture investor of the company in 2010. The investment firm noted online that the new device’s simplicity lets patients “manage treatments independently whether in clinic or at home.”

The machine, called Tablo, makes dialysate continuously

using regular tap water. “Tablo . . . makes clean water, produces dialysate, takes blood pressure and delivers medication all in a compact table-height package according to the company’s website.

Outset is also appealing to consumers through an online marketing campaign. ●



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