Aquestive®

Pivotal Study and FDA Meeting Supplemental Slides

March 2024

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Disclaimer

This presentation and the accompanying oral commentary have been prepared by Aquestive Therapeutics, Inc. ("Aquestive", the "Company", "our" or "us") and contains 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 for the emergency treatment of severe allergic reactions, including anaphylaxis, through clinical development and approval by the U.S. Food and Drug Administration (FDA), including the expected clinical studies and clinical study dates, the timing of the pre-NDA meeting with the FDA and Aquestive's goal of filing an NDA for Anaphylm before the end of 2024, the receipt and release of topline data from the Company's Anaphylm clinical studies and addressing the FDA's comments on the Company's pivotal pharmacokinetic (PK) study and other concerns identified in the FDA minutes from the Company's Type C meeting with the FDA for Anaphylm, the potential benefits Anaphylm could bring to patients, 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; risk of the Company's ability to generate sufficient data in the clinical trials for Anaphylm and addressing the FDA's comments on the Company's pivotal pharmacokinetic (PK) study and other concerns identified by the FDA in its minutes for the Type C meeting with the Company for Anaphylm; risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of delays in regulatory advancement through the FDA of Anaphylm or failure to receive FDA approval at all; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of the success of any competing products; risk of the rate and degree of market acceptance of our product candidates, including Anaphylm; risk of sufficient capital and cash resources, including insufficient 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 the Company's short-term and longer term liquidity and cash requirements and other cash needs, at the times and in the amounts needed, including to fund future clinical development activities for Anaphylm; risk of failure to satisfy all financial and other debt covenants and of any default under our existing debt financing; risk that our manufacturing capabilities will be sufficient to support demand for existing and potential future licensed products in the U.S. and other countries; risk of achieving growth in our base business; risk of our ability to enter into other commercial transactions with third parties that will support growth of our business and execution of key initiatives; risk of development of a sales and marketing capability for future commercialization of our product candidates; risk related to product liability and other claims against Indivior Inc. for which we license, manufacture and sell Suboxone® and which accounts for the substantial part of our current operating revenues; risk of eroding market share for Suboxone and its market position as a sunsetting product; 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 of our product and product candidates; risk of the success of any competing products including generic products; 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 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 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 cyberattacks; risk of increased cybersecurity attacks and data accessibility disruptions due to remote working arrangements; risk of the uncertainties of global business and macroeconomic conditions including adverse developments affecting the financial services industry, instability of the global banking system, and as a result of inflation and rising interest rates; risks and uncertainties related to general economic, geopolitical conflicts (including the wars in Ukraine and Israel and other acts of war and terrorism), business, industry, regulatory and market conditions and other unusual items; risks related to the impact of the COVID-19 global pandemic 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; and other risks and uncertainties affecting Aquestive, including those described in the "Risk Factors" section and in other sections included in the Company's recent 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 (SEC). Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. We assume no obligation to update forward-looking statements 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.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy any of the Company's securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

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Anaphylm Pivotal Study Results

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Phase 3 pivotal study meets all primary and secondary endpoints

Pivotal Study meets endpoints for single dose and repeat dose

- Single dose: maximum concentration (Cmax) and partial area under the curve (AUC) measures met as predefined
- Repeat dose: Safety and pharmacokinetic (PK) sustainability measures met as predefined

Positive FDA Type C meeting provides clarity on path to filing

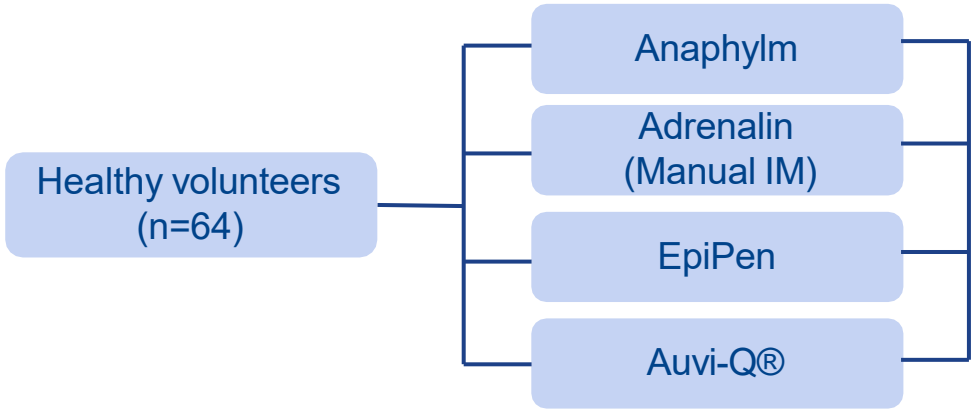
- Alignment reached on open items from end-of-phase 2 meeting
- FDA remains consistent on approach to PK sustainability and comparability to existing autoinjectors

We continue to anticipate a pre-NDA meeting with FDA prior to filing

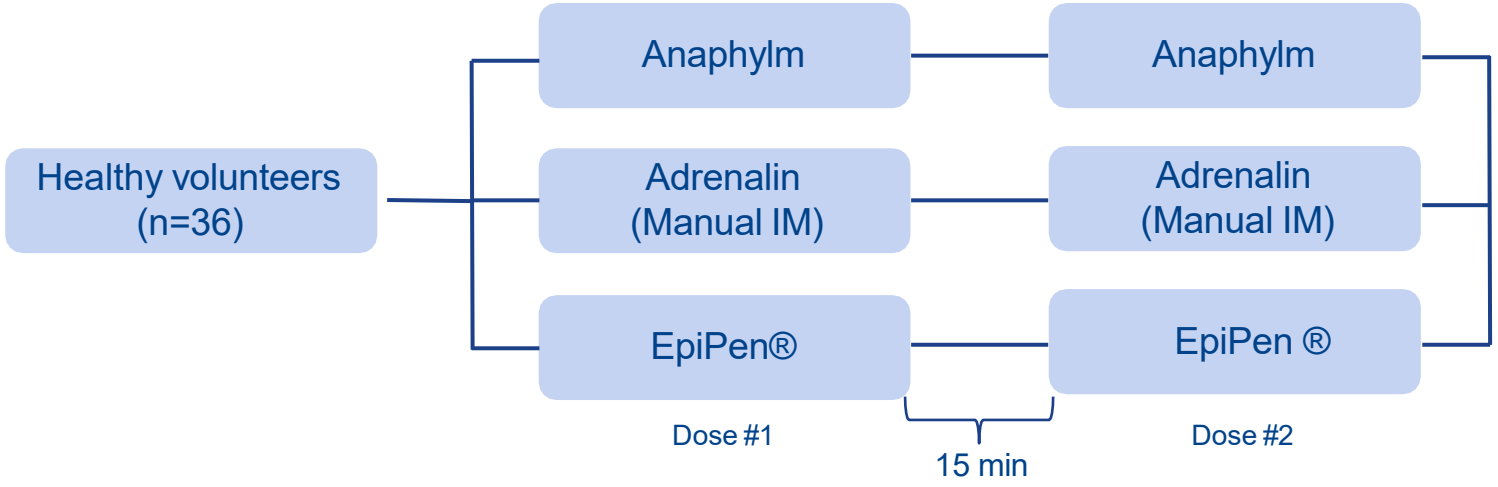
- Pre-NDA meeting to align on content and format of the NDA submission

Anaphylm™ pivotal study design

Single Dose



Repeat Dose



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Key endpoints

Pharmacokinetic (PK)

- Maximum plasma concentration (Cmax)
- Time to maximum plasma concentration (Tmax)
- Partial area under the curve at 10, 20, 30, and 45 minutes
- Subjects reaching 100pg/mL over time

Pharmacodynamic (PD)

- Change in systolic blood pressure (SBP)
- Change in diastolic blood pressure (DPB)
- Change in heart rate (Pulse)

Anaphylm Topline Pivotal Study Results: Single Dose (n=64)

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Anaphylm 12mg single dose study meets primary endpoints

Primary endpoints predefined as Anaphylm values bracketed between injectable products for (1) Cmax and (2) $AUC_{0\text{-}10min}$, $AUC_{0\text{-}20min}$, $AUC_{0\text{-}30min}$, $AUC_{0\text{-}45min}$.

