Results

CEM-102 Plasma Concentrations after Single and Multiple Doses

Table 1. Mean PK Parameters for CEM-102 at Plasma Concentrations after Single and Multiple Doses

<table>
<thead>
<tr>
<th>Dose (mg)</th>
<th>Cmax, µg/mL</th>
<th>AUC(0-24), µg·h/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>550</td>
<td>130</td>
<td>102</td>
</tr>
<tr>
<td>1100</td>
<td>324</td>
<td>26.8</td>
</tr>
<tr>
<td>1650</td>
<td>324</td>
<td>26.8</td>
</tr>
<tr>
<td>2200</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

CEM-102 was well tolerated at all dose levels. Plasma exposure was higher after MD compared to SD, indicating tolerability of single doses (SD) and multiple doses (MD) of CEM-102 was assessed.

Safety and Tolerability

• AEs were all grade 1-2 in severity
• No AEs seen at 1650 mg
• GI AEs in 4 subjects at 2200 mg

Pharmacokinetics

Descriptive statistics of CEM-102 plasma PK parameters are summarized in the following tables & figures.

Conclusions

• Cmax and AUC showed more than dose proportional increases from 550 µg/mL to 1100 µg/mL to 1650 µg/mL.
• Accumulation occurred from Day 1 to last day of dosing at all dose levels.
• No power calculations were performed.
• AEs were all mild in severity and were generally well tolerated.
• No clinically meaningful changes in laboratory tests were observed.
• No clinically meaningful changes in ECGs or laboratory tests were observed.
• No clinically meaningful changes in vital signs were observed.
• CEM-102 was well tolerated at MDs up to 1650 mg and in both LD regimens.
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