## Baqsimi™ (glucagon) – New drug approval

- On July 24, 2019, the FDA announced the approval of Eli Lilly's Baqsimi (glucagon) nasal powder, for the treatment of severe hypoglycemia in patients with diabetes ages 4 years and above.

- Severe hypoglycemia occurs when a patient's blood sugar levels fall to a level where he or she becomes confused or unconscious or suffers from other symptoms that require assistance from another person to treat. Typically, severe hypoglycemia occurs in people with diabetes who are using insulin treatment.

    — Injectable glucagon for the treatment of hypoglycemia has been approved for use in the U.S. for several decades.

- Baqsimi is the first nasally administered formulation of glucagon. It is ready to use with no reconstitution required.

- The efficacy of Baqsimi was evaluated in an open-label, crossover study in 70 adult patients with type 1 diabetes. The efficacy of a single 3 mg dose of Baqsimi was compared to a 1 mg dose of intramuscular glucagon (IMG). The primary efficacy measure was the proportion of patients achieving treatment success, which was defined as either an increase in blood glucose to ≥ 70 mg/dL or an increase of ≥ 20 mg/dL from glucose nadir within 30 minutes after receiving glucagon, without receiving additional actions to increase the blood glucose level.

    — Baqsimi demonstrated non-inferiority to IMG in reversing insulin-induced hypoglycemia with 100% of Baqsimi-treated patients and 100% of IMG-treated patients achieving treatment success.

- The efficacy of Baqsimi was also evaluated in a similarly designed study in 83 adult patients with type 1 or type 2 diabetes.

    — Baqsimi demonstrated non-inferiority to IMG in reversing insulin-induced hypoglycemia with 98.8% of Baqsimi-treated patients and 100% of IMG-treated patients achieving treatment success within 30 minutes.

- In addition, the efficacy of Baqsimi was evaluated in 48 pediatric patients aged 4 years and older with type 1 diabetes. Patients received a single dose of Baqsimi 3 mg or 0.5 mg or 1 mg of IMG (based upon body weight). Efficacy was assessed based on percentage of patients with a glucose increase of ≥ 20 mg/dL from glucose nadir within 30 minutes following Baqsimi administration.

    — All patients in both treatment arms achieved an increase in glucose ≥ 20 mg/dL from glucose nadir within 20 minutes of glucagon administration.

- Baqsimi is contraindicated in patients with pheochromocytoma, insulinoma, or known hypersensitivity to glucagon or to any of the excipients in Baqsimi.

- Warnings and precautions for Baqsimi include catecholamine release in patients with pheochromocytoma, lack of efficacy in patients with insulinoma, hypersensitivity and allergic reactions, and lack of efficacy in patients with decreased hepatic glycogen.

- The most common adverse reactions (≥ 10%) with Baqsimi use were nausea, vomiting, headache, upper respiratory tract irritation (ie, rhinorrhea, nasal discomfort, nasal congestion, cough, and epistaxis), watery eyes, redness of eyes, and itchy nose, throat and eyes.

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- The recommended dose of Baqsimi is 3 mg administered as one actuation of the intranasal device into one nostril.
    - If there has been no response after 15 minutes, an additional 3 mg dose of Baqsimi from a new device may be administered while waiting for emergency assistance.
    - Refer to the Baqsimi drug label for additional administration instructions.
- Eli Lilly plans to launch Baqsimi within one month. Baqsimi will be available as an intranasal device containing one 3 mg dose of glucagon as a powder.