Cmax Bracketing

	Amnt (pg/mL)
Auvi-Q	520.6
Anaphylm	470.2
EpiPen	469.2
Adrenalin	308.2

All figures are baseline corrected and geometric means

Partial AUCs Bracketing (hr*pg/mL)

	$AUC_{0\text{-}10min}$	$AUC_{0\text{-}20min}$	$AUC_{0\text{-}30min}$	$AUC_{0\text{-}45min}$
Adrenalin	3.3	11.3	29.7	74.6
Anaphylm	17.7	71.5	104.8	138.6
EpiPen	23.4	62.0	109.7	179.8
Auvi-Q	21.8	61.5	112.4	200.3

$pAUC_{0\text{-}20min}$ not statistically different ($p > 0.05$) (comparison to EpiPen))

All figures are baseline corrected and geometric means

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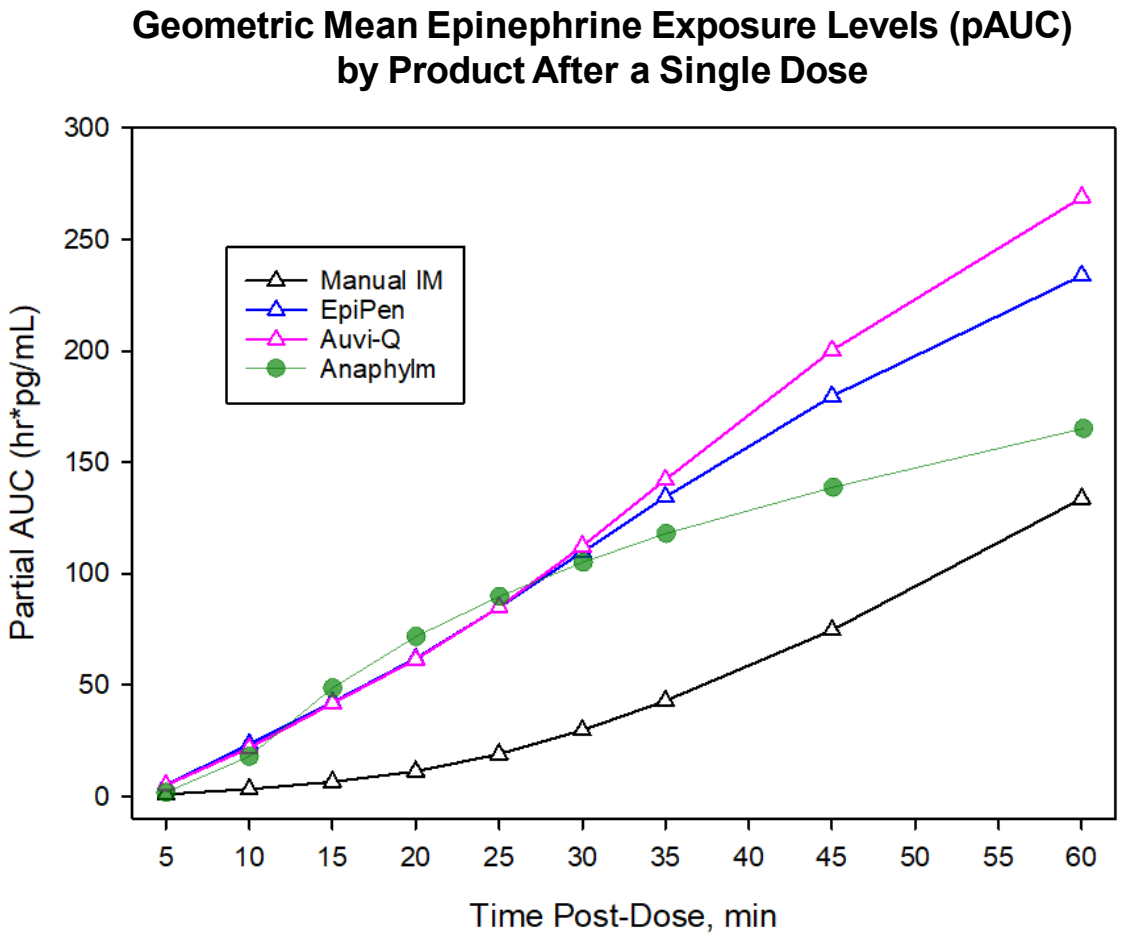
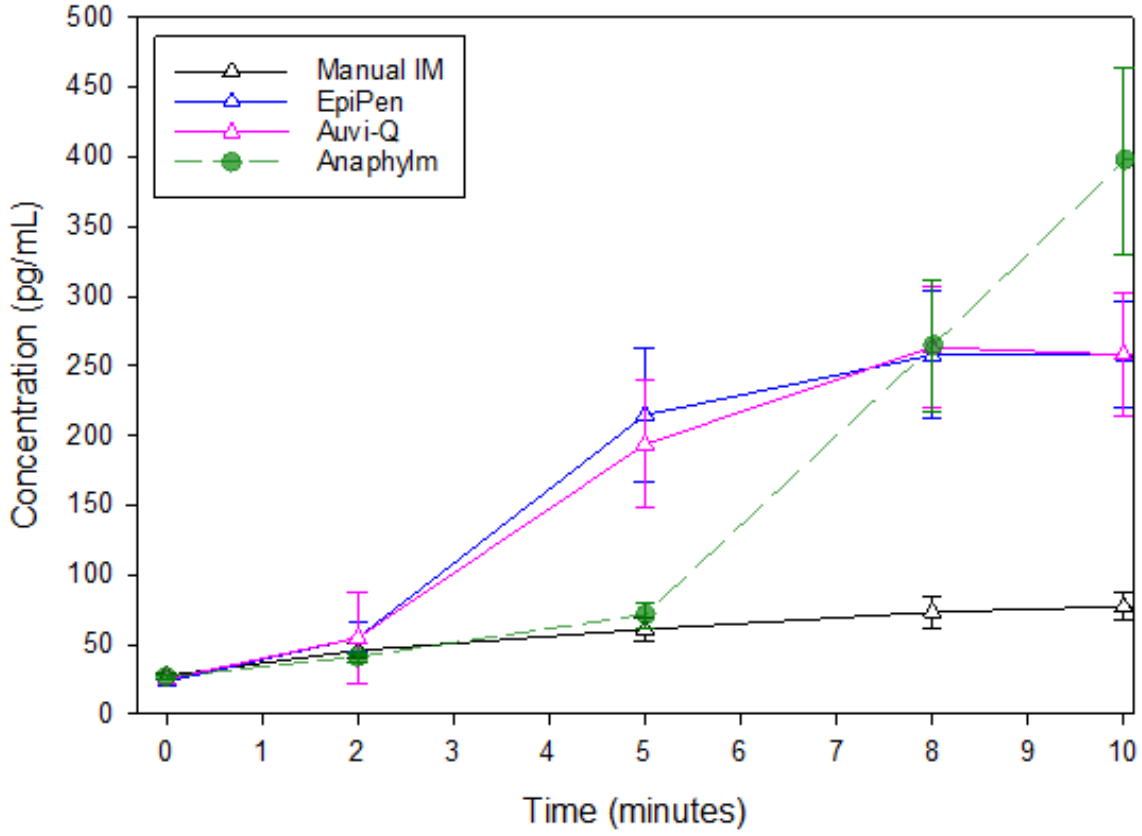
Anaphylm is biocomparable to injectors



- Anaphylm partial AUC values are comparable to autoinjectors for 30 minutes post dosing and remain bracketed past 60 minutes after dosing

AnaphyIm continues to show rapid uptake during the first 10 minutes after dosing

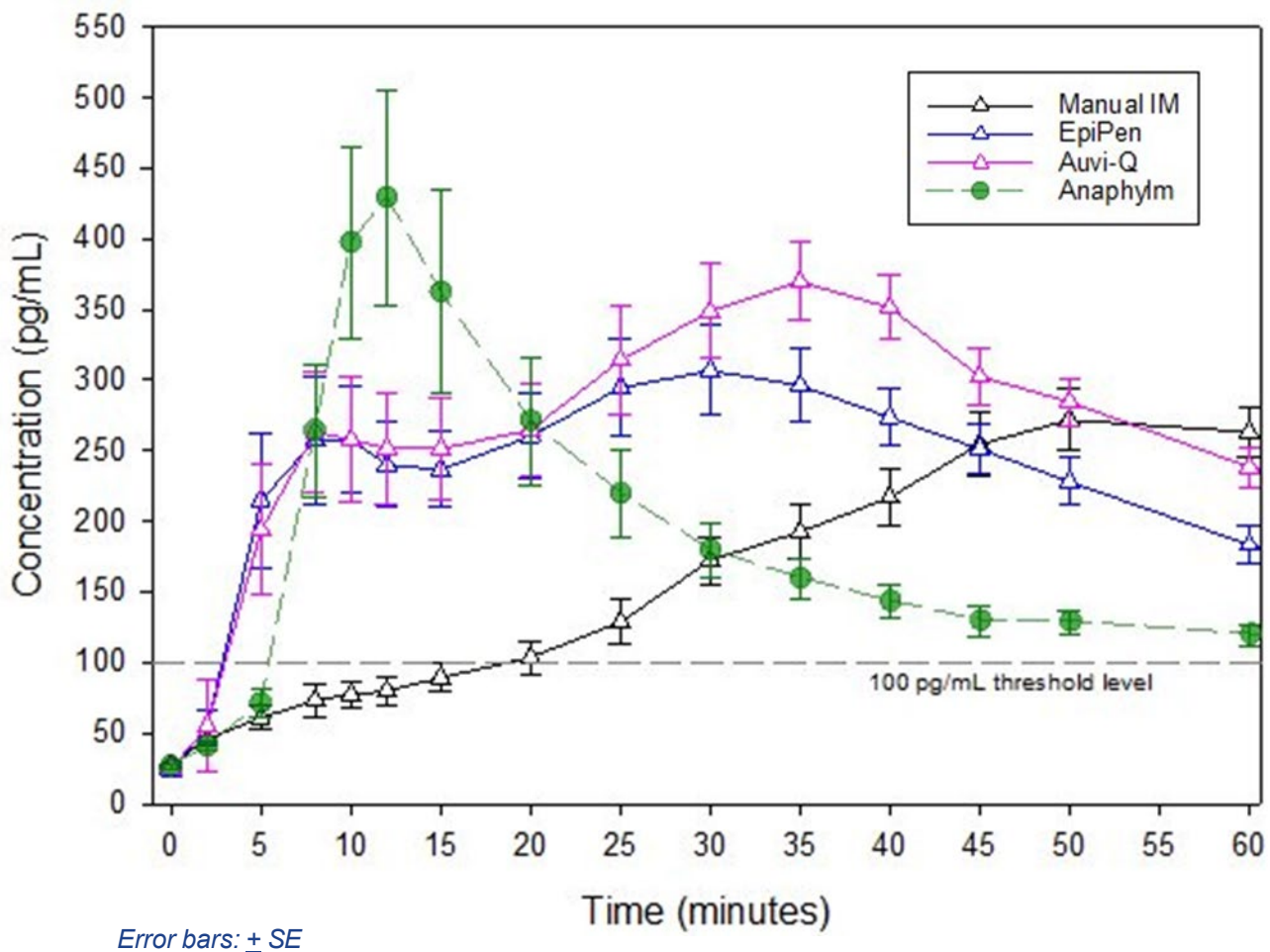
Geometric Mean Epinephrine Timepoint Concentrations by Product After a Single Dose



