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**Long-term Safety and Efficacy of Ebdarokimab in Patients with Moderate to Severe Plaque Psoriasis: Results from a Single Arm, Open Label, Multicenter Phase III Clinical Study**

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**Introduction & Objectives:**

Interleukin-12 (IL-12) and interleukin-23 (IL-23) are two essential cytokins involved in the immune-mediated inflammatory disorders of psoriasis. Anti-IL-12/IL-23 therapy has been developed for the treatment of psoriasis. AK101 is a fully human monoclonal antibody (mAb) targeting IL-12/IL-23 pathway, and specifically binds to the P40 subunit of both IL-12 and IL-23, resulting in inhibition of the signaling of IL-12 and IL-23 cytokines. This study was aimed to evaluate the long-term safety and efficacy of AK101 in Chinese patients with moderate to severe plaque psoriasis.

**Materials & Methods:**

A total of 950 subjects with age ≥ 18 years old were planned to enroll. Subjects (group 1) who received AK101 treatment in the previous study (a 16 weeks, double blind, placebo controlled study) continued to receive AK101 in this study. With AK101 135mg at week 16, followed by maintenance treatment every 12 weeks, and follow-up until week 52. Subjects (group 2) from placebo group in the previous study received AK101 135mg at week 16/week 20 in this study, followed by maintenance treatment every 12 weeks, and follow-up until week 52. Subjects who directly participated in this study (group 3) received AK101 135mg treatment at week 0/4. Followed by maintenance treatment every 12 weeks, and follow-up until week 52.

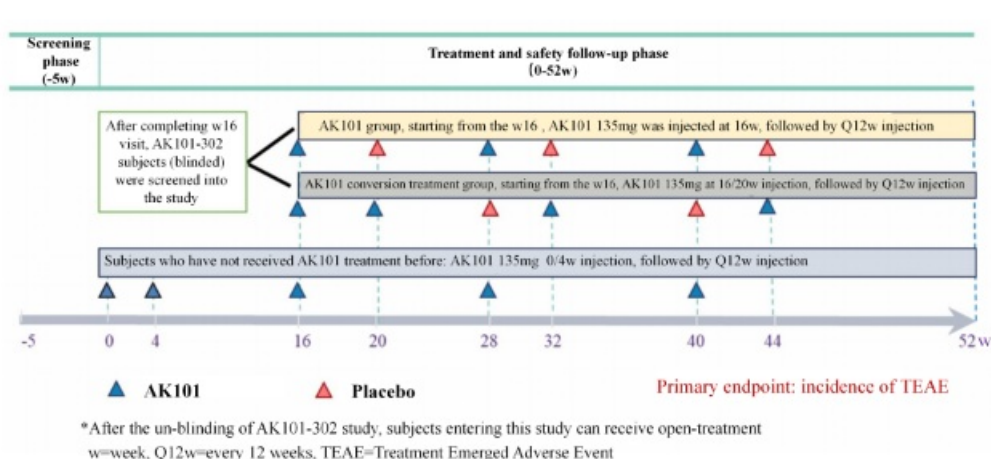


Figure 1 Study design

**Results:**

*Efficacy:* The ≥75% improvement in Psoriasis Area and Severity Index (PASI75) and Static Physicians Global Assessment (sPGA) 0/1 response rates of group 1 at week16 were 80.5% and 66.0%,

respectively. The improvement in PASI75 and sPGA0/1 response rates of group 1 subjects were consistently maintained until week 52. After switching to AK101 at week 16, the PASI score of subjects in group 2 decreased. The response rates of PASI75 and sPGA0/1 at week 32 were 81.4% and 71.1%, respectively, the response rates maintained until week 52. The response rates of PASI75 and sPGA0/1 at week 16 of group 3 were 69.5% and 59.1%, respectively, which were consistent with the results from group 1. All subjects were followed up to week 28 at least, and showed a stable long-term efficacy.

*Safety:* A total of 788 (82.9%) subjects experienced at least one Treatment-Emergent Adverse Event (TEAE), and 314(33.1%) subjects had TEAE related to study drug (TRAE). The incidence of TEAE in group 1 (89.1%) and group 2 (85.6%) was slightly higher than group 3 (79.3%); The incidence of TRAE among different groups is similar. The majority of TEAE/TRAE were classified as mild and moderate. 32(3.4%) subjects experienced Serious Adverse Event (SAE), and 1 (0.1%) death was reported due to traffic accident(unrelated to study drug).

**Conclusion:**

AK101 was generally safe and well tolerated, with good improvement in PASI 75 and sPGA0/1 response in Chinese subjects with moderate to severe plaque psoriasis.

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