Aquestive®

Anaphylm™ (epinephrine) Sublingual Film

Pilot Clinical Studies Supplemental Materials

May 2023

Advancing medicines.
Solving problems.
Improving lives.

Forward Looking Statement

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; the potential benefits Anaphylm could bring to patients, that the brand name of Anaphylm will promote accurate prescription and safety interpretation by healthcare prescribers, and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on the Company’s business including with respect to its clinical trials including site initiation, enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approval of Anaphylm; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; and ongoing availability of an appropriate labor force and skilled professionals.

These forward-looking statements are based on the Company’s 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 the Company’s development work, including any delays or changes to the timing, cost and success of its product development activities and clinical trials for Anaphylm; risk of the Company’s failure to generate sufficient data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company’s failure to address the concerns identified in the FDA End-of-Phase 2 meeting for Anaphylm, including the risk that the FDA may require additional clinical studies for FDA approval of Analphylm; risk of delays in or the failure to receive FDA approval of Anaphylm and there can be no assurance that we will be successful in obtaining FDA approval of Anaphylm; risk of insufficient capital and cash resources, including insufficient access to available debt and equity financing 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 the rate and degree of market acceptance of our product candidate Anaphylm; risk of the success of any competing products; uncertainties related to general economic, political, business, industry, regulatory, financial and market conditions and other unusual items; and other risks and uncertainties affecting the Company described in the “Risk Factors” section and in other sections included in its Annual Report on Form 10-K, in its Quarterly Reports on Form 10-Q, and in its Current Reports on Form 8-K filed with the Securities and Exchange Commission.

In addition, topline and interim data from clinical trials may not be indicative of final results, and the results of early clinical trials may not be indicative of the results of later clinical trials. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical and clinical trials have nonetheless failed to obtain marketing approval of their products. There is a risk that additional nonclinical and/or clinical safety studies will be required by the FDA or that subsequent studies will not match results seen in prior studies. As a result, topline data should be viewed with caution until the final data are available. 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 Current Report on Form 8-K, whether as a result of new information, future events or otherwise, except as may be required by applicable law. Readers should not rely upon this information as current or accurate after its publication date.

The product profile, data from our trials, and related statements regarding Anaphylm have not been approved by the FDA. Aquestive has received conditional acceptance of the use of the trade name Anaphylm, which is subject to final FDA approval of the product candidate.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy the Company’s securities, nor shall there be any sale of the Company’s securities in any state or 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 jurisdiction.

Goals of Pilot Study Work Following FDA End-of-Phase 2 (EOP2) Meeting

- Analyze the pharmacokinetic (PK) performance of several epinephrine auto-injectors and the 0.3mg manual injection – identify comparators for planned pivotal study
- Simplify the Anaphylm administration instructions to eliminate hold time
- Characterize PK and pharmacodynamic (PD) performance under different administration conditions

Key Takeaways from the Post-EOP2 Meeting Pilot Studies

Anaphylm (epinephrine) Sublingual Film 12mg

- Revised administration demonstrated a 10-minute median time to maximum concentration (Tmax)
- PK bracketed between available comparators for proposed pivotal study endpoints –both geometric mean maximum epinephrine concentration (Cmax) and partial area under the curve (pAUC)
- Safety profile in line with previous studies – no severe or serious events were observed

Auto-injector and 0.3mg Manual Injection Characterization

- Established PK variability within and across available auto-injectors
- Highlighted similarities across auto-injectors and a target range (bracket) between IM and auto-injectors
- Data will be utilized to statistically power the pivotal study