- Rapid uptake follows film dissolution and absorption profile

Anaphylm remains above 100 pg/mL at 60 minutes after dosing

Geometric Mean Epinephrine Concentrations by Product After a Single Dose

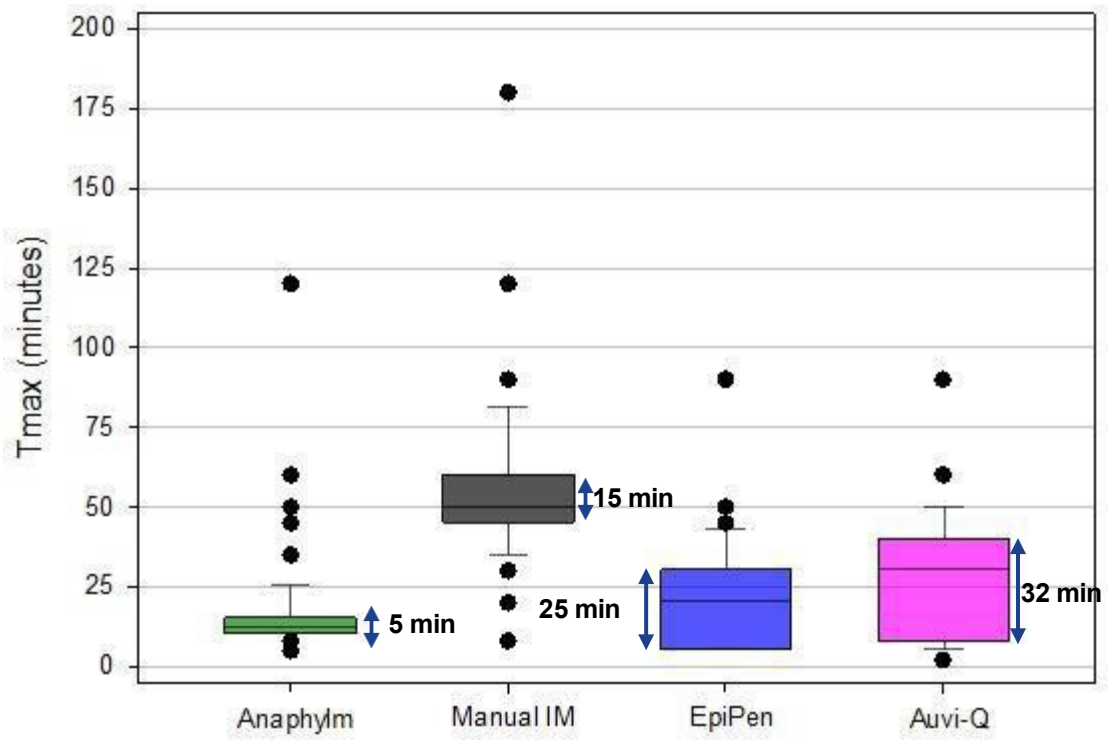


Error bars: ± SE

- Anaphylm achieves rapid PK within first 10 minutes similar to autoinjectors
- Anaphylm exceeds Adrenalin beginning at 2 minutes
- PK is sustained greater than Adrenalin out to 35 minutes
- PK is sustained greater than 100 pg/mL for duration of observation period

Time to maximum concentration (Tmax) of Anaphylm significantly more consistent compared to autoinjectors

Time Post-Dosing to Maximum Concentration of Epinephrine



- Tmax is a surrogate for speed of absorption, a critical factor in treating anaphylaxis
- Tmax consistency is an important measure of clinical performance
- Anaphylm Tmax interquartile range (5 min) is significantly more consistent than EpiPen, Auvi Q, and Adrenalin
- Anaphylm median Tmax of 12 minutes is faster than EpiPen (20 mins), Auvi Q (30 mins), and Adrenalin (50 mins)

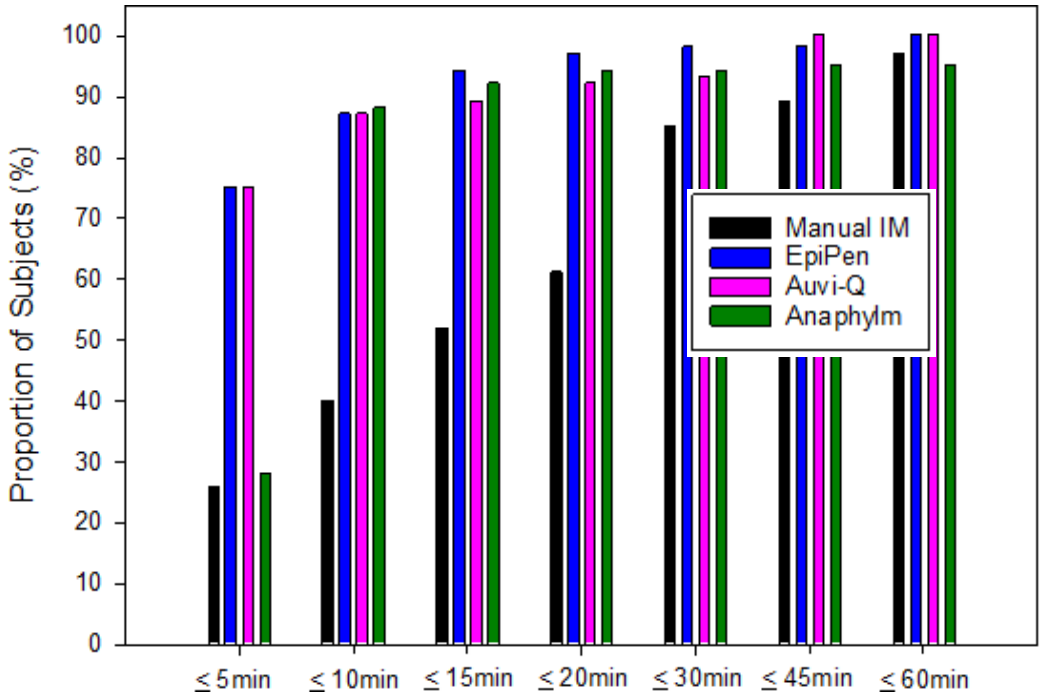
Anaphylm reaches 100 pg/mL threshold as rapidly as EpiPen and faster than Adrenalin

Common FDA-cited key threshold level is an important target to achieve hemodynamic stability and curb the progression of anaphylaxis.

Time (minutes)	Number and Proportion of Subjects >100 pg/mL			
	Adrenalin* (N=62)	EpiPen (N=63)	Auvi-Q (N=61)	Anaphylm (N=64)
5	16 (26%)	47 (75%)	46 (75%)	18 (28%)
10	**25 (40%)**	**55 (87%)**	**53 (87%)**	**56 (88%)**
15	32 (52%)	59 (94%)	54 (89%)	58 (92%)
20	37 (61%)	61 (97%)	56 (92%)	59 (94%)
30	53 (85%)	62 (98%)	57 (93%)	60 (94%)
45	55 (89%)	62 (98%)	61 (100%)	61 (95%)
60	60 (97%)	63 (100%)	61 (100%)	61 (95%)

* Subject 139 is missing the 15-, and 20-minute concentration. Therefore, the percent at these timepoints is based on N=61.
@ Subject 108 is missing the 15- and 20-minute concentration. Therefore, the percent at these timepoints is based on N=63.

