Anaphylm™ (epinephrine) Sublingual Film Oral Allergy Syndrome Challenge Study Supplemental Materials

October 24, 2024

Advancing medicines.
Solving problems.
Improving lives.

Disclaimer

Certain statements in this presentation include “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “may,” “will,” or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the advancement and related timing of our product candidate Anaphylm™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, including the timing of submission of supporting and pediatric clinical studies, holding a pre-NDA meeting with the FDA and filing the NDA for Anaphylm with the FDA, and the following launch of Anaphylm, if approved by the FDA; that the results of the Company’s clinical studies for Anaphylm are sufficient to support submission of the NDA for approval of Anaphylm by the FDA; the potential indications and potential benefits our products and product candidates could bring to patients; and business strategies, market opportunities, and other statements that are not historical facts.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with our development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans, including those relating to Anaphylm (including for pediatric patients); risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including the filing of the respective NDAs, including for Anaphylm, or the failure to receive FDA approval at all of any of these product candidates; risk of the Company’s ability to generate sufficient clinical data for approval of our product candidates, including with respect to our pharmacokinetic and pharmacodynamic comparability submission for FDA approval of Anaphylm; risk of the Company’s ability to address the FDA’s comments on the Company’s clinical trials and other concerns identified in the FDA Type C meeting minutes for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of the success of any competing products; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility and the Lincoln Park Purchase Agreement, and revenues from operations, to satisfy all of our short-term and longer-term liquidity and cash requirements and other cash needs, at the times and in the amounts needed, including to fund commercialization activities relating to fund future clinical development and commercial activities for our product candidates, including Anaphylm, should these product candidates be approved by the FDA; risk of eroding market share for Suboxone® and risk as a sunsetting product, which accounts for the substantial part of our current operating revenue; risk of default of our debt instruments; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance in the U.S. of Anaphylm and our other product candidates, should these product candidates be approved by the FDA, and for our licensed products in the U.S. and abroad; risk of the success of any competing products including generics; risk of the size and growth of our product markets; risk of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to our products; risk that our patent applications for our product candidates, including for Anaphylm, will not be timely issued, or issued at all, by the U.S. Patent and Trademark Office: risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business including relating to our products and products candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against Aquestive including patent infringement, securities, business torts, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; risks related to any disruptions in our information technology networks and systems, including the impact of cybersecurity attacks; risk of increased cybersecurity attacks and data accessibility disruptions due to remote working arrangements; risk of adverse developments affecting the financial services industry; risks related to inflation and rising interest rates; risks related to the impact of the COVID-19 global pandemic and other pandemic diseases on our business, including with respect to our clinical trials and the site initiation, patient enrollment and timing and adequacy of those clinical trials, regulatory submissions and regulatory reviews and approvals of our product candidates, availability of pharmaceutical ingredients and other raw materials used in our products and product candidates, supply chain, manufacture and distribution of our products and product candidates; risks and uncertainties related to general economic, political (including the Ukraine and Israel wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in the Company’s Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the U.S. Securities and Exchange Commission. Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to the Company or any person acting on its behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements or outlook or guidance after the date of this presentation whether as a result of new information, future events or otherwise, except as may be required by applicable law.

PharmFilm® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. The “Anaphylm™” trade name for AQST-109 has been conditionally approved by the FDA. Final approval of the Anaphylm™ proprietary name is conditioned on FDA approval of the product candidate, AQST-109. All other registered trademarks referenced herein are the property of their respective owners.

Aquestive

Key messages: Oral Allergy Syndrome (OAS) challenge study

1. Subjects experienced rapid symptom relief

- 94% of subjects were categorized as having moderate or severe reactions after exposure to an allergen
- Administration of Anaphylm™ (epinephrine) Sublingual Film resulted in rapid symptom relief in as little as two minutes
- The median time to complete symptom resolution after Anaphylm was administered is 12 minutes (includes single and repeat dose administrations)

2. Comparable pharmacokinetic (PK) profiles were observed

- Exposure to an allergen had little to no impact on the PK profile of Anaphylm when compared to no exposure to an allergen
- A consistent PK profile was observed for both single and repeat doses of Anaphylm

