READY-TO-USE DASIGLUCAGON INJECTION AS A FAST AND EFFECTIVE TREATMENT FOR SEVERE HYPOGLYCEMIA

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Introduction

• At the present time, glucagon is a first-line treatment option for severe hypoglycemia in patients with insulin-treated diabetes1,2. Overall, patients with type 1 diabetes mellitus (T1DM) do not receive adequate prescription for, or education and proper training regarding the use of glucagon kits to treat or prevent severe hypoglycemia3,4.

• Presently available glucagon kits have required user training and multiple preparation steps that are barriers to their prescription and utilization, especially under emergent circumstances5,6.

Dasiglucagon

• Is a peptide analogue of glucagon, with 7 amino acid substitutions designed to eliminate peptide degradation and fibril formation7.

• Is physically and chemically stable in aqueous solution, making it a good candidate for use in single-injection pen applicators8.

• Is a specific agonist at the glucagon receptor9.

• Dasiglucagon is presented in a ready-to-use formulation10.

• Allows for easy-to-use, simple, auto-injector or pre-filled safety syringe administration.

• Allows for refrigerated and room temperature storage.

Dasiglucagon Phase 3 Clinical Trial Design

Study of dasiglucagon versus placebo for treatment of insulin-induced hypoglycemia in T1DM using GlucaGen® as reference

Primary and Secondary Endpoints

Primary endpoint - Time to plasma glucose recovery defined as first increase in plasma glucose ≥ 20 mg/dL (1.1 mmol/L) from time of SC injection11.

Secondary endpoints** - Plasma glucose recovery within 15, 20, and 30 min from time of injection12; Plasma glucose change from baseline at 10, 15, 20, and 30 min from time of injection13.

*Without administration of rescue intravenous glucose.

**Multiplicity adjusted.

Baseline Characteristics Were Balanced Between Treatment Groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Dasiglucagon (n = 82)</th>
<th>Placebo (n = 43)</th>
<th>GlucaGen® (n = 43)</th>
<th>Total (n = 168)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Median (range)</td>
<td>37 (18-71)</td>
<td>36 (18-65)</td>
<td>38 (23-66)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>Median (range)</td>
<td>25 (19-38)</td>
<td>26 (20-34)</td>
<td>26 (19-35)</td>
</tr>
<tr>
<td>Gender</td>
<td>Female</td>
<td>32 (39%)</td>
<td>16 (27%)</td>
<td>15 (35%)</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>Median (range)</td>
<td>7.4 (6.2-9.7)</td>
<td>7.1 (6.0-9.2)</td>
<td>7.4 (5.4-8.9)</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>Median (range)</td>
<td>22 (5-64)</td>
<td>18 (4-42)</td>
<td>18 (3-57)</td>
</tr>
</tbody>
</table>

BMI: Body Mass Index.

Primary and All Secondary Endpoints Were Met

Primary endpoint - Median time to plasma glucose recovery of 10 min with dasiglucagon (placebo 40 min, GlucaGen® 22 min)** - 65% of dasiglucagon patients recovered within 10 min (placebo 0%, GlucaGen® 49%) - 99% of dasiglucagon patients recovered within 15 min (placebo 2%, GlucaGen® 99%)

• Similar rates of nausea and vomiting were reported for both dasiglucagon and GlucaGen®.

• Dasiglucagon has the potential to be a fast and effective treatment for severe hypoglycemia.

References


Disclosures and Acknowledgements

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* The developer of dasiglucagon, and the sponsor of this clinical trial

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