Proportion of Subjects Achieving 100 pg/mL in Single Dose Pivotal Study



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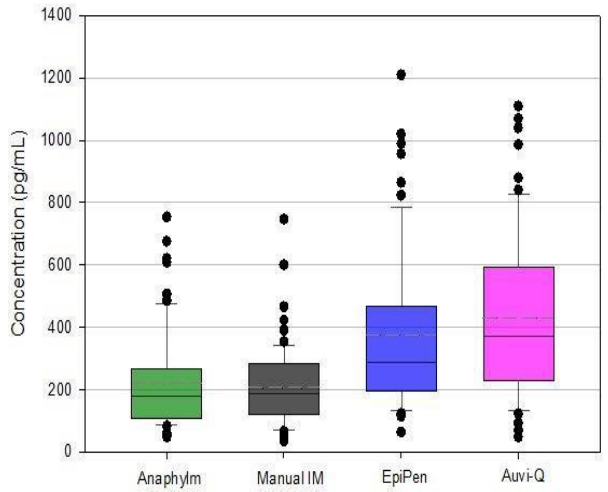
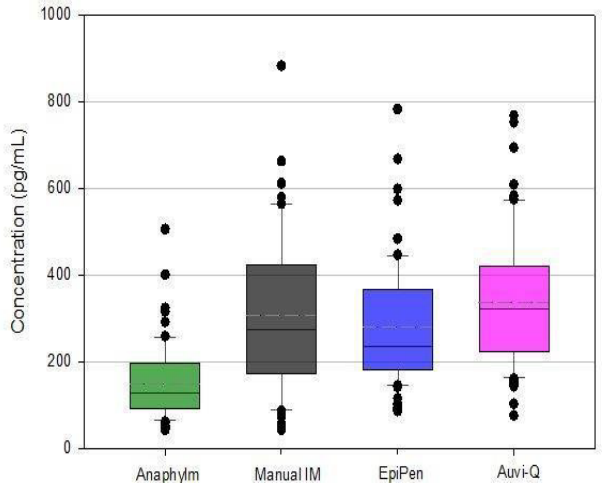
Anaphylm overlaps with comparators at later timepoints (PK Sustainability)

- Anaphylm remains above the 100 pg/mL threshold well past the critical time for treatment
- Overlapping exposures even after 30 minutes with comparators reinforces comparable sustainability beyond the critical time for treatment

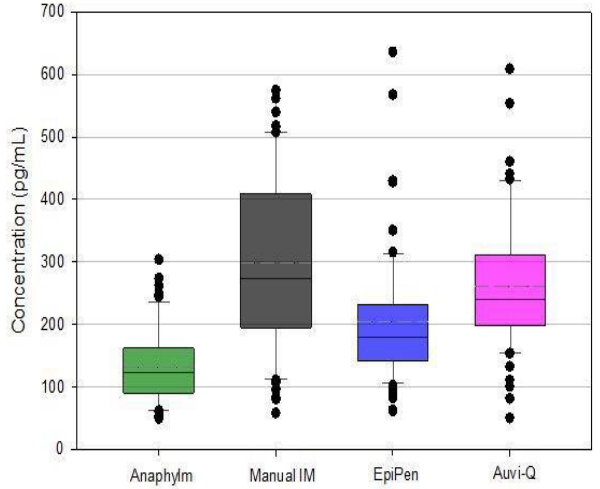
Timepoint: 30 minutes



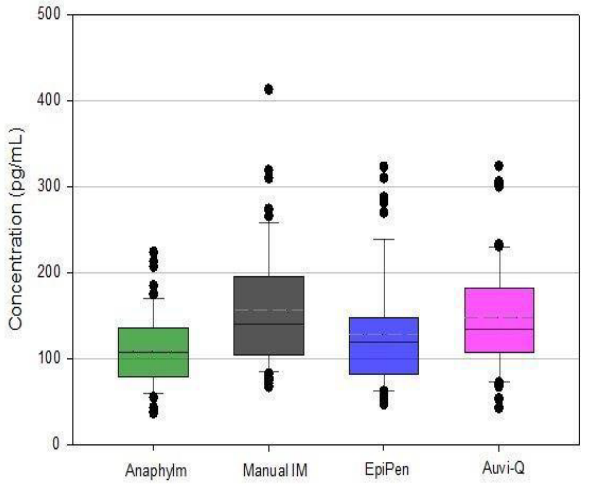
Timepoint: 45 minutes



Timepoint: 60 minutes



Timepoint: 90 minutes



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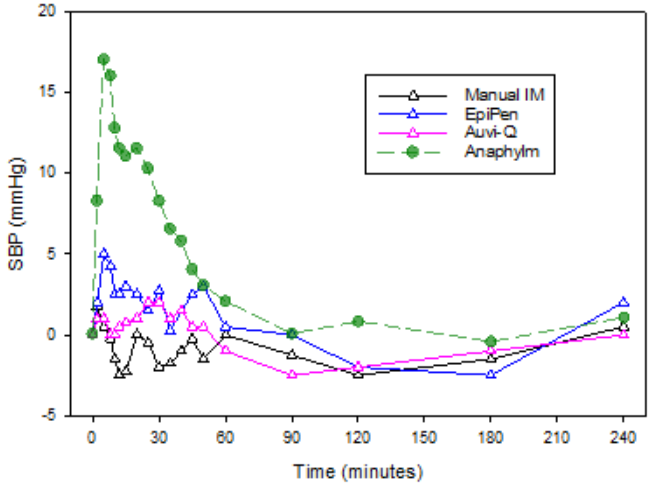
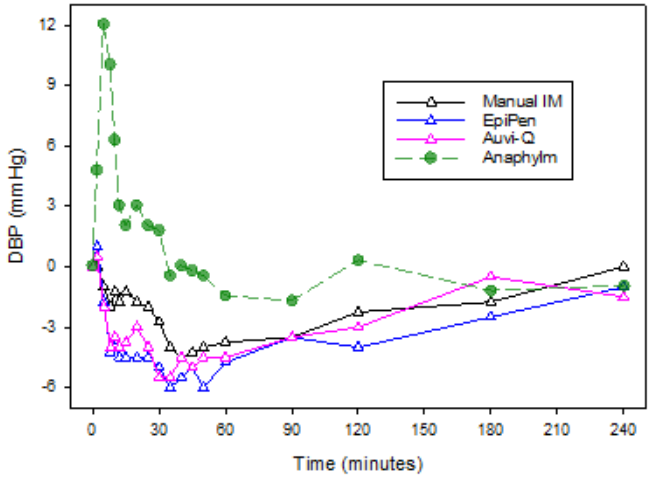
Pharmacodynamics consistent with previous results

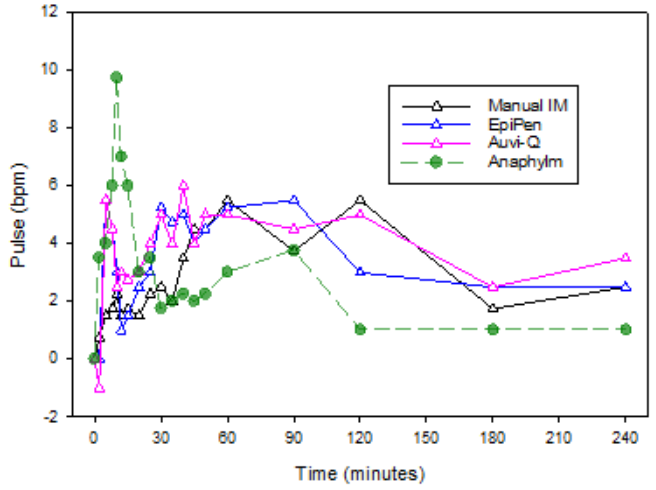
Median Change in Systolic Blood Pressure over Time



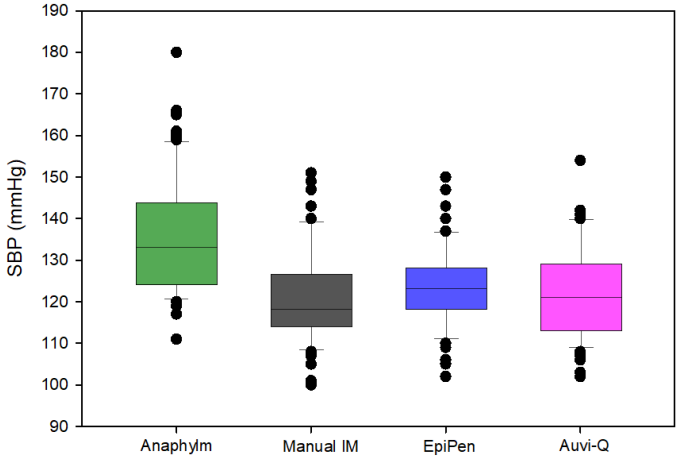
Median Change in Diastolic Blood Pressure over Time



