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June 30, 2025 4 min read

FDA accepts new drug application for sublingual epinephrine film

Key takeaways:

- Aquestive Therapeutics' Anaphylm sublingual film is about the size of a postage stamp.
- Anaphylm's time to maximum epinephrine concentration is faster than other delivery vehicles.

 Perspective from [Lynda Mitchell, MA, CAE](#)

The FDA has accepted Aquestive Therapeutics' new drug application for its Anaphylm sublingual epinephrine film for treating anaphylaxis and other type 1 allergic reactions, according to a press release from the company.

Despite the availability of autoinjectors, research indicates that patients with allergy often do not carry these epinephrine devices with them, and when they do have one, they fail to use it, **Daniel Barber, MBA**, president and CEO of Aquestive, told Healio.



“It's the same epinephrine that is known in the medical community.”

Daniel Barber, MBA

Healio

“We think we solve that carry issue by being a product that is very easy to put in your pocket, on the back of your phone, in your wallet,” he continued. “We think that will create a much more compliant patient base.”

Carl N. Kraus, MD, FACP, chief medical officer at Aquestive, added that Anaphylm (AQST-109) “fills an innovation gap.”

“People are inherently fearful of needle-based therapy,” Kraus told Healio.

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IPR2025-00874

Aquestive Therapeutics, Inc. v. Iono Pharma, LLC

Iono's Exhibit 2038

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Carl N. Kraus

Anaphylm is a polymer matrix-based epinephrine prodrug. Each dose is about the size of a postage stamp and weighs less than an ounce. Doses come in a flexible foil sachet that is thinner and smaller than a credit card.

“It’s the same epinephrine that is known in the medical community,” Barber said. “We use a prodrug to deliver the drug through tissue to create absorption. As soon as that prodrug gets into your bloodstream, it cleaves back into base epinephrine.”

The NDA seeks approval for patients who weigh 30 kg or more, which Barber said would be appropriate for children who are aged 7 or 8 years and older. Future applications will seek approval for younger children, he added.

Barber further noted that Anaphylm’s [time to maximum concentration](#) (T_{max}) has ranged from 12 to 15 minutes in the company’s previous studies, which he called the fastest T_{max} of other epinephrine products that are currently available or under development.

“That’s critical, primarily because patients are having an acute reaction,” Kraus said. “This is definitely meant for a rescue therapy.”

Also, Kraus said, approximately 40% of patients will have some form of hypotension such as presyncope or syncopal episodes with lightheadedness.

“We’re very pleased with our pharmacodynamic profile,” he said. “Anaphylm will raise your systolic blood pressure rather quickly and keep it elevated at least 10 mm of mercury or above for the first 30 minutes or so. And when someone is experiencing an anaphylactic reaction, that is a rather important element.”

Previous studies have indicated no evidence of serious adverse events as well, Barber said, with approximately 99% of adverse events classified as mild and self-resolving without any need for intervention.

“Really importantly, it does avoid the injection site reactions and the risk of accidental intravascular injections associated with [intramuscular] administration,” Kraus said. “We’re pleased with the safety profile that we’ve gleaned so far.”

The film and packaging are durable as well, he continued, with testing [designed to mirror real-world conditions](#).

“If you find yourself in a rainstorm, the foil sachet will protect the product. If you accidentally left the film in your pocket and put it through the washing machine, the foil will protect the product,” Barber said.

“You can be on top of a ski mountain and our product will still be usable. It doesn’t freeze. You can leave it on the seat of your car in Phoenix in the summertime, and it will still be durable,” he added.

Barber further noted that Aquestive is currently working with the FDA about how these parameters will be included in Anaphylm’s product label.

Additionally, Kraus said that Anaphylm was [tested against oral allergy syndrome](#) (OAS) in a challenge model.

“OAS is on the continuum of typical type 1 reactions. Individuals with significant and severe OAS symptomatology do end up, in one way or another, having anaphylactic-type reactions,” Kraus said.

Globally, approximately 5% to 7% of patients with OAS develop type 1 reactions, he continued, but this testing gave Aquestive the confidence that if Anaphylm works in OAS, it can potentially work in more severe manifestations of type 1 reactions.