3. Consistent pharmacodynamic (PD) profiles were observed

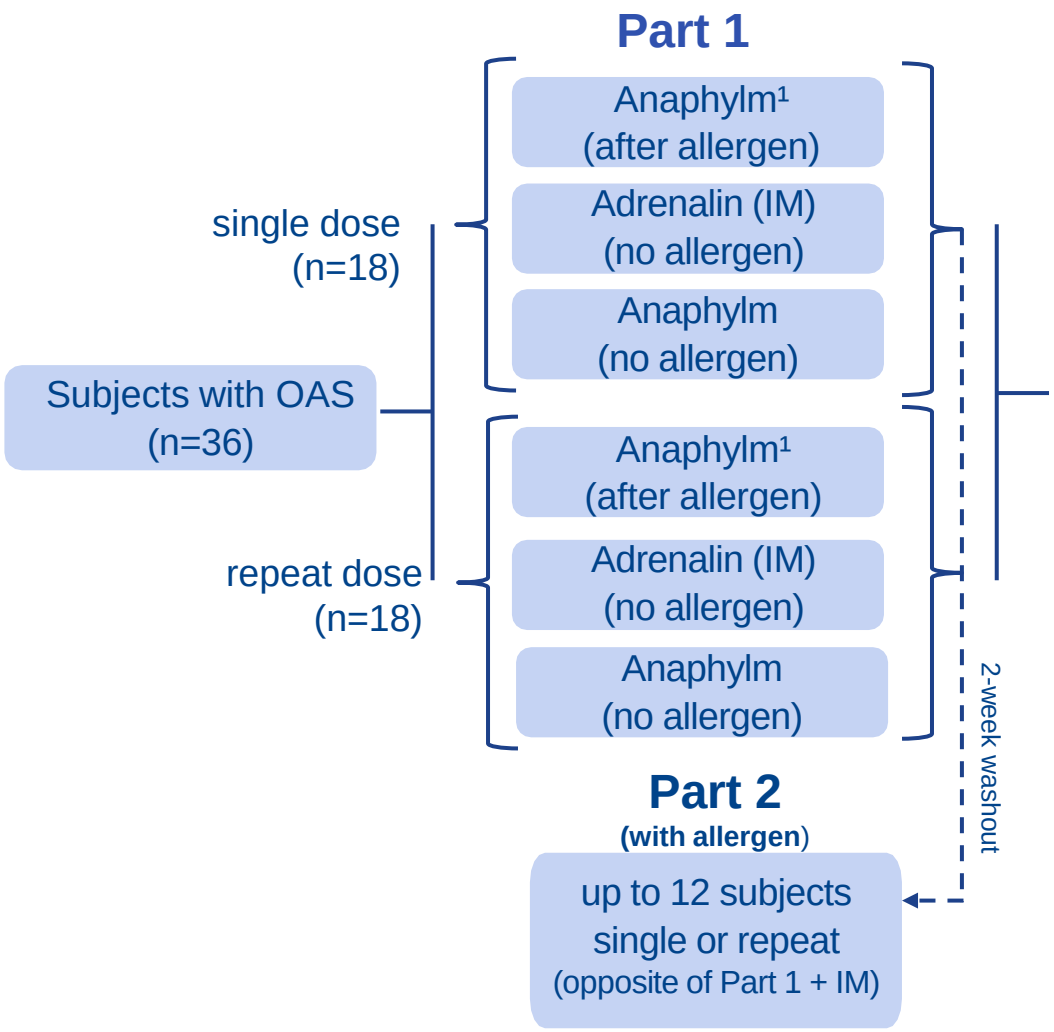
- Change from baseline for blood pressure and heart rate remained consistent with previous studies

4. All adverse events were either mild or moderate and resolved without medical intervention

OAS challenge study design

Study Design

Two-part investigation to evaluate the pharmacokinetics (PK) and pharmacodynamics (PD) of Anaphylm in adults with allergen-induced oral physiological change



Pharmacokinetics/ Pharmacodynamics

Primary endpoints: a comparison of PK after allergen exposure to the Adrenalin intramuscular (IM) injection with no allergen exposure

Clinical

Verbal Rating Scale (VRS) of subject reported symptoms (0 – resolved, 1 – resolving, 2 – no change, 3 – worsening)

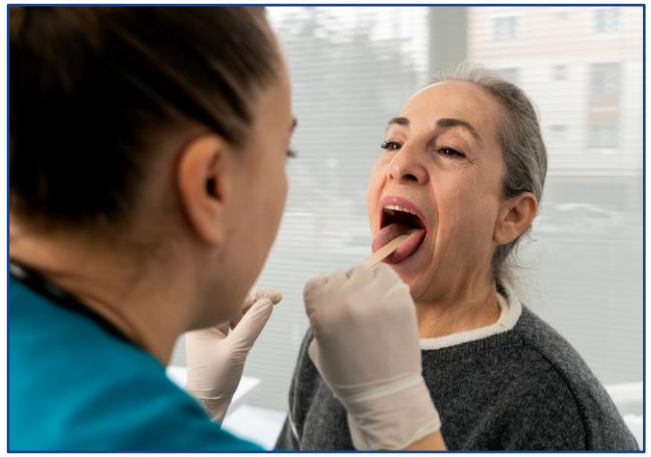
1.Volunteers with OAS were challenged by exposure to the allergen known to trigger their reaction (e.g., apple, cherry, mango, melon, kiwi, celery, banana or carrot).

Aquestive

OAS challenge study induced subject reactions

Step #1:
OAS subject's oral cavity exposed to allergen

Step #2:
Assessment of symptom severity[1]



First subject visit

Screening
Clinician tracks subject's symptoms until resolution

Second subject visit

Dosing

1. **Subjects received either single dose or repeat dose of Anaphylm**
2. **Clinician tracks subject's symptoms from time of dosing until resolution**

1. Steps #1 and #2 repeated until symptom score is moderate/severe; Only occurred in one subject.

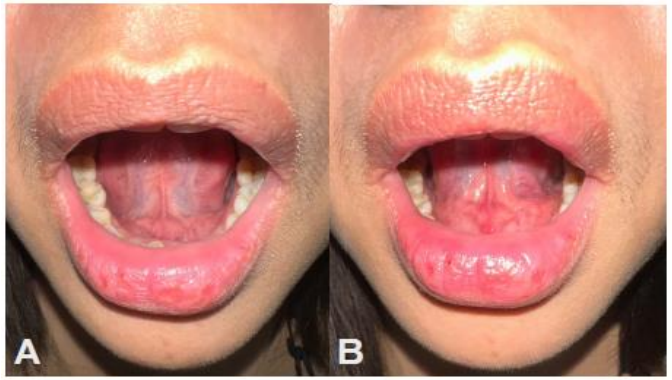
Aquestive

Subjects were exposed to an allergen prior to dosing

Allergen	# Exposures
Pineapple	14
Red Apple	7
Kiwi	7
Cherry	3
Banana	2
Avocado	2
Fig	2
Grapefruit	2
Lychee	2
Tangerine	2
All other	4
Total	**47[1]**

Subject profile	Post allergen challenge	Mucosal changes
17% severe 77% moderate 6% mild	100% had oral symptoms 36% also had systemic symptoms 100% successful administration of film	100% reported symptoms of allergic response in mucosa 81% reported ≥ 2 symptoms of allergic response in mucosa 25% reported swelling

Select Symptoms of Interest	% of dosing's with specified symptom
Lip swelling	31.9%
Throat swelling	10.6%
Tongue swelling	6.4%
Cheek swelling	4.3%
Nasal congestion	2.1%
Sublingual swelling	2.1%



