ABSTRACT

Background/Summary: Lenabasum (JBI 101-040), a selective Janus kinase (JAK) inhibitor, reduces interferon α, tumor necrosis factor (TNF) and interleukin-6 (IL-6) production by cultured peripheral blood mononuclear cells in patients with dermatomyositis (DM). Data from the OLE to date, lenabasum:

- Improves skin activity and multiple patient-reported outcomes
- Improves physician Global Overall Disease (PROMIS) score and multiple patient-reported outcomes
- Stable doses of concomitant medicines for DM treatment
- Favorable safety profile to date support further clinical testing of lenabasum for treatment of DM

Study Design: Stable standard care, including immunosuppressive drugs (IOM), for patients with DM between cohorts at entry

Inclusion: Patients with DM
Exclusion: Patients with other systemic autoimmune disease

Data of OLE Part A: MMRM, 2-week intervals
Data of OLE Part B: MMRM, 2-week intervals

Baseline Disease Assessments, Study Entry, mean (SD) or n (%)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>n</th>
<th>N = 11</th>
<th>N = 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>%</td>
<td>4.6 (0.5)</td>
<td>0.3</td>
</tr>
<tr>
<td>Sex</td>
<td>%</td>
<td>60</td>
<td>28</td>
</tr>
<tr>
<td>Race</td>
<td>%</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Table 1</td>
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<tr>
<td>Baseline Disease Assessments, Study Entry</td>
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</tr>
</tbody>
</table>

- No significant differences or correlations in entry to Part A
- Only white and Hispanic

- No significant differences or correlations in entry to Part A
- No significant differences or correlations in entry to Part B
- No significant differences or correlations in entry to Part A
- No significant differences or correlations in entry to Part B

Safety and Tolerability

- No adverse events to date in OLE
- No deaths
- No significant differences in laboratory, vital signs, physical examination

Results

- No significant differences in disease activity score (CDASI) activity score ≥ 14 between OLE Part A and B
- No significant differences in physician-reported outcomes
- No significant differences in multiple patient-reported outcomes
- No significant differences in laboratory, vital signs, physical examination

Conclusions

- Lenabasum 20 mg BID improves physician-reported outcomes and multiple patient-reported outcomes
- Favorable safety profile to date support further clinical testing of lenabasum for treatment of DM

SUMMARY AND CONCLUSIONS

- 0% enrolment in OLE shows excellent patient and physician acceptance of lenabasum
- Has a favorable safety profile and is well-tolerated despite concomitant treatment with immunosuppressive drugs in most subjects
- Is associated with improvement in multiple measures of skin involvement
- Is associated with improvement in multiple patient-reported measures of quality of life
- Shows a consistent pattern of effect across many outcomes

THANK YOU

- To the individuals with DM who participated in this study
- To the study staff who are executing this trial
- To Data Safety Committee Chairperson Dr. Philip Cohen
- To NIH/NIAMS for funding this study

This study was funded in part and sponsored by Corbus Pharmaceuticals, Inc.