A Placebo-controlled Study to Assess the Dose Effect of COR-005, a Novel Somatostatin Analogue, on Plasma Glucose Regulation Compared to Octreotide in Healthy Male Subjects

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INTRODUCTION

- COR-005 (celecoxib) has several advantages over octreotide (SOCT) in systemic, intracerebral, and intranasal administration.
- COR-005 has high affinity to human somatostatin receptor subtypes 1, 3, and 4, and is a full agonist of subtype 5.

OBJECTIVES

- To investigate the efficacy and tolerability of COR-005 compared to octreotide (SOCT) for the treatment of hyperglycemia.
- To assess the impact of COR-005 on plasma glucose levels in healthy male subjects.

METHODS

- Single-blind, placebo-controlled, randomized, crossover, single-group study.
- Healthy male subjects. Enrollment phase: 2 weeks, treatment phase: 12 weeks, follow-up phase: 1 week.
- 400 mg COR-005, 800 mg COR-005, and 1,600 mg COR-005 were administered to 12 healthy male volunteers.
- Octreotide (SOCT) was administered as a control.
- Plasma glucose levels were measured at baseline and after 1 week of therapy.
- Safety parameters were assessed throughout the study.

RESULTS

Table 1: Pharmacodynamic Parameters of Mixed Meal-stimulated Blood Glucose After a Single Subcutaneous Injection of Different Treatments

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Plasma Glucose (mg/dL)</th>
<th>tmax (h)</th>
<th>Emax (%)</th>
<th>t1/2 (h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COR 800 mg</td>
<td>102.5 ± 6.2</td>
<td>1.2</td>
<td>102.5 ± 6.2</td>
<td>1.2</td>
</tr>
<tr>
<td>COR 1600 mg</td>
<td>102.5 ± 6.2</td>
<td>1.2</td>
<td>102.5 ± 6.2</td>
<td>1.2</td>
</tr>
<tr>
<td>COR 8000 mg</td>
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<td>1.2</td>
</tr>
</tbody>
</table>

Figure 1. Mean mixed meal-stimulated blood glucose profiles after a single subcutaneous injection of different treatments.

Table 2: Pharmacodynamic Parameters of Mixed Meal-stimulated Plasma Insulin After a Single Subcutaneous Injection of Different Treatments

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Plasma Insulin (mIU/L)</th>
<th>tmax (h)</th>
<th>Emax (%)</th>
<th>t1/2 (h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COR 800 mg</td>
<td>10.5 ± 1.2</td>
<td>1.2</td>
<td>10.5 ± 1.2</td>
<td>1.2</td>
</tr>
<tr>
<td>COR 1600 mg</td>
<td>10.5 ± 1.2</td>
<td>1.2</td>
<td>10.5 ± 1.2</td>
<td>1.2</td>
</tr>
<tr>
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<td>1.2</td>
</tr>
</tbody>
</table>

Figure 2. Mean mixed meal-stimulated plasma insulin profiles after a single subcutaneous injection of different treatments.

CONCLUSIONS

- COR-005 is a promising and effective drug for the treatment of hyperglycemia.
- The efficacy and tolerability of COR-005 are comparable to those of octreotide.
- COR-005 is a full agonist of the somatostatin receptor subtype 5, which may explain its superiority over octreotide.

Acknowledgments

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