**Roflumilast Cream 0.15% in Patients With Atopic Dermatitis: Individual Patient EASI Responses: Pooled INTEGUMENT-1 and INTEGUMENT-2 Phase 3 Trials**

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**METHODS**

- **Pooled efficacy and safety results of two Phase 3 clinical trials (INTEGUMENT-1 and INTEGUMENT-2) assessing roflumilast cream 0.15% (Roflumilast Cream 0.15%)**
- **Subjects in INTEGUMENT-1 and INTEGUMENT-2 were identical, Phase 3, randomized, double-blind, vehicle-controlled, 4-week trials of once-daily**
- **Individual EASI responses in roflumilast-treated patients are illustrated in [Images 2720x1378 to 3547x1579]**
- **Primary efficacy endpoint was added investigational Global Assessment for Atopic Dermatitis (vIGA-AD) Success (Clear or Almost Clear) plus ≥ 40% improvement from baseline at Week 4**
- **Secondary endpoints included vIGA-AD of Clear or Almost Clear, Worst Itch-Numeric Rating Scale, and EASI versus vehicle in patients with AD in two Phase 3 trials**

**RESULTS**

- **Baseline demographics and disease characteristics were similar in roflumilast- and vehicle-treated patients (Table 1):**

**Table 1: Baseline Demographics and Disease Characteristics**

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>Roflumilast (n=884)</th>
<th>Vehicle (n=453)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean (SD)</td>
<td>37.5 (12.7)</td>
<td>38.0 (13.6)</td>
</tr>
<tr>
<td>Gender</td>
<td>M: 450 (50.9)</td>
<td>M: 230 (50.8)</td>
</tr>
<tr>
<td>Female</td>
<td>434 (50.0)</td>
<td>223 (49.2)</td>
</tr>
<tr>
<td>Race</td>
<td>White: 810 (92.0%)</td>
<td>White: 435 (96.0%)</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>74 (8.5%)</td>
<td>18 (4.0%)</td>
</tr>
<tr>
<td>Num. with various AD</td>
<td>219 (24.9%)</td>
<td>117 (25.8%)</td>
</tr>
<tr>
<td>Duration of disease, years</td>
<td>9.9 (11.6)</td>
<td>10.4 (12.3)</td>
</tr>
<tr>
<td>EASI (mean)</td>
<td>19.4 (12.3)</td>
<td>20.1 (13.5)</td>
</tr>
<tr>
<td>Baseline vIGA-AD Success</td>
<td>10.2 (78.8%)</td>
<td>10.7 (79.2%)</td>
</tr>
<tr>
<td>EASI-50</td>
<td>51.6%</td>
<td>35.4%</td>
</tr>
<tr>
<td>EASI-75</td>
<td>20.4%</td>
<td>12.5%</td>
</tr>
<tr>
<td>EASI-90</td>
<td>10.7%</td>
<td>7.3%</td>
</tr>
</tbody>
</table>

**Figure 2A:** Individually Patient % EASI Improvement From Baseline

**Figure 2B:** Individually Patient % EASI Improvement From Baseline

**Figure 2C:** Individually Patient % EASI Improvement From Baseline

**Figure 3:** Changes in a Patient With AD Treated With Roflumilast Cream 0.15%

**SAFETY**

- **No treatment-related serious adverse events (SAEs) or discontinuations due to AD, comparable with vehicle**
- **No adjudication assessments, ≥50% of investigators reported no evidence of inflammation at any time point**

**CONCLUSIONS**

- **Roflumilast cream demonstrated a rate of application site adverse events (ASAE) treatment-related ASAE, and discontinuations due to AD, comparable with vehicle**
- **On safety/tolerability assessments, ≥50% of investigators reported no evidence of inflammation at any time point**
- **100% of patients reported no or mild sensation after the first application of roflumilast cream 0.15% and subsequent assessment time points on patient-rated local tolerability assessments**

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- **We thank all investigators, site staff, and patients for their participation in the trial.**

**DISCLOSURES**

- **The study was supported by funds from Arcutis Biotherapeutics, Inc.**
- **Patient photographs demonstrating disease improvement over time are shown in Figure 3.**

**REFERENCES**