AQ109301 Clinical Abstract

Epinephrine Delivered via Sublingual Film (Anaphylm™) Elicits Rapid and Consistent Pharmacokinetic and Pharmacodynamic Responses

Carl Kraus, MD[1], Stephen Wargacki, PhD[1], David Golden, MD[2], David Bernstein, MD[3], Matthew Greenhawt, MD[4]

[1] Aquestive Therapeutics, Inc, [2] Medstar Franklin Square Hospital, Baltimore, MD, [3]Cincinnati Children's Hospital Medical Center, University of Cincinnati, Cincinnati, OH, [4]Children's Hospital Colorado, University of Colorado, Aurora, CO

Rationale: Epinephrine is the first-line treatment for severe allergic reactions, including anaphylaxis. Prompt, reliable treatment is critical for patient outcomes. Anaphylm is a sublingual film containing a novel prodrug of epinephrine in development for the treatment of Type I allergic reactions, including anaphylaxis.

Methods: A phase 3 cross-over trial (AQ109301) was conducted in 64 healthy adults evaluating the pharmacokinetics (PK, including time to peak plasma concentration [T_{max}]) and pharmacodynamics (PD, heart rate [HR], systolic [SBP] and diastolic blood pressure [DBP]) of Anaphylm compared to epinephrine autoinjectors (EAI) and manual intramuscular epinephrine injection (IM).

Results: After single dose administration, the T_{max} variability as reflected by interquartile range (IQR) was 5.0 minutes (min) for Anaphylm (median T_{max} 12 min), 23.5 min for EpiPen (median T_{max} 20 min), 32.0 min for Auvi-Q (median T_{max} 30 min), and 15.0 min for manual IM injection (median T_{max} 50 min). After Anaphylm administration, clinically meaningful changes in median SBP, DBP, and HR were seen in 5 minutes (>10mmHg), 5 minutes (>10mmHg), and 8 minutes (>10bpm), respectively.

Conclusion: Anaphylm data demonstrates a more rapid and consistent PK profile in comparison to EAIs and IM. Moreover, Anaphylm's PD profile showed clinically relevant increases in SBP, DBP, and HR. These results further support the development of sublingual epinephrine film as a reliable needle-free alternative for the treatment of Type I allergic reactions, including anaphylaxis.