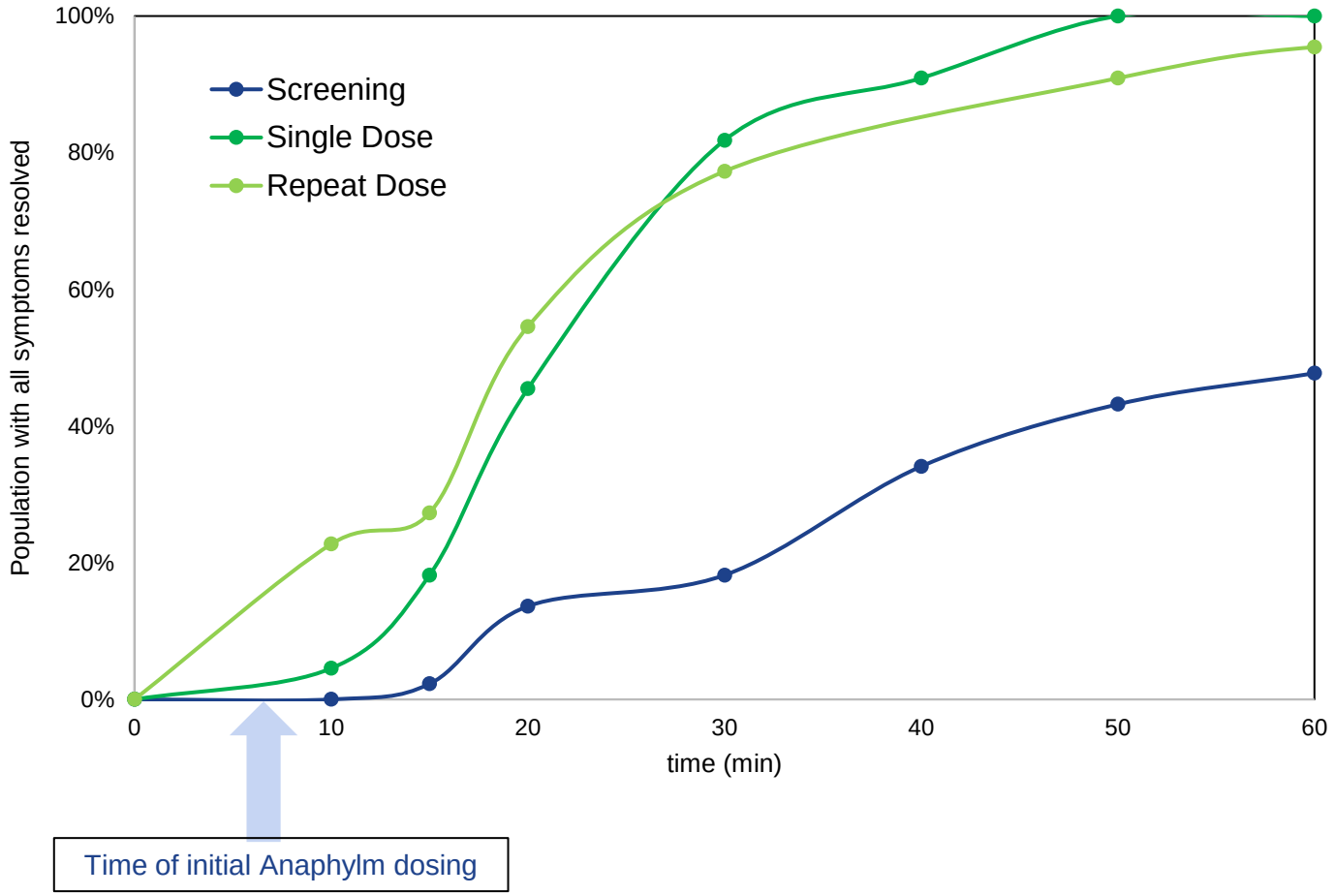
For illustrative purposes, not a subject in OAS challenge study[2]

1. Thirty-five subjects participated in Part 1, 12 patients returned for participation in optional Part 2, totaling forty-seven exposures. 2. Irin Vichara-anont JAAAAI Volume 153, (2) 2024.

Aquestive

Complete symptom resolution occurs rapidly after Anaphylm administration[1]

Time from allergen exposure to complete symptom resolution following screening, single dose, and repeat dose administration of Anaphylm



