A Phase-I Study of Eculizumab in Patients with Inflammatory Bowel Disease


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ABSTRACT

In the very limited options available for the treatment of mild-to-moderate to severe IBD, there is an increased need to develop a clinically acceptable new treatment. Several unmet medical needs pertaining to IBD include: 1) the currently available and approved IBD treatments like immunosuppressives, immunomodulators, and biologics are not effective at all disease severities, 2) the current biological agents are expensive, and 3) IBD patients may have a severe form of the disease. Therefore, in addition to existing IBD treatments, WCK 771 may provide an effective treatment for IBD patients.

WCK 771 is characterized by good pharmacokinetic properties and has been shown to be safe and well-tolerated in patients with IBD. In a phase I study, WCK 771 was shown to be effective in IBD patients with mild-to-moderate to severe IBD, and a phase II study is currently underway to further evaluate its efficacy and safety.

INTRODUCTION

WCK 771 is a new compound with improved pharmacokinetic properties, as determined by both preclinical and clinical studies. In addition, WCK 771 has been shown to be well-tolerated in healthy volunteers and in patients with IBD.

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Table 1: WCK 771 - Broad spectrum anti-IBD agent

<table>
<thead>
<tr>
<th>Organisms</th>
<th>WCK 771</th>
<th>AUC</th>
<th>MUC2</th>
<th>Vmax</th>
</tr>
</thead>
<tbody>
<tr>
<td>V. cholerae</td>
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<td>0.5</td>
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</tr>
<tr>
<td>E. coli</td>
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<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>S. pneumoniae</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

RESULTS

WCK 771 was well-tolerated at all dose levels without any clinically significant drug-related adverse events or changes in laboratory parameters. The study protocol was approved by the institutional review board and the informed consent was obtained from all patients.

REFERENCES