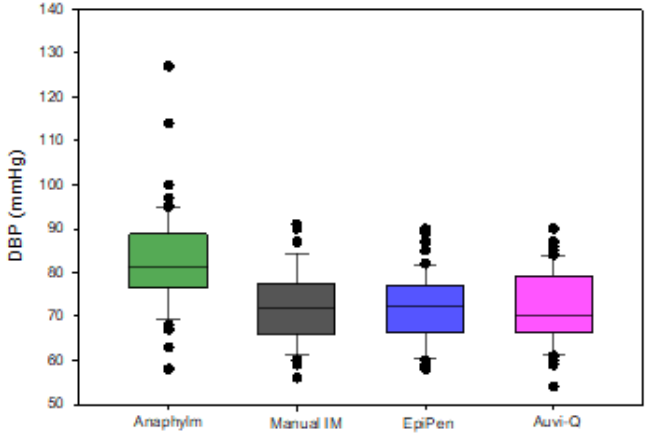
Median Change in Pulse over Time



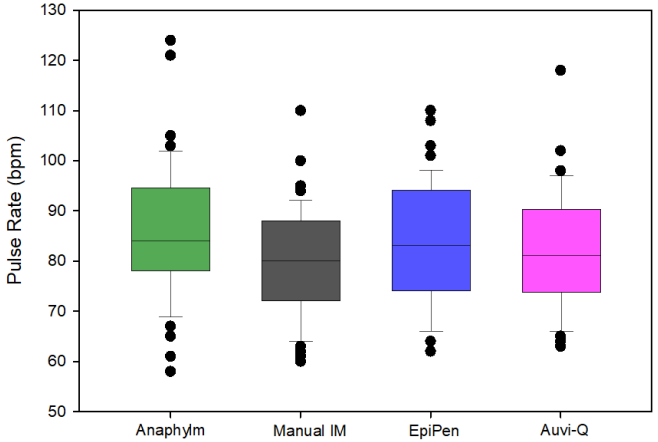
Maximum Systolic Blood Pressure



Maximum Diastolic Blood Pressure



Pulse Rate



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Tolerability summary

	Severity	12 mg DESF[1] Incidence (%)	0.3 mg Man. IM[2] Incidence (%)	0.3 mg EpiPen[3] Incidence (%)	0.3 mg Auvi-Q[4] Incidence (%)	0.5 mg Man. IM[5] Incidence (%)
Cardiac Disorders		**1.6%**	**1.6%**	**9.5%**	**1.6%**	**18.8%**
Palpitations (subjective, patient-reported)	Mild	1.6%	1.6%	6.3%	1.6%	12.5%
Tachycardia (objective, clinician-measured)	Mild	0%	0%	3.2%	0%	6.3%
GI						
Emesis*	Mild	1.6%	0%	0%	0%	0%

- All TEAE categorized as mild (Grade 1).
- No SAEs; No severe AEs
- TEAEs were transient and resolved without major intervention
- Primary cardiovascular TEAE associated with mild palpitations
- No intervention required
- No AEs of AV block or tachycardia for DESF group
- No severe cardiac events observed

1. AQ109301, T1, N=64; 2. AQ109301, R1, N=62; 3. AQ109301, R2, N=63; 4. AQ109301, R5, N=61; 5. DESF-AX-101, R1, N=16
**emetic event must be observed and have pH<4*

Anaphylm TopLine Pivotal Study Results:
Repeat Dose (n=36)

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Anaphylm 12mg repeat dose study meets primary endpoints

Primary endpoints predefined as Anaphylm values greater than or equal to (1) geometric mean concentration at 45 minutes and 60 minutes and (2) $AUC_{0\text{-}10min}$, $AUC_{0\text{-}20min}$, and $AUC_{0\text{-}30min}$.

Geometric Mean Concentrations (pg/mL)

	45 minutes	60 minutes	Cmax	CV%
Anaphylm	380	275	2028	91%
EpiPen	497	347	899	47%
Adrenalin	365	432	539	56%

**Model based estimates from ANOVA for Conc45min and Conc60min Difference between Anaphylm and EpiPen concentrations at 60 minutes not statistically different (p>0.05)*

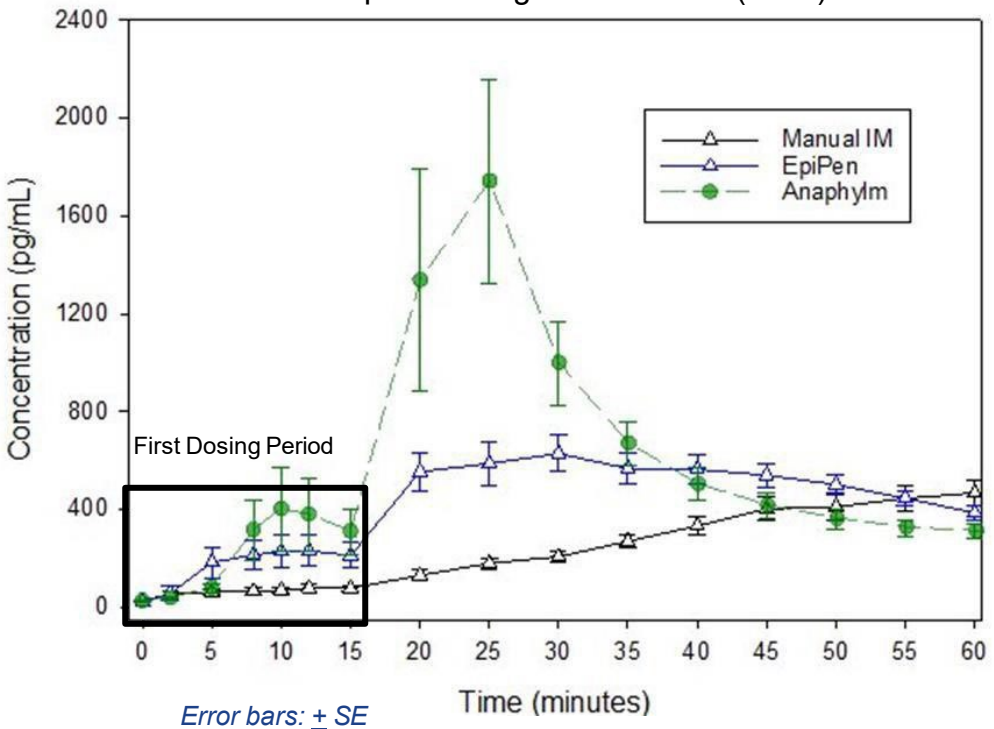
Partial AUCs Bracketing (hr*pg/mL)

	$AUC_{0\text{-}10min}$	$AUC_{0\text{-}20min}$	$AUC_{0\text{-}30min}$
Adrenalin	4.1	13.8	39.0
Anaphylm	20.3	120.8	378.5
EpiPen	21.0	69.8	172.3

Repeat dose study indicates subjects at risk for needing a second dose rapidly exceed threshold value of 100 pg/mL with Anaphylm

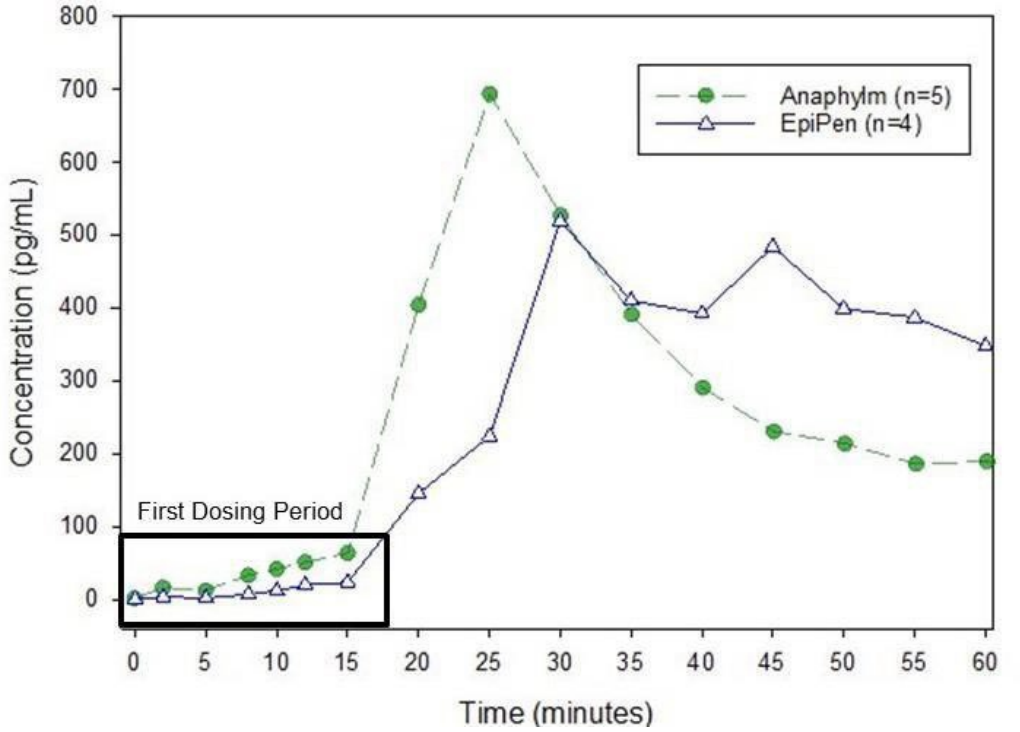
*100% of subjects were > 100 pg/mL within **5 minutes** of receiving a second dose of Anaphylm compared to 30 minutes for EpiPen. Overall study data demonstrates repeat dosing is well-tolerated for all evaluated subjects.*

