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Summary

PHARMACOKINETIC COMPARABILITY OF ABP 654 ADMINISTERED EITHER VIA PREFILLED SYRINGE OR AUTOINJECTOR IN HEALTHY ADULT SUBJECTS: RESULTS FROM A RANDOMIZED, OPEN-LABEL, PARALLEL-GROUP STUDY

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A randomized study in 156 healthy adults established pharmacokinetic comparability between ABP 654 (ustekinumab biosimilar) administered via prefilled syringe and autoinjector, with similar safety and immunogenicity profiles.

KEY POINTS

- Pharmacokinetic comparability was established with 90% confidence intervals of geometric mean ratios for AUCinf (1.0069; 0.92, 1.10) and Cmax (1.0503; 0.97, 1.14) both within the prespecified margin of 0.8 to 1.25.
- Mean serum concentration-time profiles showed high similarity between prefilled syringe and autoinjector groups, with peak concentrations observed approximately 8 days post-injection and half-life of approximately 23 days for both delivery methods.
- Frequency, type, and severity of adverse events were comparable between groups and consistent with the known safety profile of ustekinumab reference product.
- Binding antidrug antibodies developed in 12.8% of prefilled syringe subjects and 20.5% of autoinjector subjects; this numerical difference was not considered clinically impactful given demonstrated pharmacokinetic comparability and similar safety profiles.
- This study supports use of the autoinjector device as an alternative delivery method for ABP 654 that may offer additional convenience for patients and healthcare professionals.

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