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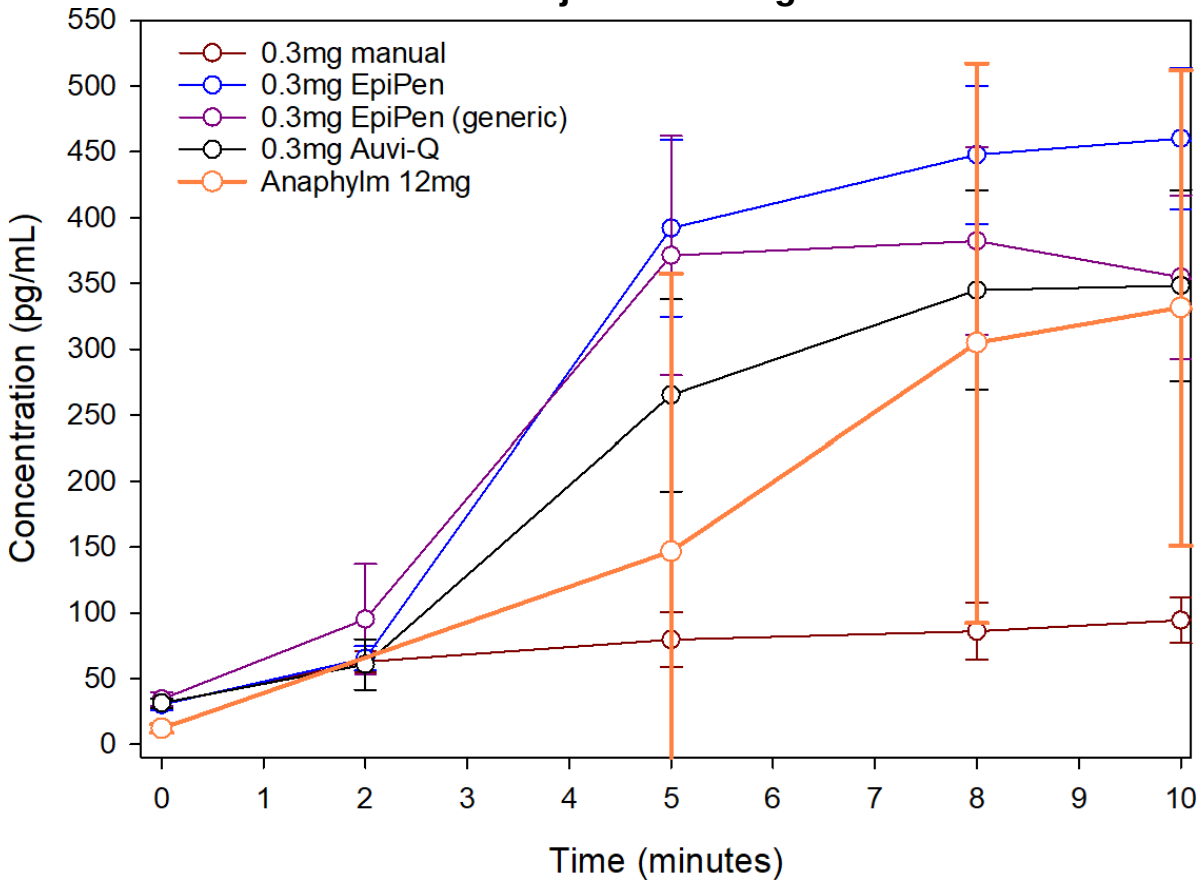
Pilot Study Designs

- Crossover Pilot PK Study Comparing Different Auto-injectors and 0.3mg Manual Injection to Anaphylm (Study AQ109102)
  - Healthy volunteers, 6-period, n=24
  - Designed to assess:
    - Variability of multiple epinephrine auto-injectors
    - Repeat dose of Anaphylm administered 25 minutes after the first dose
    - Anaphylm results providing minimal administration instruction

- Single Administration Pilot PK Study (Study AQ109106)
  - Healthy volunteers, 1-period, 3 cohorts, n=12 each cohort
  - Designed to assess:
    - Anaphylm performance utilizing updated administration instructions
    - Cross-study comparison to RLD bracket in AQ109102

Anaphylm: similar exposure to auto-injectors during the first 10 minutes following dosing*

Comparison of epinephrine plasma concentrations over time of Anaphylm 12mg to various approved auto-injectors 0.3mg



Comparison of epinephrine exposure at 10 minutes of Anaphylm 12mg to various approved auto-injectors 0.3mg

Parameter	0.3mg Manual (N=27)	Auvi-Q (N=29)	Anaphylm (N=12)	EpiPen (generic) (N=29)	EpiPen (N=27)
$AUC_{0\text{-}10min}$ (hr*pg/mL)	5.3	26.7	**28.3****	37.7	43.7

