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Positive Phase 3 Results Announced for Sublingual Epinephrine Treatment

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In an announcement by Aquestive Therapeutics, these new findings demonstrated the potential of this orally-administered epinephrine treatment.

An announcement by Aquestive Therapeutics, Inc., suggests that sublingual epinephrine (Anaphylm Sublingual Film) for serious allergic reactions such as [anaphylaxis](#), met all of its predefined primary and secondary pharmacokinetic endpoints.¹

The March 14 announcement described both the phase 3 findings from the pivotal pharmacokinetic clinical study of the sublingual epinephrine treatment as well as developments expressed in the [US Food and Drug Administration \(FDA\)](#) Type C meeting on the drug.



David Golden, MD

Credit: Aquestive Therapeutics

"The data from the Anaphylm pivotal study build on the compelling data generated from the prior Anaphylm pilot studies," David Golden, MD, of Sinai Hospital of Baltimore and Franklin Square Hospital in Baltimore, said in a statement. "These latest study results show that the sublingual administration of epinephrine provides rapid and sustained levels of epinephrine similar to approved treatments."

The sublingual epinephrine treatment is an orally-administered epinephrine prodrug candidate which was formulated for patients with severe and life-threatening [allergic reactions](#). This single-center, open-label, randomized, phase 3 study on adult patients was carried out to assess the pharmacokinetic profile and pharmacodynamics of both individual and repeated treatment doses compared to injectable epinephrine treatments such as the EpiPen.

The investigators' main objective was to evaluate the pharmacokinetics of epinephrine after a single administration of the sublingual epinephrine treatment compared to epinephrine IM injection and autoinjector. Their secondary goals were to assess the drug's sustainability after repeated administration and to evaluate its safety and tolerability compared to the other treatments.

The study involved a 4-period, 4-treatment, 4-sequence comparative analysis of the pharmacokinetics of the epinephrine prodrug candidate. The research team recruited 64 adult subjects.

Overall, the investigators found that the sublingual treatment's time to maximum concentration was shown to have been consistently faster than the autoinjectors to which



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they compared the treatment. The treatment's exposure levels were also shown to be comparable to the autoinjectors for half an hour following dosing, and the drug had no serious adverse events.

Aquestive also finished up a Type C meeting with FDA officials with the goal of addressing outstanding questions drawn from the phase 2 ending meeting in 2022. The meeting involved discussion of the possibility of emesis, the product's hold time impact, and the impact of mouth conditions such as angioedema on its effects.

The company's announcement suggested that the FDA officials, over the course of the meeting, acknowledged the moves made to address such issues. The company removed the product hold time from the instructions and allowed for new insights on emesis characterization in their NDA submission.

The mouth condition note was also addressed, as the FDA officials at the meeting suggested the administration of the sublingual epinephrine treatment in the time following oral allergen exposure to better evaluate the drug's performance. Epinephrine concentrations must, according to those with the agency, be justified in terms of safety if they are above known levels for the EpiPen.

The second quarter of 2024 is the scheduled time for pediatric research, following the conclusion of the study for adults. These new findings contribute to the growing number of initiatives seeking alternatives to injectable epinephrine, though notable recent examples had proven to be un-approved by the FDA thus far.²

"Anaphylm is a promising needle-free alternative to the current standard of care, allowing patients to easily carry and administer this life-saving medication," Golden concluded.¹

References

1. Aquestive Therapeutics Announces Pivotal Study for Anaphylm™ (epinephrine) Sublingual Film Successfully Meets Primary and Secondary Endpoints and Provides Clinical Development Update Following FDA Meeting. Aquestive. March 14, 2024. <https://aquestive.com/aquestive-therapeutics-announces-pivotal-study-for-anaphylm-epinephrine-sublingual-film-successfully-meets-primary-and-secondary-endpoints-and-provides-clinical-development-update-following/>. Date accessed: March 18, 2024.
2. Smith T. FDA Declines to Approve of Epinephrine Alternative to EpiPen, Requests Further Study. HCPLive. September 20, 2023. <https://www.hcplive.com/view/fda-declines-to-approve-of-epinephrine-alternative-to-epipen-requests-further-study>. Date accessed: March 18, 2024.

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