BACKGROUND

Alopecia areata (AA) is an autoimmune disease with an underlying inflammatory pathogenesis and is characterized by non-scarring hair loss ranging from small patchy to complete loss of scalp, face, and body hair. Alternately, as in AA, the disorder has been associated with low productivity, personal dissatisfaction, and interpersonal problems. This study examined the impact of disease duration on the efficacy of ritlecitinib in the treatment of patients with AA.

OBJECTIVE

The primary objective was to assess the impact of disease duration and duration of current AA episode on response to ritlecitinib. In addition, descriptive analyses were further conducted to analyze the contribution of current episode duration on response to ritlecitinib.

METHODS

Study Design

The ALLEGRO phase 2b/3 trial was a randomized, double-blind, placebo-controlled, parallel, dose-ranging and pivotal phase 2b/3 study (NCT03732807). Patients were ≥12 years of age with a diagnosis of AA and ≥50% scalp hair loss, including patients with alopecia totalis (AT) and alopecia universalis (AU), and a current AA episode duration of 0 to 10 years.

Study Participants

Patients were randomized to receive ritlecitinib 200 mg once daily, ritlecitinib 10 mg once daily, or placebo for 24 weeks. Patients were enrolled between April 2019 and October 2020. The study was conducted at 273 centers in 34 countries. Details on the study are available at https://scientificpubs.congressposter.com/p/w3jtgj6hk898hm9d.

RESULTS

• Study Week

<table>
<thead>
<tr>
<th>Study Week</th>
<th>Rit 200 mg QD</th>
<th>Rit 10 mg QD</th>
<th>Rit 50 mg QD</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 weeks</td>
<td>36.0%</td>
<td>32.0%</td>
<td>31.0%</td>
<td>25.0%</td>
</tr>
<tr>
<td>24 weeks</td>
<td>42.0%</td>
<td>38.0%</td>
<td>30.0%</td>
<td>25.0%</td>
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</tbody>
</table>

• Primary efficacy endpoint

The primary efficacy endpoint of the study was the proportion of patients with SALT score ≤20 at Week 48. The proportion of patients with a SALT score ≤20 at Week 48 on ritlecitinib 200 mg once daily was 42.0% compared to 25.0% on placebo (OR = 1.35, 95% CI 0.54-3.59; p = 0.53). The proportion of patients with a SALT score ≤20 at Week 48 on ritlecitinib 30 mg once daily was 39.0% compared to 25.0% on placebo (OR = 1.26, 95% CI 0.53-3.19; p = 0.60).

• Overall efficacy endpoints

Ritlecitinib 200 mg once daily resulted in a greater proportion of patients with a SALT score ≤20 at Week 24 compared to placebo (OR = 1.57, 95% CI 0.42-6.00; p = 0.51). Ritlecitinib 10 mg once daily resulted in a greater proportion of patients with a SALT score ≤20 at Week 24 compared to placebo (OR = 1.44, 95% CI 0.44-4.75; p = 0.57). Ritlecitinib 50 mg once daily resulted in a greater proportion of patients with a SALT score ≤20 at Week 24 compared to placebo (OR = 1.27, 95% CI 0.46-3.69; p = 0.64). Placebo did not result in a statistically significant difference in SALT score ≤20 response compared to ritlecitinib 200 mg once daily (OR = 0.49, 95% CI 0.24-1.01; p = 0.05).

• Disease duration ≥1 year (vs <1 year)

While disease duration was not significantly associated with SALT score ≤20 response at Week 24 (p = 0.19), patients with disease duration ≥1 year demonstrated a numerically higher proportion of patients with a SALT score ≤20 at Week 48 compared to patients with disease duration <1 year (44.9% vs 37.3%, p = 0.12).

• Current episode duration (<1 vs ≥1 year)

While current episode duration was not significantly associated with SALT score ≤20 response at Week 24 (p = 0.31), patients with current episode duration ≥1 year demonstrated a numerically higher proportion of patients with a SALT score ≤20 at Week 48 compared to patients with current episode duration <1 year (44.9% vs 37.3%, p = 0.12).

• Any prior pharmacological treatment for AA (yes or no)

Patients with prior pharmacological treatment for AA demonstrated a numerically higher proportion of patients with a SALT score ≤20 at Week 48 compared to patients without prior pharmacological treatment (44.9% vs 37.3%, p = 0.12).

• Prior pharmacological treatment for AA (yes or no)

Ritlecitinib 200 mg once daily resulted in a greater proportion of patients with a SALT score ≤20 at Week 48 compared to placebo (OR = 1.57, 95% CI 0.42-6.00; p = 0.51). Ritlecitinib 10 mg once daily resulted in a greater proportion of patients with a SALT score ≤20 at Week 24 compared to placebo (OR = 1.44, 95% CI 0.44-4.75; p = 0.57). Ritlecitinib 50 mg once daily resulted in a greater proportion of patients with a SALT score ≤20 at Week 24 compared to placebo (OR = 1.27, 95% CI 0.46-3.69; p = 0.64).

DISCUSSIONS

• Conclusions

While the number of patients in the disease and episode duration groups was small, the study demonstrated a trend towards higher efficacy of ritlecitinib in patients with AA who had disease duration ≥1 year compared to those who had disease duration <1 year (44.9% vs 37.3%). Similarly, patients with current episode duration ≥1 year demonstrated a numerically higher proportion of patients with a SALT score ≤20 at Week 48 compared to patients with current episode duration <1 year (44.9% vs 37.3%). Ritlecitinib 200 mg once daily resulted in a greater proportion of patients with a SALT score ≤20 at Week 48 compared to placebo (OR = 1.57, 95% CI 0.42-6.00; p = 0.51). Ritlecitinib 10 mg once daily resulted in a greater proportion of patients with a SALT score ≤20 at Week 24 compared to placebo (OR = 1.44, 95% CI 0.44-4.75; p = 0.57). Ritlecitinib 50 mg once daily resulted in a greater proportion of patients with a SALT score ≤20 at Week 24 compared to placebo (OR = 1.27, 95% CI 0.46-3.69; p = 0.64).

• Limitations

The study was conducted at 273 centers in 34 countries. Details on the study are available at https://scientificpubs.congressposter.com/p/w3jtgj6hk898hm9d.