*Cross-study comparison from AQ109102 and AQ109106 **Data updated

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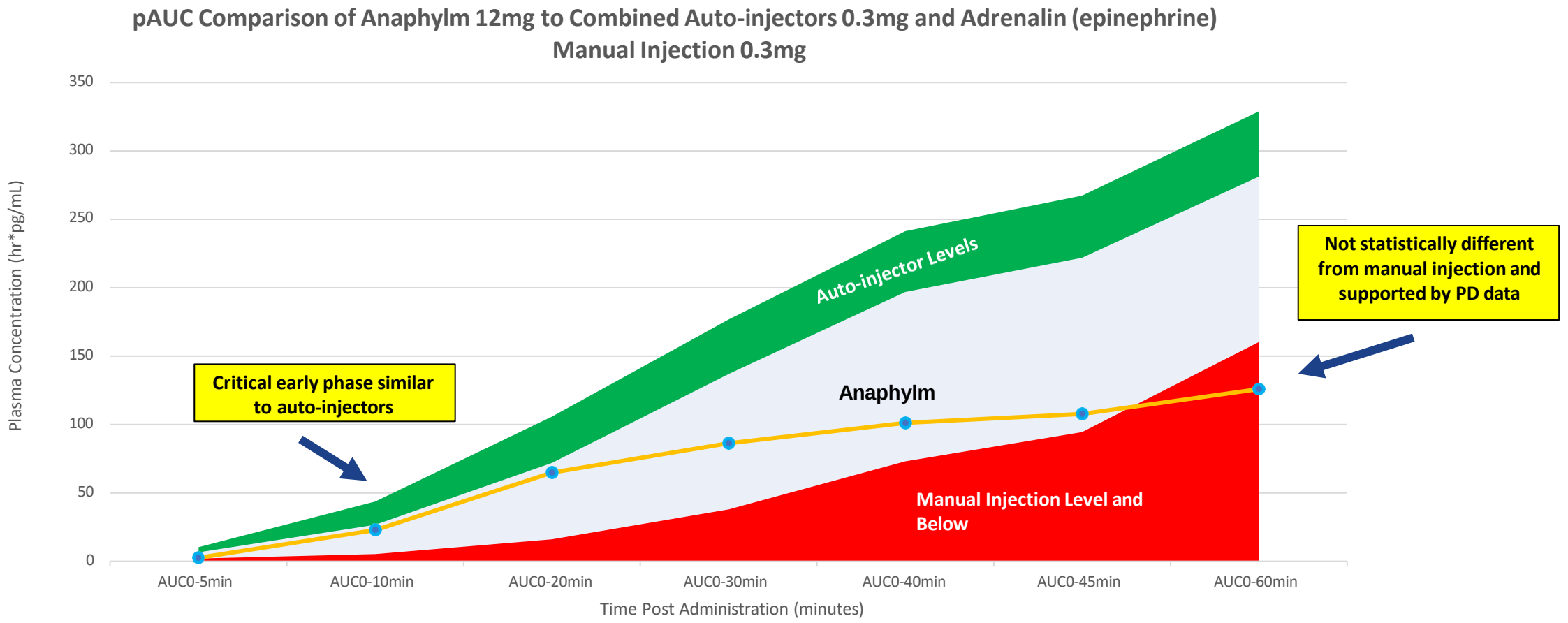
Anaphylm data brackets existing products to 45 minutes*

FDA recommended bracketing between the exposures produced by auto-injectors and manual injection across a range of relevant time points characterized as pAUC.



*Bracketing end points subject to alignment with FDA. Cross-study comparison from AQ109102 and AQ109106.