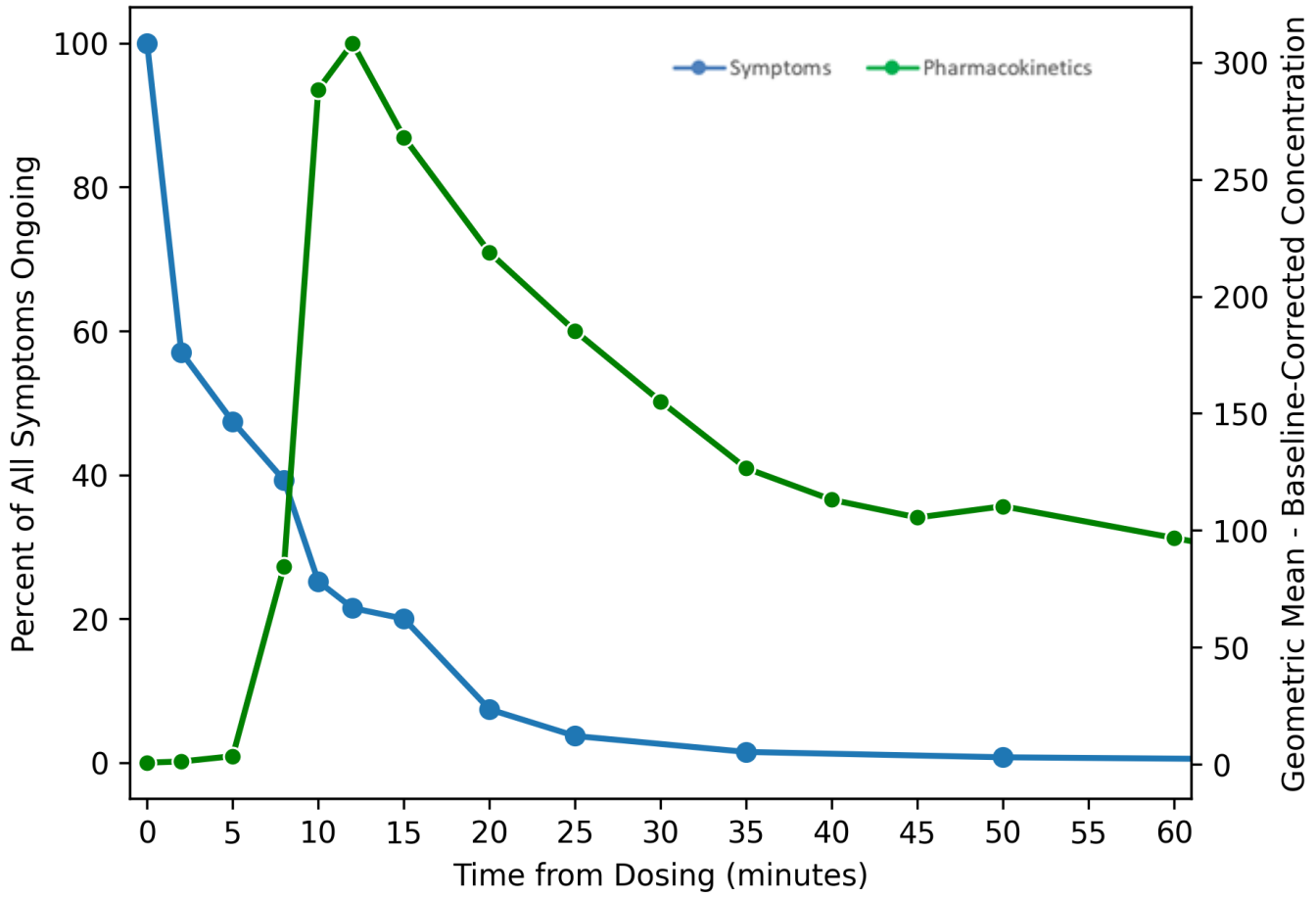
- Median time to complete symptom resolution was 12 minutes after Anaphylm administration
- Median time to resolution was 74 minutes without Anaphylm administrations

1. Aquestive Therapeutics data on file.

Aquestive®

Symptom relief correlates to Anaphylm PK levels[1,2]

Time comparison of geometric mean baseline corrected epinephrine concentration and symptom resolution following allergen exposure and single dose administration of Anaphylm



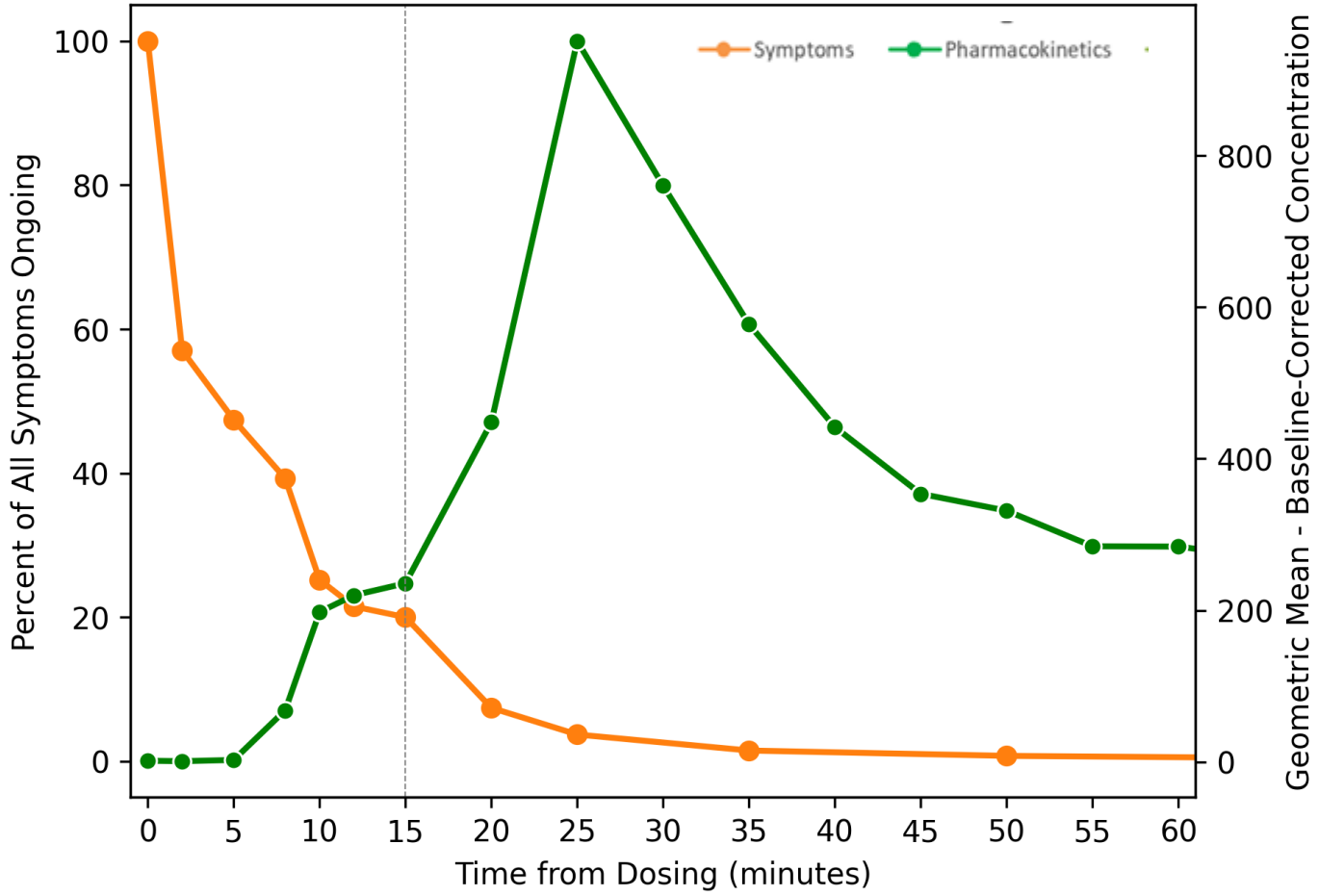
- Symptom resolution was observed as early as 2 minutes in some subjects
- Median symptom resolution was 5 minutes