“We’re very pleased with the challenge model in allowing us to assess the [pharmacokinetic] profile of Anaphylm in that kind of environment, but we also had the inadvertent benefit of also evaluating symptom resolution data, and those were all quite positive,” he said.

Barber said that Aquestive now has “a complete clinical package” for its NDA and does not anticipate any additional research before Anaphylm’s potential approval.

“The FDA will engage with us, ask questions, look for clarification, and we’ll respond and make sure they have everything they need for their review,” Barber said.

The FDA has assigned a Prescription Drug User Fee Act target action date of Jan. 31, 2026, although Barber noted that the agency has told Aquestive that it may decide to conduct an advisory committee meeting before approval.

“The FDA, at times, wants to get the viewpoint of the community that would be serviced by whatever product is under review,” he added.

If approved, Aquestive reported, Anaphylm would be the first and only orally delivered epinephrine option for treating severe allergic reactions in the United States. Based on the company’s interactions with advocacy groups, Barber said, the allergy community is eager to use it.

“They do a really good job of focusing on how do we get more choice? How do we get better products? How do we get more innovation for our patient population?” Barber said. “There’s a lot of excitement about what we bring to the table.”

Barber added that he and his colleagues are excited as well.

“We think we have a product that truly can make a difference,” he said. “We want to get it in the hands of patients so they can benefit from it.”

For more information:

Daniel Barber, MBA, and Carl N. Kraus, MD, FACP, can be reached at allergy@healio.com.

[Lynda Mitchell, MA, CAE](#)

PERSPECTIVE



We know that many people do not carry epinephrine autoinjectors for a variety of reasons. We want people to carry epinephrine so they have it readily available in the event that anaphylaxis occurs. As the saying goes, accidents are never planned. We know some people do not carry autoinjectors because of their size or their fear of needles. That is why we welcome alternatives to needle-based autoinjectors. This will encourage more people to carry epinephrine with them and use it without hesitation when needed.

The advantages of using a sublingual form of epinephrine include that it is needle-free. It is more compact and easier to carry, and it is also simpler to use than an autoinjector. A sublingual film will avoid situations that can occur sometimes with autoinjectors, such as inadvertent injections into a person’s thumb from it being used incorrectly.

The disadvantages may include unfamiliarity with this new way to administer epinephrine. People will have to learn to have confidence in taking or administering a sublingual film to treat anaphylaxis. They must learn that the medication should be placed under the tongue until it dissolves and that it should not be swallowed. Some people may prefer using their tried-and-true autoinjectors, and that is OK! We want people to choose whatever is best for them in an emergency.

Allergy & Asthma Network is keeping an eye on the price point for Anaphylm. In general, the affordability of epinephrine is sometimes a barrier to filling a prescription for it. Anaphylm may offer a more affordable option compared with autoinjectors, which have faced criticism for high costs in the past.

This is a new day for those living with anaphylaxis. New treatment options now provide choices that we hope will encourage more people to carry epinephrine and use it when needed. Our mantra is “epi first, epi fast.” Poor outcomes often result from a delay in administering epinephrine when signs and symptoms of anaphylaxis are apparent.

Anaphylm, once approved, is a new option that will allow more people to carry and use epinephrine. More lives will be saved, and quality of life will improve for many people who may not carry or who hesitate to use autoinjectors. It will be especially helpful to people who care for children who have anaphylaxis, such as babysitters, teachers and grandparents. The process of administering a sublingual treatment is simpler than an autoinjector, which can be a scary thing for those who are unfamiliar with managing anaphylaxis.

Lynda Mitchell, MA, CAE
CEO, Allergy & Asthma Network

Disclosures: Mitchell reports no relevant financial disclosures.

Sources/Disclosures

Collapse —

Source: [Press Release](#)

Disclosures: Barber and Kraus report having employment with Aquestive Therapeutics.

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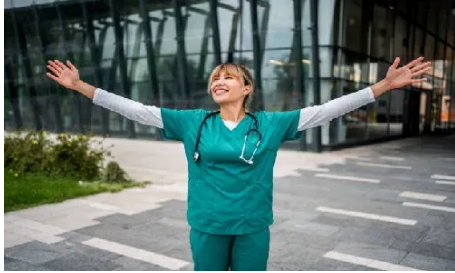


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