Zegalogue® (dasiglucagon) – New drug approval

- On March 23, 2021, Zealand Pharma announced the FDA approval of Zegalogue (dasiglucagon), for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above.

- The efficacy of Zegalogue was demonstrated in three double-blind, randomized trials in patients with type 1 diabetes. A total of 215 adult patients were enrolled in 2 trials and received Zegalogue, placebo or glucagon. In the pediatric trial, 42 children ages 6 – 17 years received Zegalogue, placebo or glucagon. The primary efficacy endpoint for all 3 trials was time to plasma glucose recovery (treatment success), defined as an increase in blood glucose of ≥ 20 mg/dL from time of administration, without additional intervention within 45 minutes. The primary hypothesis test was superiority of Zegalogue vs. placebo. There was no formal hypothesis test of Zegalogue vs. glucagon for injection.

    - In the first adult trial, the median time to plasma glucose recovery was 10 minutes for the Zegalogue group vs. 40 minutes for the placebo group ($p < 0.001$).
    - In the second adult trial, the median time to plasma glucose recovery was 10 minutes for the Zegalogue group vs. 35 minutes for the placebo group ($p < 0.001$).
    - In the pediatric trial, the median time to plasma glucose recovery was 10 minutes for the Zegalogue group vs. 30 minutes for the placebo group ($p < 0.001$).

- Zegalogue is contraindicated in patients with pheochromocytoma because of the risk of substantial increase in blood pressure and insulinoma because of the risk of hypoglycemia.

- Warnings and precautions for Zegalogue include hypersensitivity and allergic reactions; and lack of efficacy in patients with decreased hepatic glycogen.

- The most common adverse reactions (≥ 2%) with Zegalogue use in adults were nausea, vomiting, headache, diarrhea, and injection site pain and in pediatrics were nausea, vomiting, headache, and injection site pain.

- The recommended dose of Zegalogue in adults and pediatric patients aged 6 years and older is 0.6 mg administered by subcutaneous injection into the lower abdomen, buttocks, thigh, or outer upper arm.

    - If there has been no response after 15 minutes, an additional 0.6 mg dose of Zegalogue from a new device may be administered.

- Zealand Pharma's launch plans for Zegalogue are pending. Zegalogue will be available as a 0.6 mg/0.6 mL single-dose autoinjector and a 0.6 mg/0.6 mL single-dose prefilled syringe