Itolizumab or Placebo (3:1)

Subjects were randomized in a 3:1 ratio (active:placebo). Dose escalation into Cohort 2 may occur after Cohort 1.

New Zealand.

= Dosing Visit

Randomization

D1 XD15 XD29 XD43 XD57

Table 2.

Study Design

Introduction

EQUIP is a phase 1b dose-escalation study of itolizumab and placebo in subjects with moderate-to-severe uncontrolled asthma. The study was designed to determine the maximum tolerated dose (MTD) and formulation selection and to characterize the pharmacodynamics (PD) and clinical activity in subjects with moderate-to-severe uncontrolled asthma.

Future Eligibility

Table 1.

Key Inclusion Criteria

1. Moderate-to-severe uncontrolled asthma requiring moderate- or high-dose inhaled corticosteroid (ICS) and one or more additional controller medications with a stable dose ≥1 month prior to the initial Screening Visit

2. Prebronchodilator FEV1 ≥ 40% and ≤ 90% of predicted value, despite use of a moderate dose of ICS

3. History of ≥ 1 clinically significant asthma exacerbation in the 12 months prior to the initial Screening Visit, with ≥ 1 additional exacerbation at the time the exacerbation resolved

4. Subjects with Dose Limiting Toxicity (DLT)*

5. Subjects with Treatment-Related TEsAEs

6. Subjects with Treatment Emergent Serious Adverse Event (TESAE)

7. Subjects with TEAEs by Maximum Common Terminology Criteria for Adverse Events (CTCAE) Severity Grade

8. All subjects in Cohort 1 completed the study, with 1 subject discontinuing study treatment due to an adverse event.

Results

Subjects were randomized in a 3:1 ratio (active:placebo). Dose escalation into Cohort 2 may occur after Cohort 1.

All subjects in Cohort 1 completed the study, with 1 subject discontinuing study treatment due to an adverse event.

Conclusion

Asthma Control Questionnaire- 6 (ACQ-6)

Baseline mean ACQ-6 for Cohort 1 was 2.5, which improved to 1.5 by Day 29, and was maintained through final treatment at Day 87 and 52 days after the last dose at Week 8 (Figure 3).

Table 2.

Study Population and Baseline Characteristics

All subjects in Cohort 1 completed the study, with 1 subject discontinuing study treatment due to an adverse event.

TABLE 1. SUBJECT DISPOSITION

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects who completed study treatment</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>Subjects who discontinued study treatment</td>
<td>1</td>
<td>Subject prematurely ended study treatment</td>
</tr>
<tr>
<td>Subjects with TEAEs during the study</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Subjects with TEAEs by CTCAE Severity Grade Grade 1 – Mild</td>
<td>2</td>
<td>22%</td>
</tr>
<tr>
<td>Grade 2 – Moderate</td>
<td>6</td>
<td>62.4%</td>
</tr>
<tr>
<td>Grade 3 – Severe</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Grade 4 – Life-threatening</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Subjects with other serious adverse events</td>
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<td>0</td>
</tr>
<tr>
<td>Subjects with a new visit for asthma exacerbation</td>
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<td>0</td>
</tr>
<tr>
<td>Subjects with exacerbations</td>
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<td>0</td>
</tr>
<tr>
<td>Subjects with asthma exacerbations requiring hospitalization</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

EQUIP is a phase 1b dose-escalation study of itolizumab and placebo in subjects with moderate-to-severe uncontrolled asthma. The study was designed to determine the maximum tolerated dose (MTD) and formulation selection and to characterize the pharmacodynamics (PD) and clinical activity in subjects with moderate-to-severe uncontrolled asthma.

Table 3.

Conclusions

EQUIP is a phase 1b dose-escalation study of itolizumab and placebo in subjects with moderate-to-severe uncontrolled asthma. The study was designed to determine the maximum tolerated dose (MTD) and formulation selection and to characterize the pharmacodynamics (PD) and clinical activity in subjects with moderate-to-severe uncontrolled asthma.

1. This study was funded by Equillium, Inc. (Lysodermin, Inc.), the sponsor and the manufacturer of the investigational product, itolizumab. The sponsor provided medical writing assistance in the creation of the manuscript, which was developed in collaboration with the authors. The sponsor had no role in the study design, data collection, analysis, or interpretation; in the writing of the manuscript; or in the decision to submit the manuscript for publication.

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