A Multi-Center, Open-Label Extension Study to Assess the Long-Term Safety, Tolerability and Pharmacokinetics, and Explore the Efficacy of Sofpironium Bromide Gel, 15% Applied Topically to Children and Adolescents, 9 to 16 Years of Age, with Primary Axillary Hyperhidrosis (BBI-4000-CL-108)

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Background
Hyperhidrosis affects approximately 15 million Americans. Sofpironium bromide is a retro-metabolically designed analog of glycopyrrolate (anticholinergic) in development for the topical treatment of primary axillary hyperhidrosis. Retro-metabolically designed drugs are intended to be rapidly metabolized in the bloodstream, potentially allowing for optimal therapeutic effect at the site of application with minimal systemic side effects.

Methods
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Objective
Evaluate the long-term safety, tolerability and pharmacokinetics of topically applied sofpirionium bromide gel, 15% for the treatment of axillary hyperhidrosis in pediatric subjects, as well as to explore efficacy.

Results

The mean age (SD) of the subjects was 13.3 (2.99) years. Sixteen subjects completed 24-weeks of treatment. Seven subjects had treatment emergent adverse events (TEAEs). Four subjects had TEAEs that were considered related to study drug, which included expected systemic anticholinergic effects (blurred vision, dry mouth, dry eyes, mydriasis) and local site reactions (pain, pruritus, rash, erythema). Two subjects discontinued the study due to adverse events, which included dry eye, dry mouth, pruritus and rash.

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The majority of subjects did not have any local signs or symptoms and none were severe. Pharmacokinetic analysis did not show any evidence of drug accumulation, with most subjects having plasma concentrations that appeared safe and generally well tolerated. The majority of subjects did not report any TEAEs, and there were no severe or serious AEs. There was no evidence of drug accumulation. There was clinically meaningful improvement in axillary hyperhidrosis. The majority of subjects did not have any local signs or symptoms and none were severe. Pharmacokinetic analysis did not show any evidence of drug accumulation, with most subjects having plasma concentrations that appeared safe and generally well tolerated. The majority of subjects did not report any TEAEs, and there were no severe or serious AEs. There was no evidence of drug accumulation. There was clinically meaningful improvement in axillary hyperhidrosis.

Conclusion
In this 24-week study in the pediatric population, sofpirionium bromide gel, 15% appeared safe and generally well tolerated. The majority of subjects did not report any TEAEs, and there were no severe or serious AEs. There was no evidence of drug accumulation. There was clinically meaningful improvement in axillary hyperhidrosis.

References

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