1. Aquestive Therapeutics data on file. 2. Data represent per protocol patient population.

Aquestive

Symptom relief was also observed with repeat dosing of Anaphylm[1,2]

Time comparison of geometric mean baseline corrected epinephrine concentration and symptom resolution following allergen exposure and repeat dose administration of Anaphylm



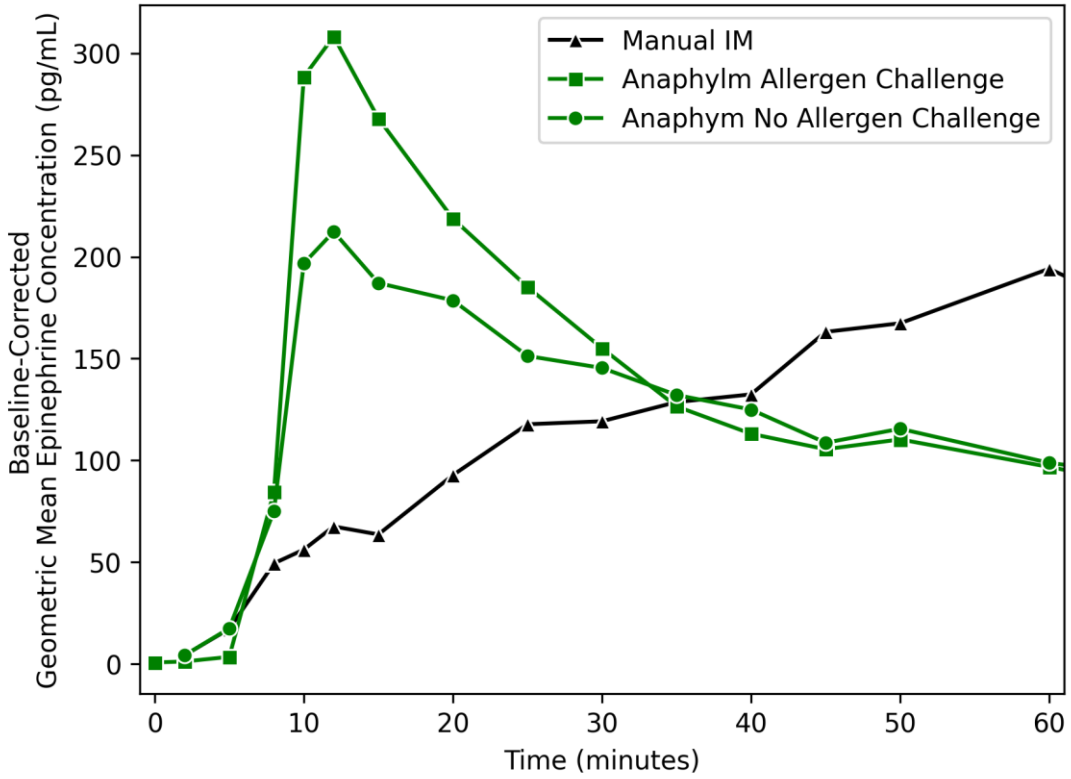
- Repeat dose at 15 minutes resulted in rapid resolution of remaining symptoms

