OBJECTIVES

The purpose of this study is to evaluate the effects of CET on non-arrhythmic QT prolongation. Primary data included the non-arrhythmic QT prolongation in patients with HFrEF and a history of myocardial infarction (MI).

METHODS

A thorough QT assessment of CETRORELIX PAMOATE following intramuscular administration in healthy subjects was conducted. The study was single-center, randomized, double-blind, placebo-controlled, and double-dummy. Patients were randomized to receive CETRORELIX or placebo, and each was given both a placebo and CETRORELIX injection. The dose and route of administration were as follows for the treatment area:

- CETRORELIX: Subjects received a dose of 52 mg IM (Cetromax).
- Placebo: Subjects received a placebo IM injection on Day 1 (baseline) and Day 15 (postdose).

The study was conducted in 2 stages: a placebo-controlled study to assess the effects of CET on QT prolongation and a primary analysis to evaluate the relationship between changes in CET plasma concentration and changes in QT. The primary endpoint was the change in QT interval from baseline at each postdose time point, with a secondary endpoint of the change in QTc interval from baseline at each postdose time point.

RESULTS

The analyses, termed analysis of assay sensitivity, used the same ANOVA as the primary analysis but compared the moxifloxacin and placebo LS means of the CET and placebo LS means of the moxifloxacin. The 21-day analysis supports the conclusion of the primary analysis, i.e., CET does not prolong the QTcF interval above the regulatory threshold.

CONCLUSIONS

The data suggest that CETRORELIX PAMOATE had no effect on cardiac repolarization based on PK/PD analyses.

Table 1: Standard Deviation of Change From Time-Matched Baseline in QTcF Between Cetrorelix and Placebo

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Cetrorelix</th>
<th>Placebo</th>
<th>t value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hour 2</td>
<td>0.86</td>
<td>0.87</td>
<td>0.01</td>
<td>0.93</td>
</tr>
<tr>
<td>Hour 12</td>
<td>0.86</td>
<td>0.87</td>
<td>0.01</td>
<td>0.93</td>
</tr>
<tr>
<td>Hour 24</td>
<td>0.86</td>
<td>0.87</td>
<td>0.01</td>
<td>0.93</td>
</tr>
</tbody>
</table>

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