

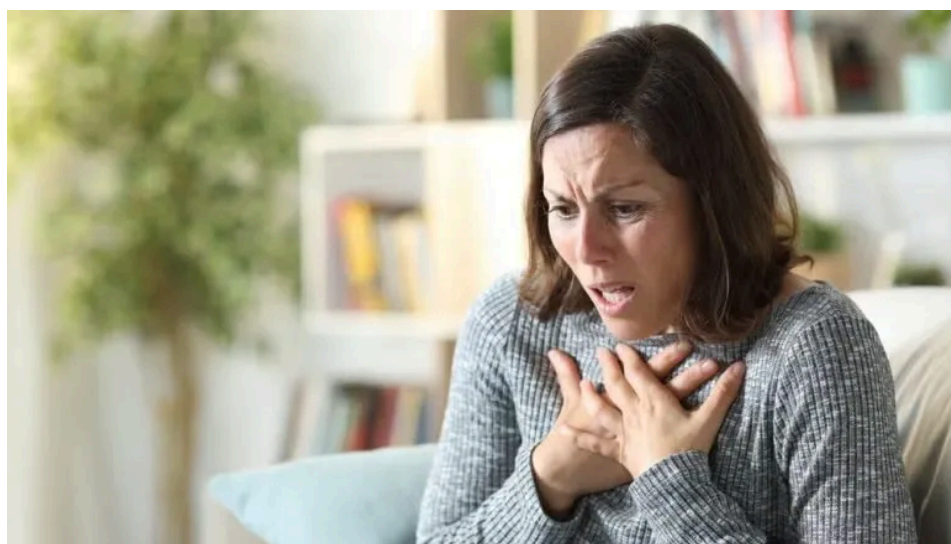
News

Aquestive maps out FDA approval for sublingual anaphylaxis drug

Anaphylm met all its primary and secondary endpoints in the Phase III trial and Aquestive plans to file for approval by the end of this year.

Phalguni Deswal | March 15, 2024

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Anaphylm is an orally administered epinephrine product that dissolves when placed under the tongue. Image Credit: Pheelings media / Shutterstock.

Aquestive Therapeutics has revealed topline data from the Phase III pharmacokinetic (PK) study of its anaphylactic drug, Anaphylm (epinephrine) sublingual film.

Anaphylaxis is a life-threatening allergic reaction that requires imitate treatment with epinephrine.

Meeting all the predefined primary and secondary pharmacokinetic endpoints, [Anaphylam](#) is an orally administered epinephrine product that dissolves when placed under the tongue.

The single-centre, open-label Phase III trial compared the PK and pharmacodynamics (PD) of single and repeat doses of Anaphylm versus single and repeat doses of the epinephrine intramuscular injection and epinephrine autoinjectors (marketed as EpiPen and Auvi-Q) in 36 healthy adult subjects. Anaphylam maintained plasma concentrations equal to or greater than existing injection products at all but one timepoint out to two hours.

The time required for Anaphylm to reach maximum concentration (time for drug absorption or T_{max}) was ten minutes following the administration of the second dose. It maintained a median T_{max} of 12 minutes compared to 20 minutes for EpiPen, 30 minutes for AUVI-Q, and 50 minutes for adrenaline. The drug was well tolerated with no reported severe adverse events.

The company also plans to file a new drug application (NDA) for Anaphylm with the US Food and Drug Administration (FDA) by the end of this year. To that end, Aquestive had a Type C meeting with the agency in November 2023.

Based on the feedback from the Type C meeting, the company plans to start a study evaluating Anaphylam's PK performance following oral exposure to a known allergen. Aquestive plans to start this trial in Q2 of this

year and it will replace the angioedema study previously planned by the company.

The company also plans to evaluate Anaphylam in the paediatric population, per the FDA recommendation. Aquestive plans to start paediatric trials after the completion of the remaining adult studies in Q3 of this year.

Another oral therapy in Aquestive's portfolio is the FDA-approved amyotrophic lateral sclerosis (ALS) therapy, [Exservan \(riluzole oral film\)](#). As ALS patients can have difficulty swallowing oral medications, Exservan's mode of administration, which requires no swallowing, can result in higher compliance and uptake among this patient group.

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