### Abstract

Results

- Baseline demographics and disease characteristics for the overall study population are shown in Table 1.
- Subjects were mostly middle-aged, white females with moderate skin thickening and moderate overall disease activity as assessed by participants and physicians, with moderate-severe disease present in 30% of subjects evaluated by HAQ-DI.
- The majority of subjects were on stable doses of background immunosuppressive treatment.

#### Table 1: Baseline Characteristics of Study Population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Baseline</th>
<th>Results 24 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>40-18</td>
<td>47.11 (0.00)</td>
</tr>
<tr>
<td>Gender, n (%): Female</td>
<td>20 (83.3)</td>
<td>10 (41.7)</td>
</tr>
<tr>
<td>Race, n (%): White</td>
<td>22 (91.7)</td>
<td>12 (50.0)</td>
</tr>
<tr>
<td>Disease duration, months</td>
<td>3 (1.3)</td>
<td>3 (1.3)</td>
</tr>
<tr>
<td>Disease stage, n (%): dcSSc</td>
<td>9 (60.0)</td>
<td>6 (25.0)</td>
</tr>
<tr>
<td>Employment status, n (%): Full-time</td>
<td>9 (60.0)</td>
<td>6 (25.0)</td>
</tr>
</tbody>
</table>

### Background

- Systemic sclerosis (SSc) is a potentially life-threatening autoimmune disease characterized by thickened skin resulting from inflammation, edema, and fibrosis (Denton and Khamas, 2017) with significant impact on overall health quality (HRQoL) (Morimoto et al, 2018).
- Lenabasum is a novel rationally designed analog of cannabinoid receptor (CB1) (Burstein, 2018) that activates the ECS with preferential activity of CB1 (Baranz, 2018).
- In a Phase 2 study, lenabasum demonstrated improved health outcomes with a favorable safety profile in patients with SSc (Sripada et al, 2020).
- The skin Patient Skin Rating (SPSR) was developed for inclusion of changes in HAQ-DI (patient function) and PROMIS (patient symptom) scores.

### Objective

- The objective of this analysis was to determine:
  - If HAQ-DI scores were correlated with PROs that assess patient function
  - If HAQ-DI scores were correlated with PROs that assess patient symptom

### Methods

- In this Phase 2 study of lenabasum, subjects with SSc were enrolled in a 24-month double-blind placebo-controlled study, followed by an open-label extension (OLE) (Figure 1).

Figure 1: Design for Phase 2 Study of Lenabasum in dcSSc

### Subject Selection Criteria

- Adults with dcSSc were included if they had disease duration 3 years or ≥ 3 and 6 years if ≤ 65 or at ≥ 65 years.
- Stable doses of concomitant drugs, including immunosuppressive drugs, were allowed.

### Summary and Conclusions

- Correlations between changes in HAQ-DI and other patient-reported functioning and between change in PGA and patient-reported symptoms were notable for their consistency across 2 years in the study. Both HAQ-DI and GCSR are included in the calculation of the ACR Combined Response Index in diffuse cutaneous Systemic Sclerosis (CRISS), score, suggesting this composite score may reflect both patient function and symptoms.

### References