Rademikibart (CBP-201), a next-generation IL-4Rα antibody, achieved all primary and secondary endpoints in a randomized pivotal trial for moderate-to-severe atopic dermatitis (AD) in China (CBP-201-CN002).

**Objective**

Rademikibart is being evaluated in CN002 (NCT05007480), a pivotal trial in China, in adults and adolescents with moderate-to-severe AD. For adult patients, we report the primary and secondary efficacy outcomes, as well as key safety data, at Week 16.

**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 1 has completed in adults; Stage 2 is ongoing. Patients had moderate-to-severe AD (GA 3, EASI 15, BSA >10%) inadequately controlled topically, no prior anti–IL-4Rα/IL-13, and no concurrent topical AD treatment except rescue medication and ointment.

**Statistics**

Binary endpoints were analyzed by CMH test; missing data were imputed by jump to reference (after the rule of intercurrent event) and multiple imputation for rademikibart and placebo, respectively. Continuous score changes were analyzed using MMRM.

**Results**

**Baseline characteristics and patient disposition**

All 255 adult patients had moderate-to-severe AD at baseline (Table 1), with generally comparable disease characteristics per treatment arm and also versus late phase trials of dupilumab in China and globally. Rademikibart treatment was completed to Week 16 by 93.3% of patients (Figure 2).

**Safety outcomes**

Rademikibart was well tolerated with no new safety signals (Table 2).

**Conclusions**

仁美基巴特 (CBP-201)，一种新世代的 IL-4Rα 抗体，在中国针对中至重度特应性皮炎（AD）的随机临床试验中，成功实现了所有主要和次要终点。研究细节如下。

- **主要终点**
  - 在第 16 周，仁美基巴特组的抗 AD 评分、EASI 和 DLQI 获得显著改善，且在所有亚组中均优于安慰剂组。在 255 名成年患者中，93.3% 的患者完成了治疗。

- **次要终点**
  - 在第 16 周，仁美基巴特组的抗 AD 评分、EASI 和 DLQI 获得显著改善，且在所有亚组中均优于安慰剂组。在 255 名成年患者中，93.3% 的患者完成了治疗。

- **安全性**
  - 仁美基巴特组的安全性数据与安慰剂组相似，未出现新的安全信号。

- **综合结论**
  - 在中至重度特应性皮炎的治疗中，仁美基巴特显示出了显著的疗效和安全性，为 AD 患者提供了新的治疗选择。