Geometric Mean Epinephrine Concentration by Product After Repeat Dosing at 15 Minutes (n=36)



Error bars: ± SE

Geometric Mean Epinephrine Concentrations by Product in Subjects with PK Concentrations < 100 pg/mL prior to Second Dosing



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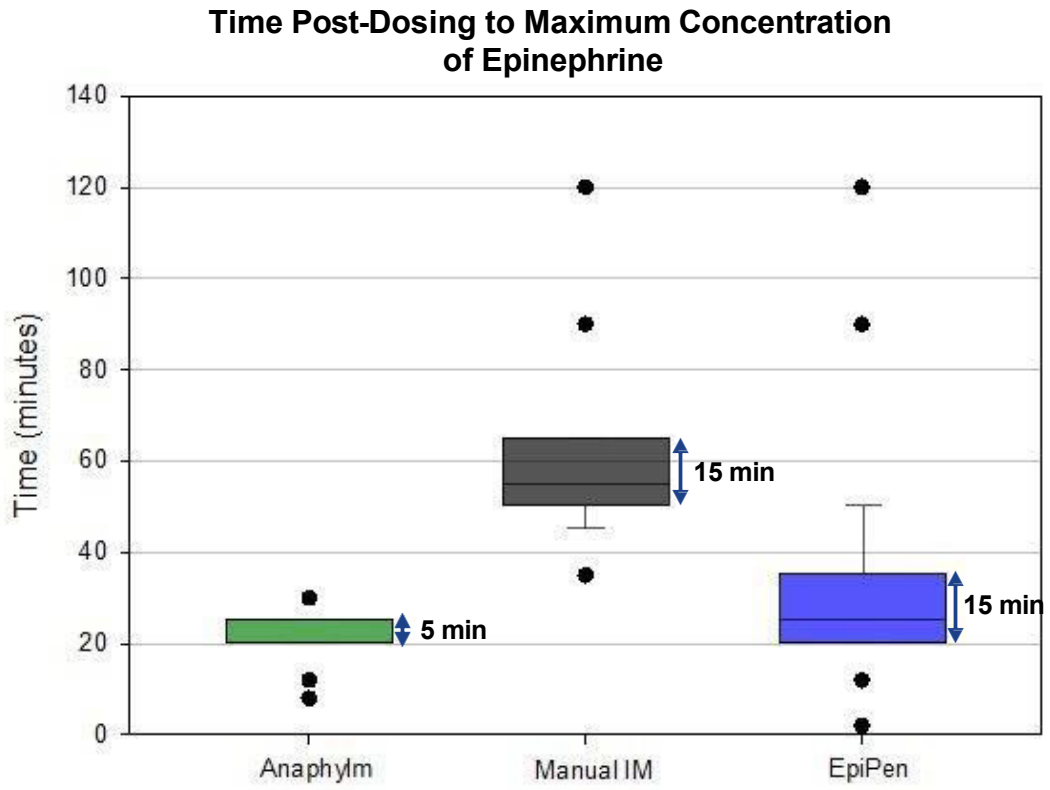
Time to maximum concentration (Tmax) of Anaphylm remained significantly more consistent compared to autoinjectors



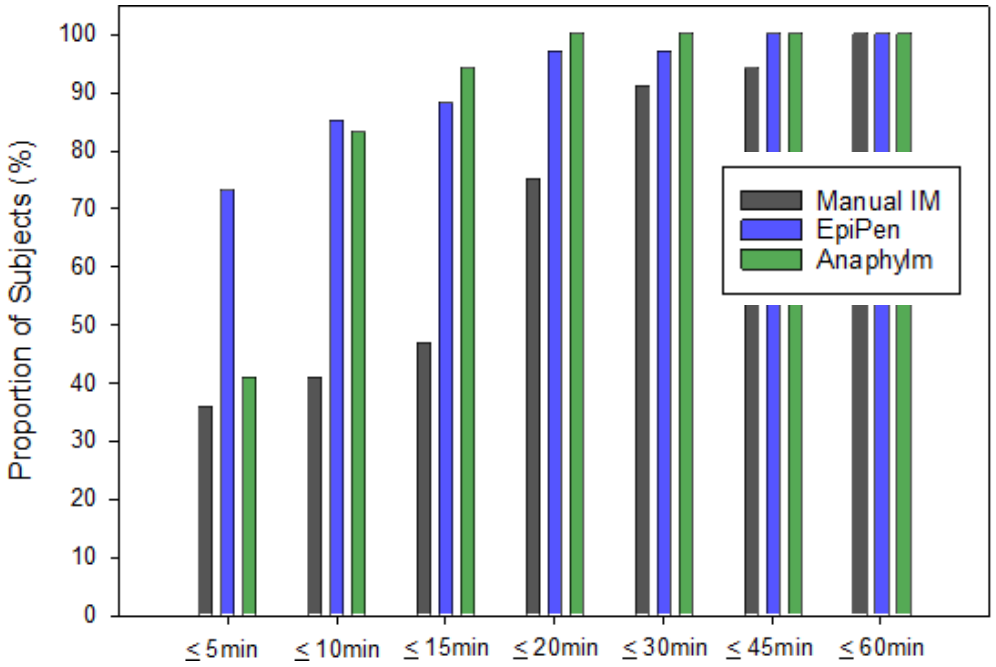
- Anaphylm median Tmax of 10 minutes after second dosing demonstrates rapid absorption, a critical factor for initial treatment failures
- Anaphylm Tmax interquartile range (5 min) is significantly more consistent than EpiPen and Adrenalin
- Anaphylm median Tmax is the same as EpiPen and is significantly faster than Adrenalin

All Anaphylm subjects reach or exceed 100 pg/mL five minutes after second dosing

Common FDA-cited key threshold level is an important target to achieve hemodynamic stability and curb the progression of anaphylaxis.

Time (minutes)	Number and Proportion of Subjects >100 pg/mL		
	Adrenalin (N=36)	EpiPen (N=35)	Anaphylm (N=36)
5	13 (36%)	25 (74%)	15 (42%)
10	15 (42%)	30 (86%)	30 (83%)
15	17 (47%)	31 (89%)	34 (94%)
20	27 (75%)	34 (97%)	**36 (100%)**
30	33 (92%)	34 (97%)	36 (100%)
45	34 (94%)	**35 (100%)**	36 (100%)
60	**36 (100%)**	35 (100%)	36 (100%)

Proportion of Subjects Achieving 100 pg/mL in Repeat Dose Pivotal Study



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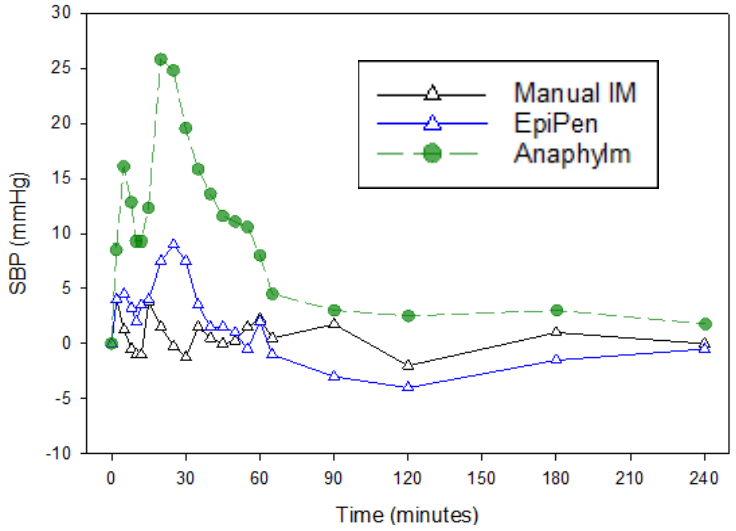
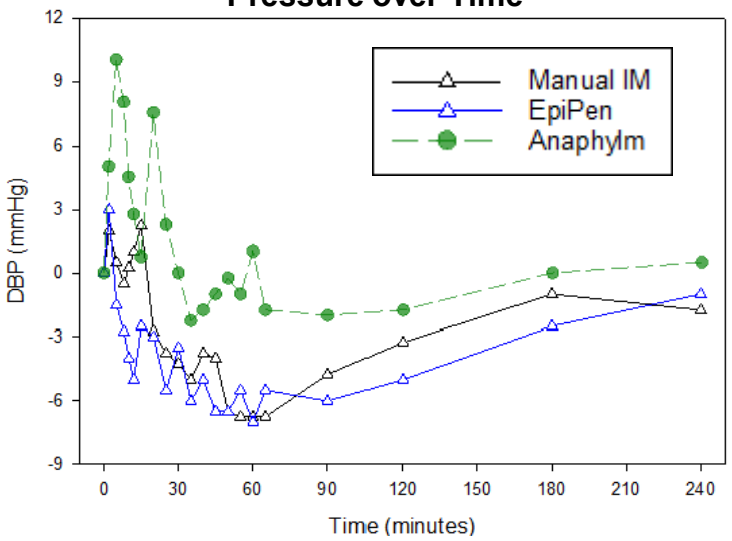
Pharmacodynamics remain consistent with past performance

