Improvements in patient-reported outcomes (PROs) across 16 weeks of treatment with rademikibart (CBP–201) for moderate-to-severe atopic dermatitis (AD): Results from a pivotal trial in China (CBP–201–CN002)

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Objectives

CN002 is a pivotal trial of rademikibart in China (NCT0507480) with a primary patient population of adults with moderate-to-severe AD. Assessments are also being conducted in adolescents.

In three other posters by Zhang et al. at this meeting (WCD2023, posters 3234, 3242, 3247), we report that the CN002 trial achieved its primary endpoint (% patients with IGA 0/1 and ≥2-point reduction from baseline at Week 16) and all secondary endpoints at 16 weeks of treatment with rademikibart in adult patients.

Here, we report improvements in PROs with rademikibart across the initial 16-week treatment period in the adult population.

Methodology

Study design

CN002 is a randomized, double-blind, placebo-controlled, pivotal trial of subcutaneous rademikibart conducted across 48 centers in China (Figure 1). Stage I has completed in adults; Stage 2 is ongoing. Patients had moderate-to-severe AD (IGA 3/4, EASI 18/36, BSA ≥10%) inadequately controlled topically, prior anti-IL-10 receptor blockers, no prior anti-IL-4/IL-13, and no concomitant topical AD treatment except rescue medication and emollient.

Baseline characteristics and patient disposition

All 255 adults had moderate-to-severe AD, with the following baseline characteristics:

- Investigator rated: median EASI 26.9; 54.5% with IGA score of 4; median BSA 44.5%
- Patient rated: median PP–NRS 7.0; median DLQI 15.0; median POEM 23.0

Results

Baseline characteristics and patient disposition

All 255 adults had moderate-to-severe AD, with the following baseline characteristics:

- Investigator rated: median EASI 26.9; 54.5% with IGA score of 4; median BSA 44.5%
- Patient rated: median PP–NRS 7.0; median DLQI 15.0; median POEM 23.0

Disease characteristics were well balanced in the rademikibart and placebo arms, and generally comparable to those in dupilumab trials conducted in China and globally.4,5

Across 16 weeks of treatment, all patients received ≥2 dose, with 95.3% and 92.9% completing to Week 16 in the rademikibart and placebo arms, respectively.

PP–NRS scores across the initial 16-week treatment period

Rapid and sustained improvements in PP–NRS were observed from Week 1 to Week 16 (Figure 2). Statistical significance with rademikibart vs placebo was achieved at the earliest assessment (Week 1) and throughout the 16-week treatment period. Placebo-adjusted PP–NRS score improvements with rademikibart were −7.6% and −25.8% at Weeks 2 and 16, respectively.

POEM scores across the initial 16-week treatment period

Rapid and sustained significant improvements in POEM* scores were observed with rademikibart (Figure 4). Placebo-adjusted improvements were −14.5% and −3.19% at Weeks 2 and 16, respectively.

Conclusions

In CN002, a large China-specific pivotal trial, adults with moderate-to-severe AD reported rapid and sustained improvements in symptoms, including pruritus, and in QoL across the initial 16-week treatment period with rademikibart.

In the background, we conducted this meeting (WCD2023, posters 3234, 3242, 3247), in the adult population, we report comparable improvements in AD extent and severity, including: • CN002 achieved its primary endpoint (% patients with IGA 0/1 and ≥2-point reduction from baseline at Week 16) and all secondary endpoints at Week 16.

- Investigator-assessed AD signs improved rapidly, without plateauling by Week 16.

- Efficacy responses were generally comparable to those in dupilumab global and China-specific trials.4–8

- The findings are also confirmatory of previously reported rapid and sustained improvements in AD signs and symptoms, and in QoL, during the WW001 global Phase 2 trial of rademikibart.1–5

- Whether patients’ perceptions of QoL differ according to cultural background requires further research, thus limiting direct comparison with global studies.

- The CN002 pivotal trial is ongoing in adults and adolescents. The 36-week maintenance treatment period will potentially demonstrate sustained patient- and investigator-assessed efficacy with rademikibart QW, as well as with a more convenient Q4W dose.

Table 2: Change in PP–NRS scores across 16 weeks of treatment

<table>
<thead>
<tr>
<th>Week</th>
<th>PP–NRS Change (%)</th>
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<tbody>
<tr>
<td>2</td>
<td>−12.3%</td>
</tr>
<tr>
<td>16</td>
<td>−38.1%</td>
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*Secondary endpoints at Weeks 2 and 16.