Gvoke™ (glucagon) – New drug approval

- On September 10, 2019, Xeris Pharmaceuticals announced the FDA approval of Gvoke (glucagon), for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above.

- Gvoke is the first ready-to-use glucagon product approved that can be administered via a prefilled syringe (Gvoke PFS) or auto-injector (Gvoke HypoPen™).

- Gvoke was evaluated in two crossover studies in adult patients aged 18 to 74 years with type 1 diabetes mellitus (T1DM). Study 1 was double-blinded with 80 patients, and Study 2 was single-blinded with 81 patients. Patients in both studies were randomly assigned to receive Gvoke 1 mg during one session and conventional glucose emergency kits (GEK) during the other. Treatment 'success' was defined as plasma glucose increase from mean value at time of glucagon administration to absolute value greater than 70 mg/dL or relative increase of 20 mg/dL or greater, at 30 minutes after glucagon administration.

    — In a pooled analysis of both studies, the proportion of patients who achieved treatment 'success' was 98.7 % in the Gvoke group and 100% in the GEK group and the comparison between groups met the prespecified non-inferiority margin.

- Gvoke was also evaluated in a study in 31 pediatric patients with T1DM. All evaluable pediatric patients (30/30) achieved a target glucose increase of at least 25 mg/dL.

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

- Warnings and precautions for Gvoke include catecholamine release in patients with pheochromocytoma, hypoglycemia in patients with insulinoma, hypersensitivity and allergic reactions, lack of efficacy in patients with decreased hepatic glycogen, necrolytic migratory erythema, and hypoglycemia in patients with glucagonoma.

- The most common adverse reactions (≥ 2%) with Gvoke use were:

    — Adults: nausea, vomiting, injection site edema raised 1 mm or greater, and headache
    — Pediatric patients: nausea, hypoglycemia, vomiting, headache, abdominal pain, hyperglycemia, injection site discomfort and reaction, and urticaria.

- In adult and pediatric patients aged 12 years and older, the recommended dose of Gvoke is 1 mg administered by subcutaneous injection into the lower abdomen, outer thigh, or outer upper arm.

    — If there has been no response after 15 minutes, an additional 1 mg dose of Gvoke from a new device may be administered while waiting for emergency assistance.

- In pediatric patients aged 2 to under 12 years of age who weigh less than 45 kg, the recommended dose of Gvoke is 0.5 mg. In pediatric patients aged 2 to under 12 years of age who weigh 45 kg or greater, the recommended dose of Gvoke is 1 mg.

    — If there has been no response after 15 minutes, an additional weight appropriate dose of Gvoke from a new device may be administered while waiting for emergency assistance.

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- Xeris Pharmaceuticals plans to launch the Gvoke PFS in the next 4 to 6 weeks and Gvoke HypoPen in 2020. Gvoke will be available as 0.5 mg/0.1 mL and 1 mg/0.2 mL single-dose pre-filled syringes and single-dose pre-filled HypoPen auto-injectors.