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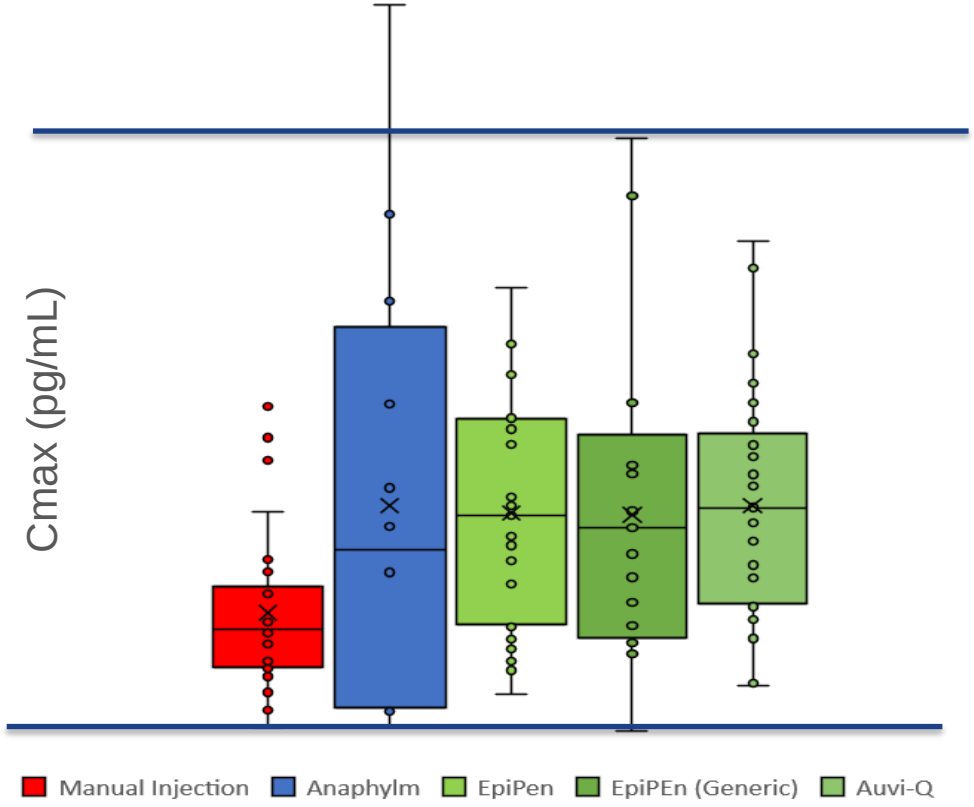
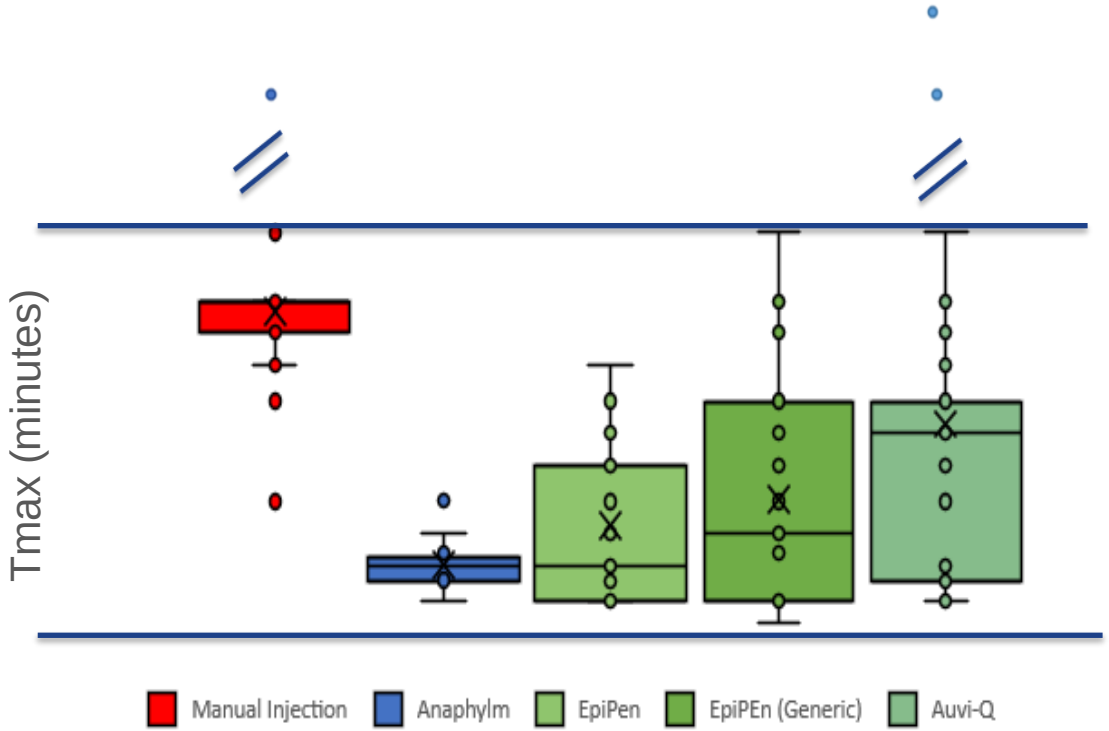
Key PK parameters compare favorably to existing treatments*

Anaphylm 12mg provides a consistently fast Tmax with median and mean Cmax levels bracketed by the current FDA approved products.