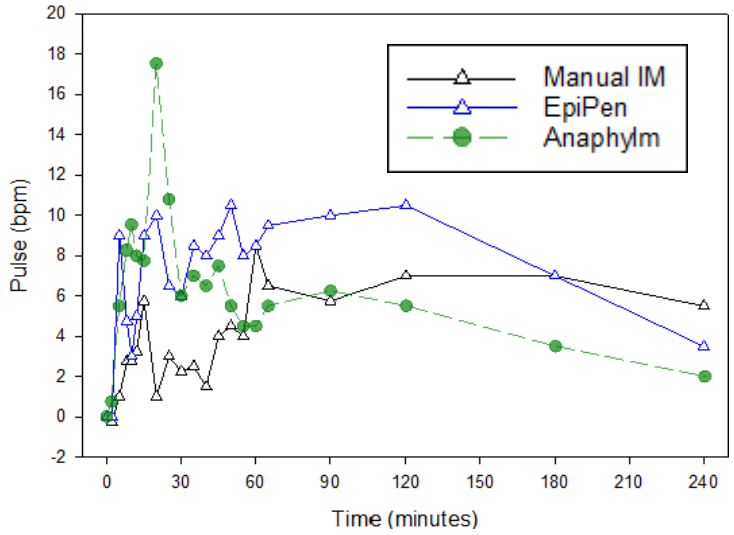
Median Change in Systolic Blood Pressure over Time



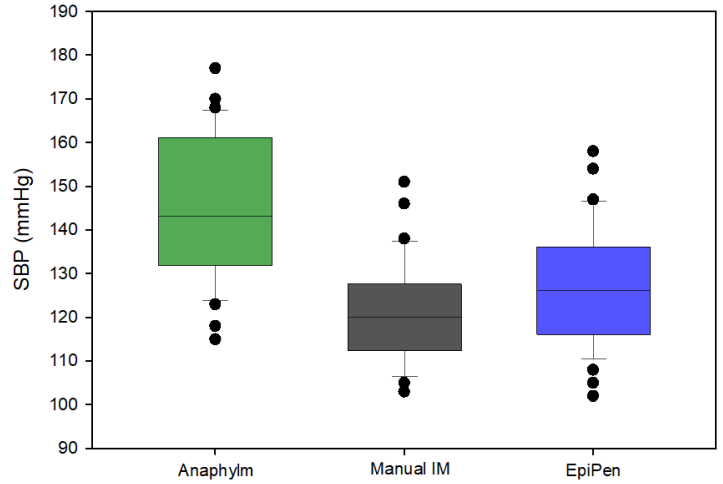
Median Change in Diastolic Blood Pressure over Time



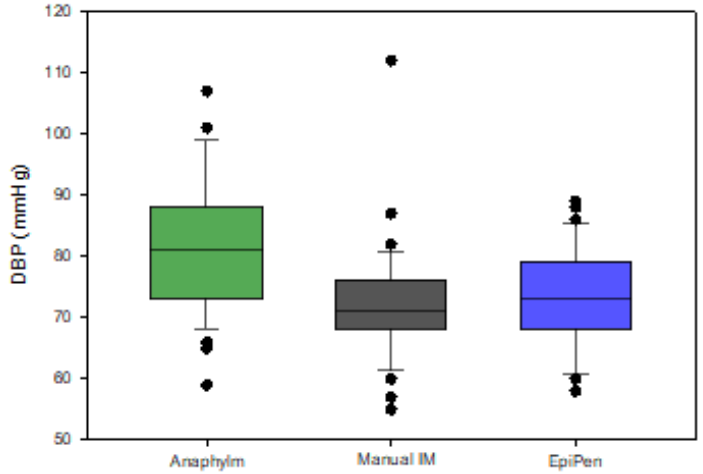
Median Change in Pulse over Time



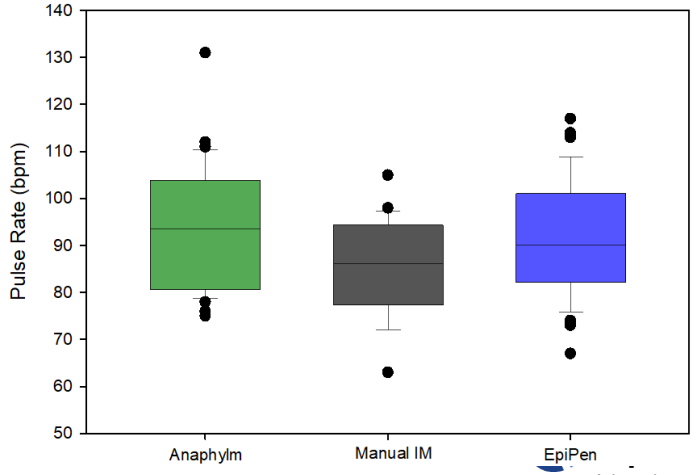
Maximum Systolic Blood Pressure



Maximum Diastolic Blood Pressure



Pulse Rate



Tolerability summary

Preferred Term System Organ Class	Severity	12 mg DESF[1] Incidence (%)	0.3 mg Man. IM[2] Incidence (%)	0.3 mg EpiPen[3] Incidence (%)	0.5 mg Man. IM[4] Incidence (%)
Cardiac Disorders		**13.9%**	**5.6%**	**8.6%**	**18.8%**
Palpitations (subjective, patient-reported)	Mild	13.9%	2.8%	5.7%	12.5%
Tachycardia (objective, clinician-measured)	Mild	0%	2.8%	2.9%	6.3%
GI					
Emesis*	Mild	5.6%*	0%	0%	0%

- Most TEAE categorized as mild (Grade 1)
- No SAEs; No severe AEs; No severe cardiac events observed
- TEAEs were transient and resolved without major intervention
- Primary cardiovascular TEAE associated with mild palpitations
- No intervention required
- No AEs of AV blocks or tachycardia for DESF repeat dose group
- For majority of subjects, Anaphylm observed concentration levels < EpiPen observed levels at all timepoints

[1]AQ109301, T2, N=36; [2]AQ109301, R3, N=36; [3]AQ109301, R4, N=35; [4]DESF-AX-101, R1, N=16

*emetic event must be observed and have pH<4

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Program Timeline

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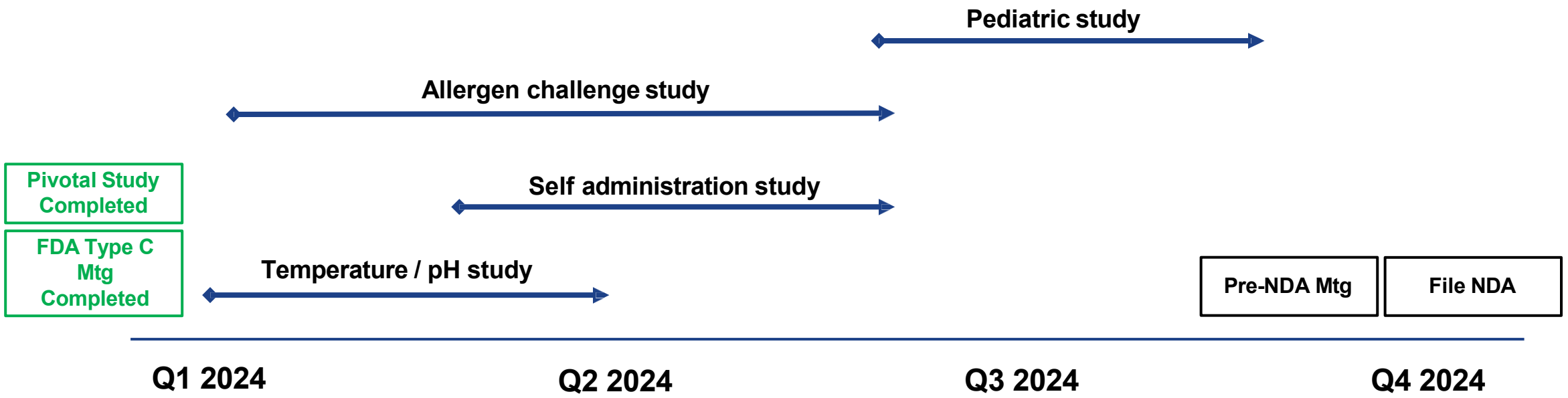
Anaphylm clinical trials to date