1. Aquestive Therapeutics data on file. 2. Data represent per protocol patient population.

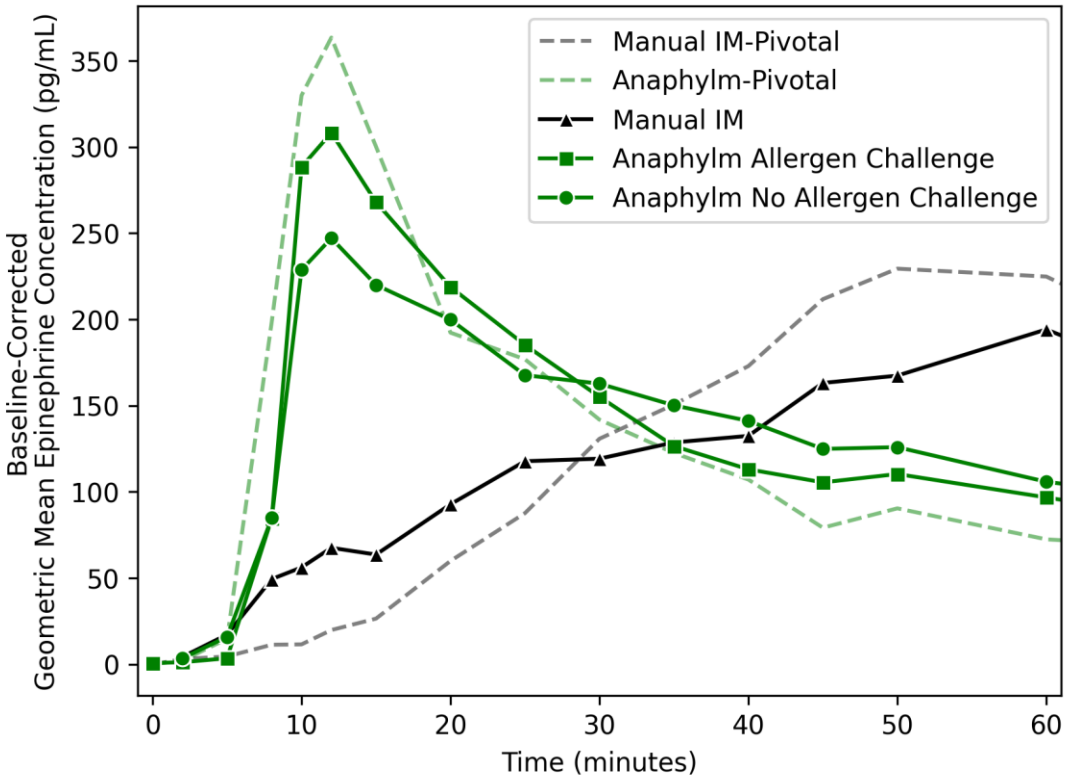
Aquestive

Anaphylm PK profile remains consistent with and without allergen exposure[1,2]

Geometric mean baseline-adjusted epinephrine concentration over time in OAS subjects after single dose administration



Geometric mean baseline-adjusted epinephrine concentration over time in OAS subjects after single dose administration compared to previously reported pivotal data



1. Aquestive Therapeutics data on file. 2. Data represent per protocol patient population.

Aquestive

Anaphylm single dose meets primary endpoints under oral allergen challenge[1,2]

- *Primary endpoints predefined as Anaphylm values above manual injection for maximum concentration (1) Cmax and (2) $AUC_{0\text{-}10min}$, $AUC_{0\text{-}20min}$, $AUC_{0\text{-}30min}$, $AUC_{0\text{-}45min}$.*
- *No statistical impact of allergen challenge on key Anaphylm pharmacokinetics*

Cmax and Tmax[3]

Administration	Cmax (pg/mL)	Median Tmax (min)
Manual IM (n=24)	261.2	50
Anaphylm with allergen (n=23)	403.5	12
Anaphylm without allergen (n=15)	372.8	12

Partial AUC's (hr*pg/mL)[3]

Administration	$AUC_{0\text{-}10min}$	$AUC_{0\text{-}20min}$	$AUC_{0\text{-}30min}$	$AUC_{0\text{-}45min}$
Manual IM (n=24)	6.0	18.9	39.0	76.0
Anaphylm with allergen (n=23)	14.4	63.2	97.0	132.1
Anaphylm without allergen (n=15)	11.0	50.3	82.6	124.1

1. Aquestive Therapeutics data on file. 2 Data represent per protocol patient population. 3. Geometric means, median for Tmax.

Aquestive

Anaphylm repeat dose meets primary endpoints under oral allergen challenge[1,2]

- *Primary endpoints predefined as Anaphylm values above manual injection for (1) Cmax and (2) $AUC_{0\text{-}10min}$, $AUC_{0\text{-}20min}$, $AUC_{0\text{-}30min}$, $AUC_{0\text{-}45min}$.*
- *No statistical impact of allergen challenge on key Anaphylm pharmacokinetics*

Cmax and Tmax[3]

Administration	Cmax (pg/mL)	Tmax (min) median
Manual IM (n=22)	538.8	57.5
Anaphylm with allergen (n=23)	1194.0	25
Anaphylm without allergen (n=13)	585.5	25

Partial AUC's (hr*pg/mL)[3]

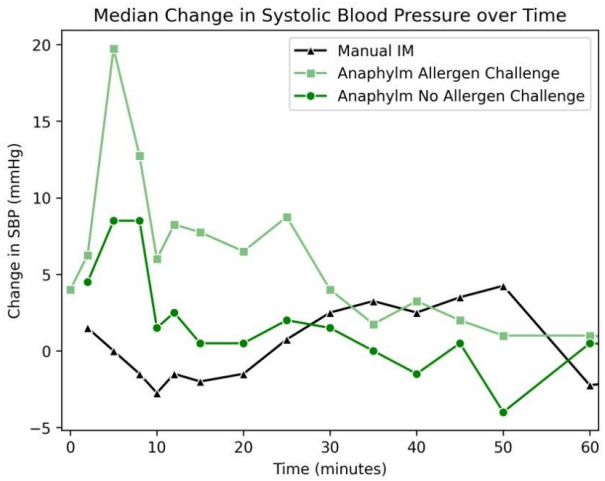
Administration	$AUC_{0\text{-}10min}$	$AUC_{0\text{-}20min}$	$AUC_{0\text{-}30min}$	$AUC_{0\text{-}45min}$
Manual IM (n=22)	5.1	15.5	39.2	99.4
Anaphylm with allergen (n=23)	10.1	62.6	216.8	360.5
Anaphylm without allergen (n=13)	9.2	35.0	106.5	180.4

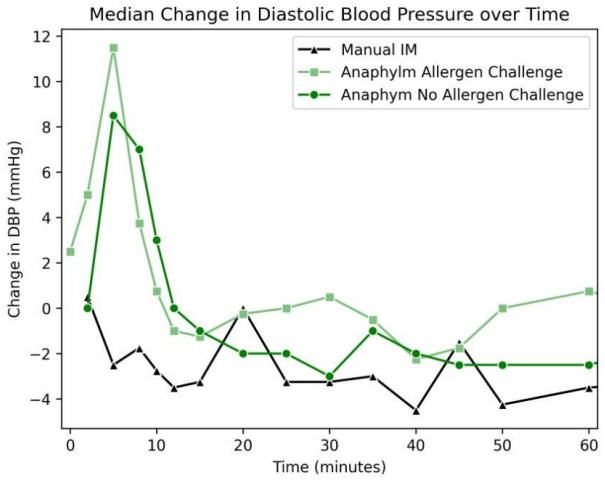
1. Aquestive Therapeutics data on file. 2 Data represent per protocol patient population. 3. Geometric means, median for Tmax.