Median and Mean Cmax



Median Tmax



Bars above show highest and lowest 75% quartile ranges of approved products

*Cross-study comparison of AQ109102 and AQ109106

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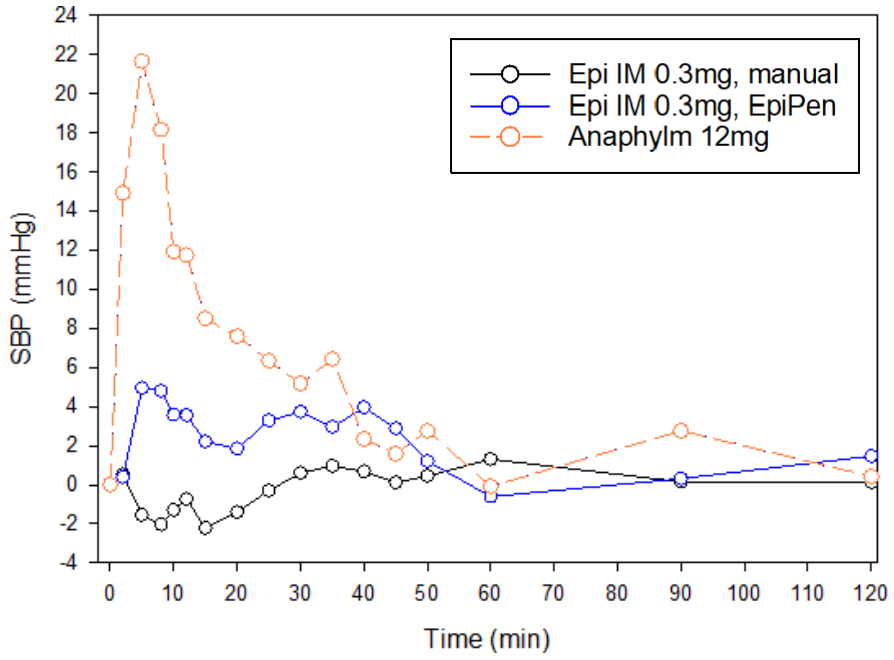
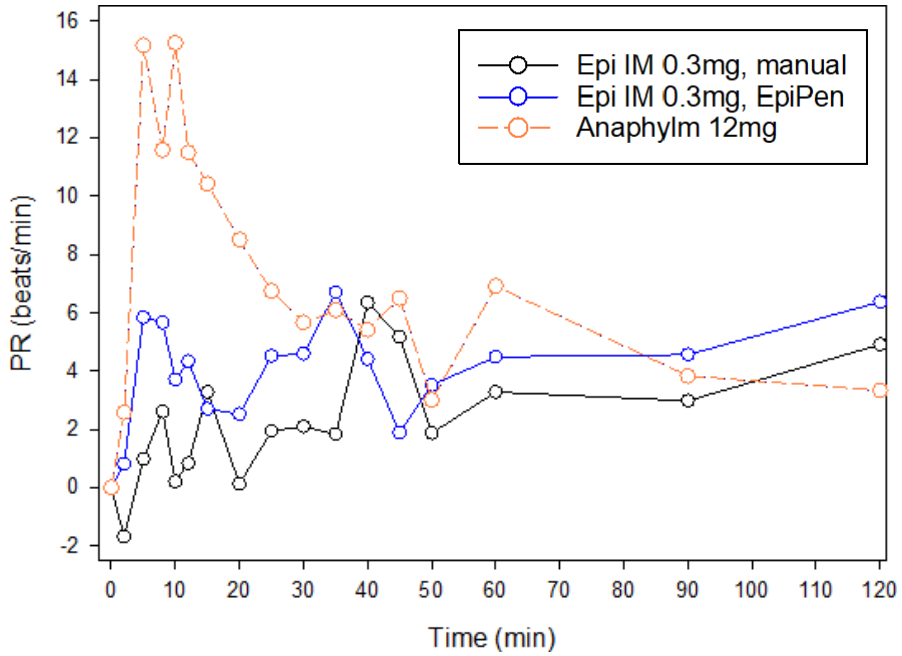
Clinically favorable PD from Anaphylm*

*Anaphylm demonstrates a rapid increase in systolic blood pressure (SBP), pulse and diastolic blood pressure (DBP) within **2 minutes.** Injected epinephrine produces moderate increases in SBP and pulse with no measurable effect on DBP.*

Mean Baseline Adjusted Changes in Systolic Blood Pressure Following Administration