Study	Description	Study Status	N	Data Publicly Disclosed
210010	First-in-Human (FIH), Single Ascending Dose (SAD) study to evaluate safety and tolerability, as well as pharmacokinetic (PK) performance and pharmacodynamic (PD) effect, of DESF (Anaphylm)	Complete	44	Y
EPIPHAST Part 1	• Evaluate multiple formulations and strengths of DESF (Anaphylm) • Benchmark against epinephrine 0.5mg manual intramuscular (IM) injection	Complete	35	Y
Part 2	• Confirm benchmarking vs. epinephrine 0.3mg manual IM injection • Evaluate intrasubject variability and adequacy of washout period	Complete	24	Y
Part 3	• Characterize conditions of use and effect of use errors (different saliva hold times and directly swallowing film) • Film performance after ingestion of sticky substance (peanut butter)	Complete	24	Y
EPIPHAST II	Characterize: • repeat dose performance of DESF (Anaphylm) • performance against EpiPen	Complete	24	Y
AQ109102	Evaluate: • differences in PK and PD results based on changes to administration instructions • additional repeat dose data on DESF (Anaphylm) • performance of various approved auto-injectors	Complete	30	Y
AQ109103	Further characterization of PK performance and PD effect of DESF (Anaphylm) to inform pivotal study design	Complete	24	Y
AQ109106	Evaluate differences in PK and PD results based on changes to administration instructions	Complete	35	Y
AQ109301	Pivotal pharmacokinetic study	Complete	Part A=64 Part B=36	N

Agency interactions on Anaphylm program to date

Interaction	Key Takeaways
Pre-IND Meeting *(December 1, 2021)*	• 505(b)(2) NDA regulatory approval pathway acceptable (no efficacy trials required) • Bracket PK to 0.3mg IM and safety to 0.5mg IM • Evaluate potential for extrinsic factors to impact DESF (ANAPHYLM) absorption
Stability Excursion Protocol Review *(July 29, 2022)*	• Design and planned analysis of the proposed excursions are reasonable and can be expected to provide data to support product and patient labeling
End Of Phase 2 (EOP2) Meeting-CMC Meeting Feedback *(October 4, 2022)*	• Proposed Chemistry Manufacturing and Controls (CMC) package for both active pharmaceutical ingredients (API) and DESF (Anaphylm) considered sufficient and reasonable for future NDA filing
Nonclinical Study Plans *(October 11, 2022)*	• Aligned with FDA on NDA, enabling nonclinical toxicology package
EOP2 Meeting *(November 15, 2022)*	• Reaffirmed 505(B)(2) regulatory approval pathway acceptable (no efficacy trials required) • Modified bracketing strategy to compare PK performance to IM and autoinjectors • Use during conditions of anaphylaxis to be considered in overall risk/benefit profile
FDA Response to General Correspondence *(March 1, 2023)*	• FDA agreed to review pivotal protocol • FDA agreed to separate meeting to align on risk/benefit characterization after pivotal study alignment
FDA Response to Pivotal Study Protocol *(October 9, 2023)*	• Received positive feedback from FDA • Proposed endpoints sample size, and statistical analysis found reasonable • Utilizes final dosing instructions from Study AQ109106
FDA Type C Meeting *(January 31, 2024)*	• Completed Q1 2024 • Addressed EOP2 open items and pediatric studies

Projected clinical timeline



Plan for allergen-induced study

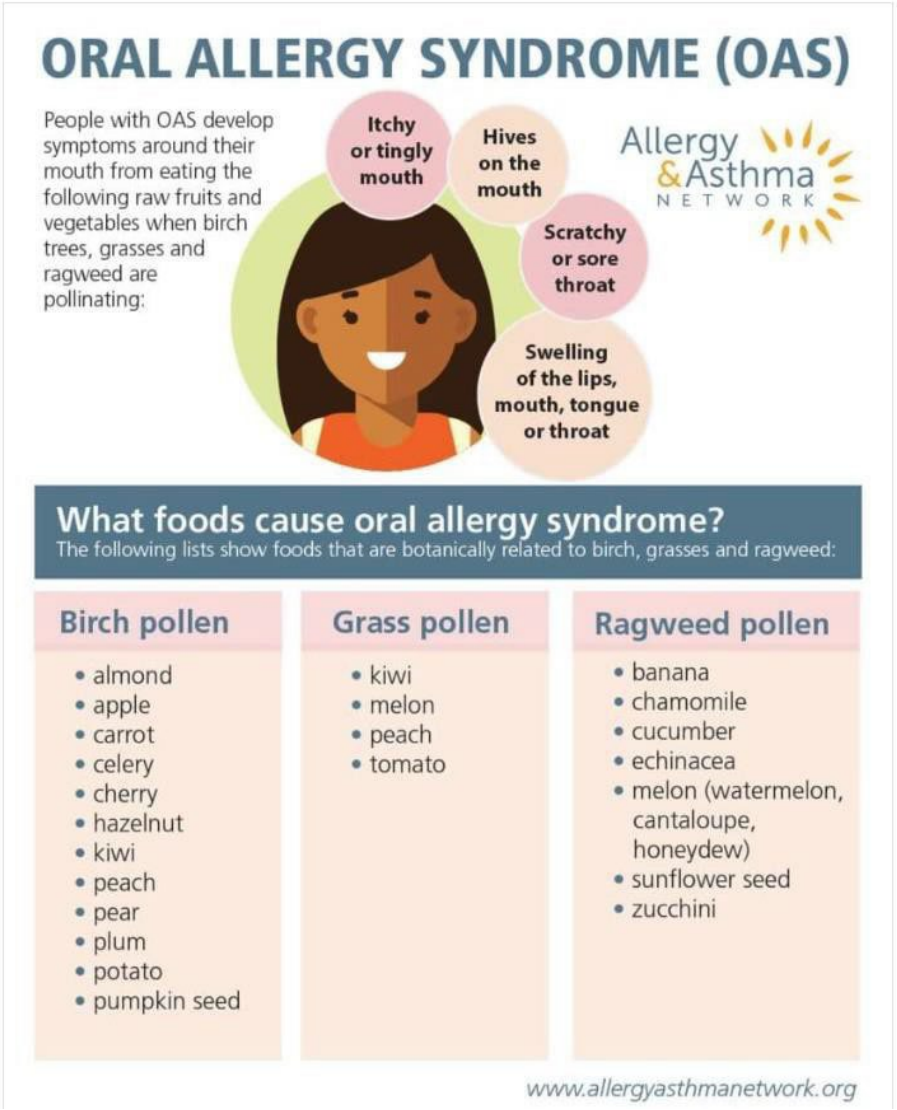
Utilize known OAS population to conduct allergen-challenge study

- Step 1: introduce allergen to patient
- Step 2: monitor for symptoms (minimum 15 minutes)
- Step 3: dose Anaphylm
- Step 4: conduct blood draws to assess Anaphylm pharmacokinetics

Note: a 2nd non-challenge arm will be performed to establish baseline

Model advantages

- Known population with localized response
- Study can be performed rapidly
- Isolates edema vs. confounding factors (such as congestion)



FDA Type C Meeting

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The Type C meeting was designed to address the open items from our End-of-Phase 2 meeting held in November 2022

Aquestive press release from December 22, 2022:

"The FDA also provided comments on potential issues the Company will need to address in regard to a sublingually delivered product including

(1) the impact of any product hold time,

(2) the potential for emesis (vomiting), and

(3) the impact of potential mouth conditions such as angioedema (swelling)."

(1) the impact of any product hold time

Our position	We removed hold time from our dosing administration thereby alleviating the issue.
Our interpretation of FDA meeting minutes	We have adequately addressed their concerns.
Additional information provided by FDA	For administration during pediatric studies, we should clarify film sizing and instructions.

(2) the potential for emesis (vomiting)

Our position	We will characterize events of emesis for consolidated analysis in the NDA.
Our interpretation of FDA meeting minutes	Recommended additional information (such as narratives for patients who require medical intervention) and reminded us that any impact on safety will be a review issue.

(3) potential for mouth conditions (such as angioedema)

Our position	We proposed a histamine study in healthy volunteers followed by the administration of Anaphylm.
Our interpretation of FDA meeting minutes	The FDA did not agree with this model. The FDA proposed a clinical model to assess the impact of allergen-induced oral physiological changes on the PK/PD of Anaphylm. We believe the FDA's proposal is a **SIGNIFICANTLY** easier study to perform and have agreed to move forward with this model.

Completeness of clinical development program

In addition to addressing the FDA comments from our EOP2 meeting, we requested the FDA provide feedback on the completeness of our overall program.

Our position	Completion of the planned clinical studies will be sufficient for filing an NDA.
Our interpretation of FDA meeting minutes	The FDA acknowledged that we have made “substantial progress” and reserved judgement until after they have reviewed our current clinical studies (i.e. the pre-NDA meeting). They reminded us that PK sustainability is an important issue for them and referenced the May 11 Ad Comm. They also reminded us that higher PK and PD profiles of the repeat dose must be justified to the extent we intend to rely on systemic safety of epinephrine injection products.
Additional information provided by FDA	We are aligned with the FDA with recommendation to initiate pediatric studies after completing our adult studies (pivotal study, self-administration, allergen study). (note: multiple nasal spray programs changed their dose strengths AFTER pediatric studies had been initiated)

Thank You

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