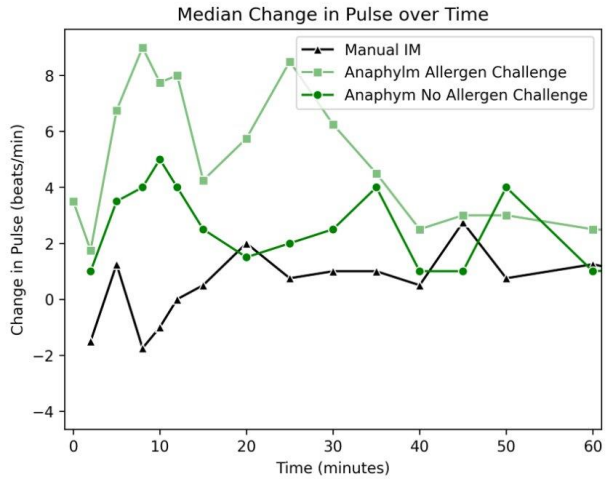
Aquestive

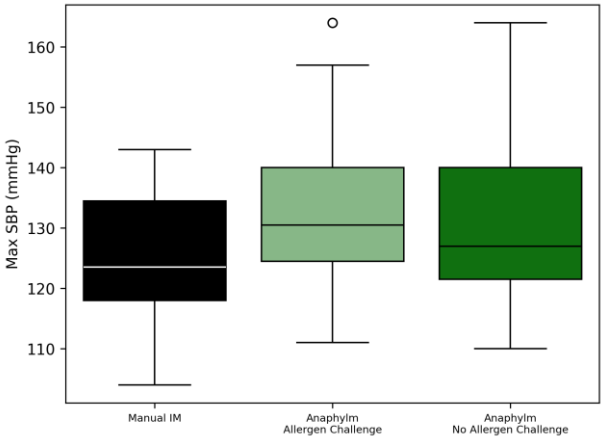
Single dose pharmacodynamics[1,2]

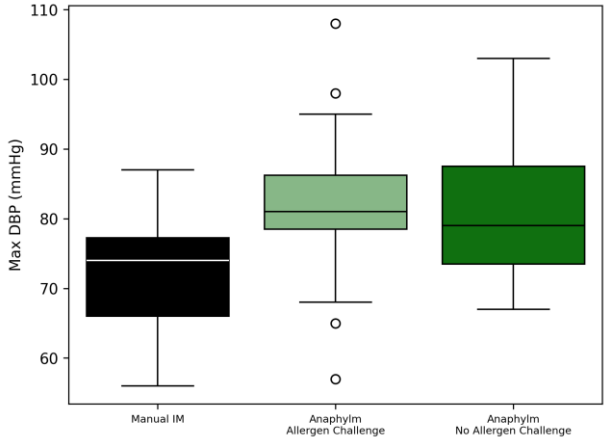
Anaphylm elicits the desired pharmacodynamic response in key metrics of Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Pulse (HR), consistent with and without allergen exposure

