# Clinical similarity of biosimilar ABP 501 to adalimumab in the treatment of patients with moderate to severe plaque psoriasis: A randomized, double-blind, multicenter, phase III study

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***Background:*** ABP 501 is a biosimilar of adalimumab.

***Objective:*** We sought to compare the efficacy and safety of ABP 501 with adalimumab.

***Methods:*** This 52-week, double-blind study randomized patients with moderate to severe psoriasis to ABP 501 or adalimumab. At week 16, those with 50% or more improvement in Psoriasis Area and Severity Index score from baseline on ABP 501 continued the same treatment, whereas adalimumab-treated patients were rerandomized to adalimumab or ABP 501. Clinical similarity in Psoriasis Area and Severity Index percent improvement from baseline to week 16 (primary end point) was established if the point estimate of treatment difference and its 2-sided 95% confidence interval between groups was within equivalence margin of ±15. Patients, including those undergoing a single transition at week 16, were evaluated for safety and immunogenicity.

***Results:*** Psoriasis Area and Severity Index percent improvement at week 16 was 80.9 for ABP 501 and 83.1 for adalimumab (least-square mean difference −2.18 [95% confidence interval −7.39 to 3.02]). Adverse events (67.2% [117/174] vs 63.6% [110/173]) and antidrug antibody incidence (55.2% [96/174] vs 63.6% [110/173]) for ABP 501 vs adalimumab were similar. Safety, including immunogenicity, was similar among groups after single transition (week 20).

***Limitations:*** The 52-week data are not reported here.

***Conclusions:*** ABP 501 was shown to be clinically similar to adalimumab. Safety and immunogenicity were not impacted immediately after single transition (adalimumab to ABP 501). (J Am Acad Dermatol 2017;76:1093-102.)

***Key words:*** ABP 501; adalimumab; biosimilar; efficacy; equivalence; psoriasis; safety.

**CAPSULE SUMMARY**

- ABP 501 is a biosimilar of adalimumab.
- Phase III clinical trial results demonstrated clinical equivalence between ABP 501 and adalimumab at week 16, and similarity in safety and immunogenicity 4 weeks after single transition.
- These findings support clinical similarity between ABP 501 and adalimumab.

Biologic treatments are highly effective for moderate to severe psoriasis[1-3]; however, the increasingly high costs associated with their use may be a treatment barrier for some patients.[4] Biosimilars are biologic drugs being developed as similar therapeutic and potentially lower-cost alternatives to already approved biologic treatments.[5] Biosimilars are not the same as generic, chemically derived drugs because of the complexities and proprietary processes involved in developing biological proteins, which can result in structural and functional differences between the biosimilar and its reference drug. As a result, regulatory agencies require that biosimilars demonstrate similarity based on a stepwise totality of evidence approach in structure, function, and clinical efficacy and safety to the reference drug.[5-7] For clinical trials, regulatory guidance recommends the inclusion of sensitive populations to detect any clinically meaningful differences between the proposed biosimilar and reference product.[6,8]

ABP 501 (AMJEVITA [adalimumab-atto], Amgen Inc, Thousand Oaks, CA) is a biosimilar of adalimumab (Humira, AbbVie Inc, North Chicago, IL),[9] a human IgG1 monoclonal antibody that binds to soluble and membrane-bound tumor necrosis factor (TNF)-alfa (anti—TNF-alfa). Both ABP 501 and adalimumab are indicated to treat several chronic inflammatory diseases including psoriasis.[9,10] Analytical assessment and human pharmacokinetic evaluation demonstrated similarity between ABP 501 and adalimumab.[11-13] To establish clinical similarity, 2 phase III studies were conducted to compare efficacy, safety, and immunogenicity of ABP 501 with adalimumab: 1 in patients with moderate to severe plaque psoriasis (NCT01970488) and 1 in patients with moderate to severe rheumatoid arthritis (NCT01970475).[14] Conducting 2 studies provided an opportunity to evaluate clinical similarity in different sensitive populations: immunocompromised patients with rheumatoid arthritis and immunocompetent patients with psoriasis.

Herein we report the results of a randomized, double-blind, multicenter phase III study designed to demonstrate clinical similarity in the efficacy,