Mean Baseline Adjusted Changes in Pulse Following Administration



*Cross-study comparison from AQ109102 and AQ109106

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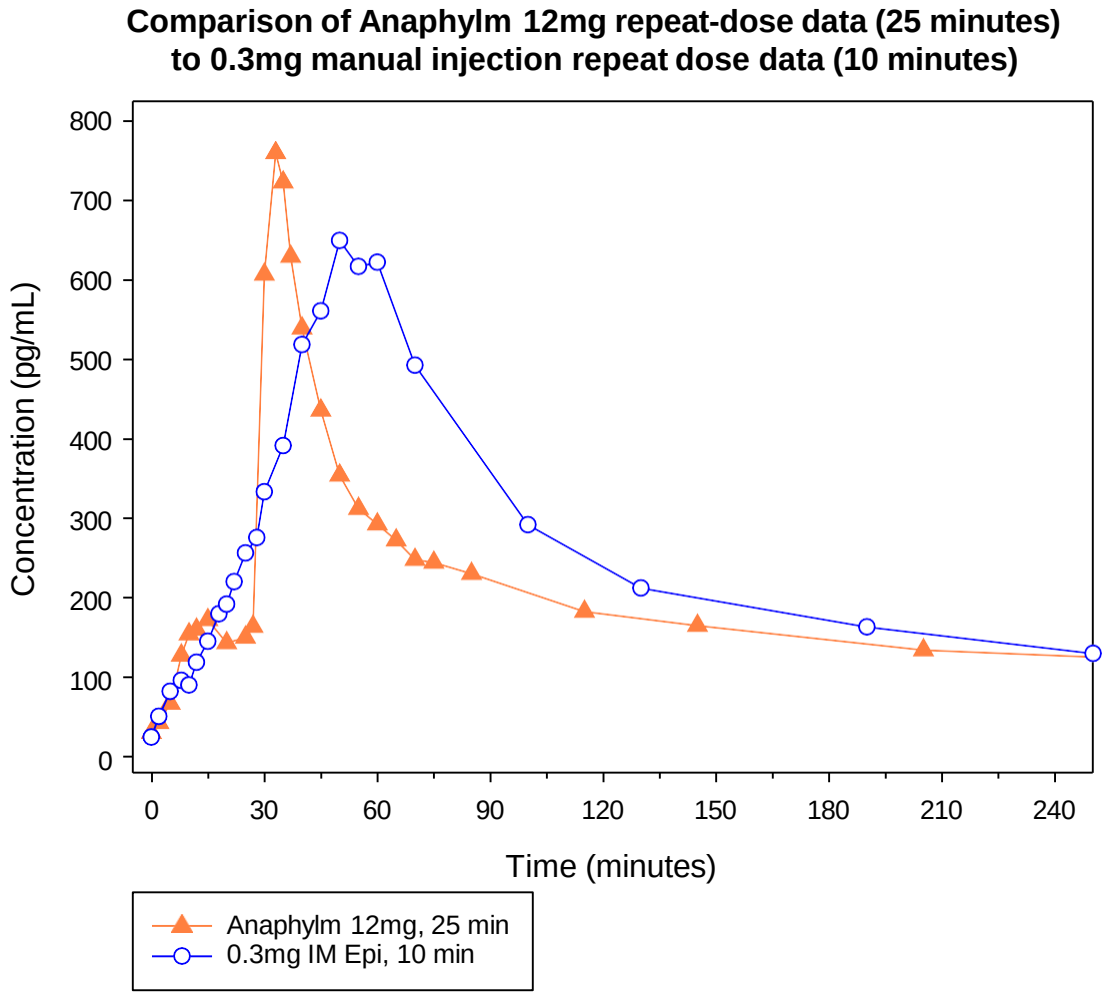
Repeat Dose – 25 Minutes*



Description	0.3mg Manual Injection Repeat Dose (10 min)	Anaphylm Repeat Dose (25 min)
# Subjects	23	27
C_{max} (pg/mL)	755	882
AUC_{0-t} (hr*pg/mL)	1300	776
AUC_{0-45} (hr*pg/mL)	181	207
Tmax (minutes)	50	33
Tmax Range (minutes)	30 - 70	10 - 70

Geometric Means presented for Cmax, AUC0-t, AUC0-45. Median Tmax.
Data presented from cross-study analysis of AQ109201 (0.3mg manual injection repeat dose at 10 min) and AQ109102 (Anaphylm repeat dose at 25 minutes - top-line results)

*Cross-study comparison from AQ109201 (EpiPhast II) and AQ109102

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Summary and Next Steps

- AQ109102 compared Anaphylm to multiple epinephrine auto-injectors
  - Confirmation of target range between existing reference listed drug (RLD) epinephrine injections
- AQ109106 focused on administration instructions
  - Confirmation of Anaphylm Cmax comparability
  - Confirmation that Anaphylm early pAUC parameters are bracketed by other RLDs
- Next Steps
  - Refine administration instructions in ongoing pilot study (AQ109103)
  - Finalize pivotal study protocol – expect to submit for FDA review/alignment in Q3 2023
  - Expect to begin execution of pivotal study in Q4 2023