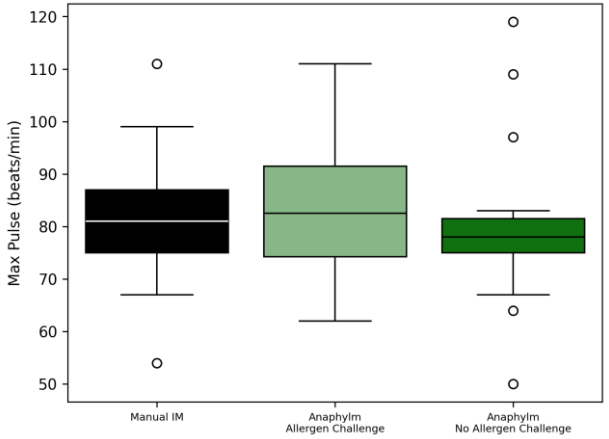








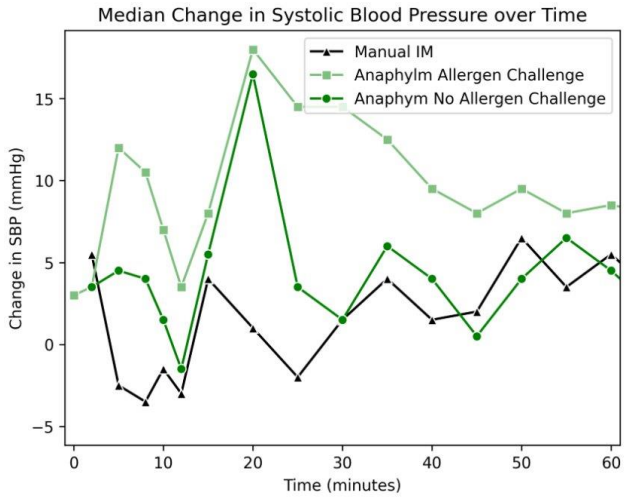


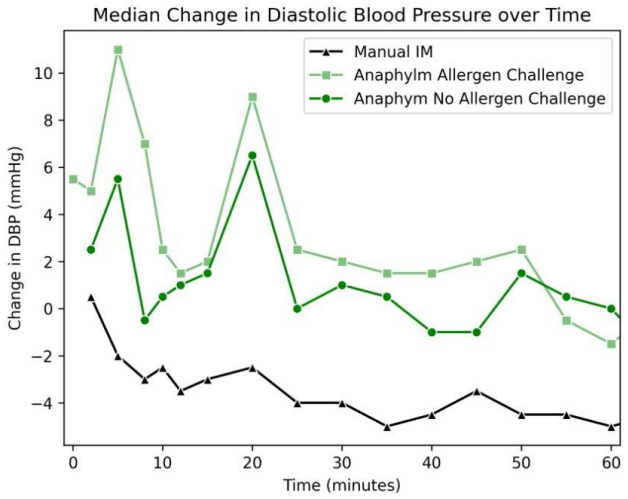


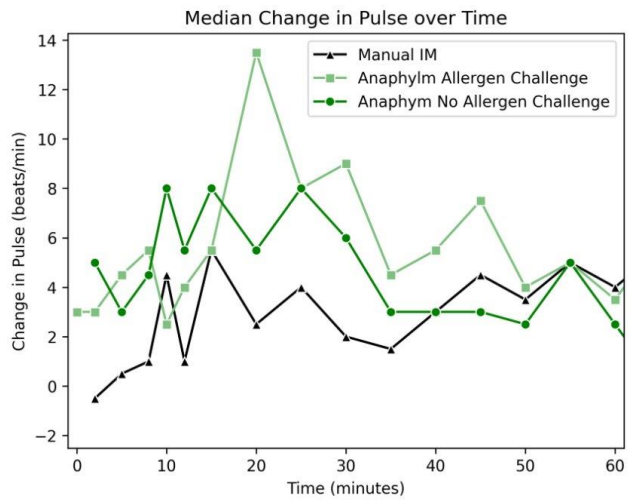
1. Aquestive Therapeutics data on file. 2. Data represent per protocol patient population..

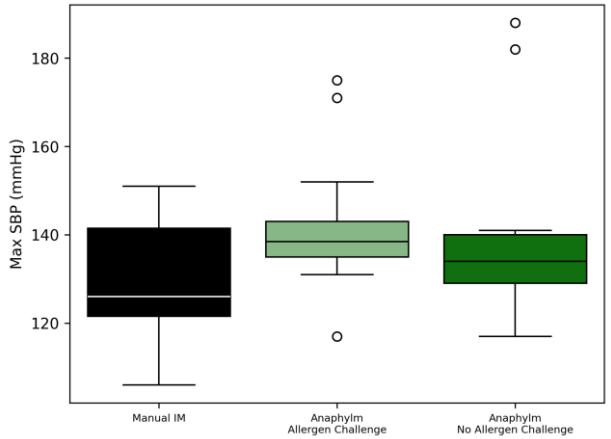
Repeat dose pharmacodynamics[1,2]

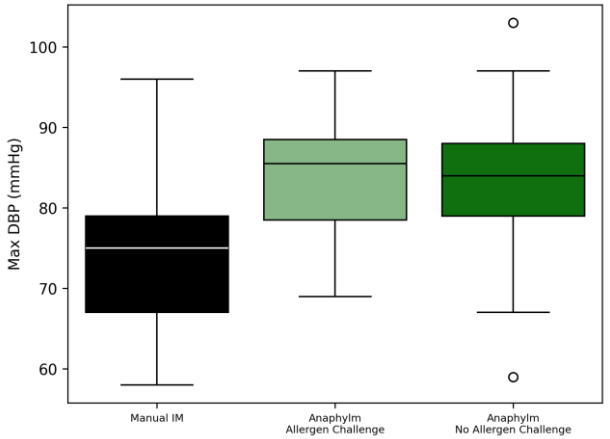
Anaphylm elicits the desired pharmacodynamic response in key metrics of SBP, DBP and HR, consistent with and without allergen exposure

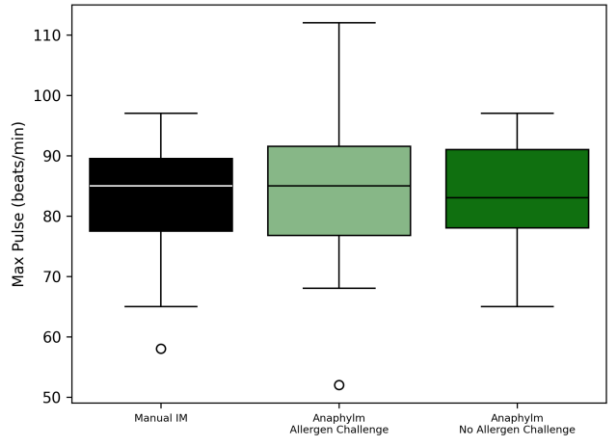












1. *Aquestive Therapeutics data on file.* 2. *Data represent per protocol patient population..*

OAS challenge study single dose safety summary[1]

- All treatment-emergent adverse events (TEAEs) were categorized as mild (Grade 1)
- No serious adverse events (SAEs) were observed
- TEAEs were transient and resolved without medical intervention
- Primary cardiovascular TEAE associated with mild palpitations were observed
- No emesis was reported in single dose administration

System Organ Class	Severity	12 mg Anaphylm with allergen challenge Incidence (%) n=24	0.3 mg Manual IM Incidence (%) n=23	12 mg Anaphylm without allergen challenge Incidence (%) n=16
Cardiac Disorders				
Palpitations (subjective, subject-reported)	Mild	2 (8.3%)	0	0
Gastrointestinal Disorders				
Nausea	Mild	1 (4.2%)	0	0

1. Aquestive Therapeutics data on file.

Aquestive

OAS challenge study repeat dose safety summary[1]

- Most TEAE (96.2%) were categorized as mild (Grade 1)
- No SAEs were observed
- TEAEs were transient and resolved without medical intervention
- Primary cardiovascular TEAE associated with mild palpitations were observed

System Organ Class	Severity	12 mg x 2 Anaphylm with allergen challenge Incidence (%) n=24	0.3 mg x 2 Manual IM Incidence (%) n=23	12 mg x 2 Anaphylm without allergen challenge Incidence (%) n=16
Cardiac Disorders				
Palpitations (subjective, subject-reported)	Mild	4 (16.7%)	0	0
Gastrointestinal Disorders				
Vomiting	Mild	1 (4.2%)	0	1 (6.3%)
Nausea	Mild	2 (8.3%)	0	0

1. Aquestive Therapeutics data on file.

Aquestive®

Thank You

Advancing medicines.
Solving problems.
Improving lives.