



EPIPHAST II Trial Results Supplemental Materials

September 2022

Advancing medicines.
Solving problems.
Improving lives.

Forward Looking Statement

This presentation includes 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 of Libervant™, AQST-109, and other product candidates through the regulatory and development pipeline; and business strategies, market opportunities, 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 our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; sale of and demand for our products; our liquidity and availability of capital resources; customer demand for our products and services; customers’ ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals. Given these uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

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 the Company’s development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans for AQST-109 and our other drug candidates; risk of delays in FDA approval of our drug candidate Libervant, AQST-109, and our other drug candidates or failure to receive approval; ability to address the concerns identified in the FDA’s Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant; risk of loss of our’ orphan drug approval and failure to obtain resulting drug exclusivity for our products; risk of our ability to demonstrate to the FDA “clinical superiority” within the meaning of the FDA regulations of Libervant relative to FDA-approved diazepam rectal gel and nasal spray products including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products as well as risks related to other potential pathways or positions which are or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. and there can be no assurance that we will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer term cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default thereof; short-term and long-term liquidity and cash requirements, cash funding and cash burn; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone® and which accounts for the substantial part of our current operating revenues; risks related to the outsourcing of certain 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; the success of any competing products, including generics; risk of the size and growth of our product markets; risks 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 the Company’s products; risk of unexpected patent developments; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory actions affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company’s products and product candidates; risk of loss of significant customers; risks related to legal proceedings, including patent infringement, investigative and antitrust litigation matters and associated costs; changes in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting the Company described in the “Risk Factors” section and in other sections included in our Annual Report on Form 10 K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities Exchange Commission (SEC). 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 us or any person acting on our 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 press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.

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Libervant™ Buccal Film (Diazepam) is an investigational drug being evaluated for use in children and adults with refractory seizures, who remain on stable regimens of antiepileptic drugs, to control bouts of increased seizure activity. The product profile, data from our trials, and related statements have not been approved by the FDA. Aquestive has received conditional acceptance of the use of this trade name, which is subject to final FDA review and acceptance.

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.

EPIPHAST II: Trial Results Key Takeaways

AQST-109 to EpiPen[®] 0.3mg (single dose)

Confirmation of 12-minute median time to maximum concentration (T_{max})

Faster observed median T_{max} than either EpiPen[®] (22 minutes) or 0.3mg IM injection (45 minutes)

Safety profile in line with previous studies – no severe or serious events were observed

AQST-109 to epi 0.3mg IM injection (repeat dose)

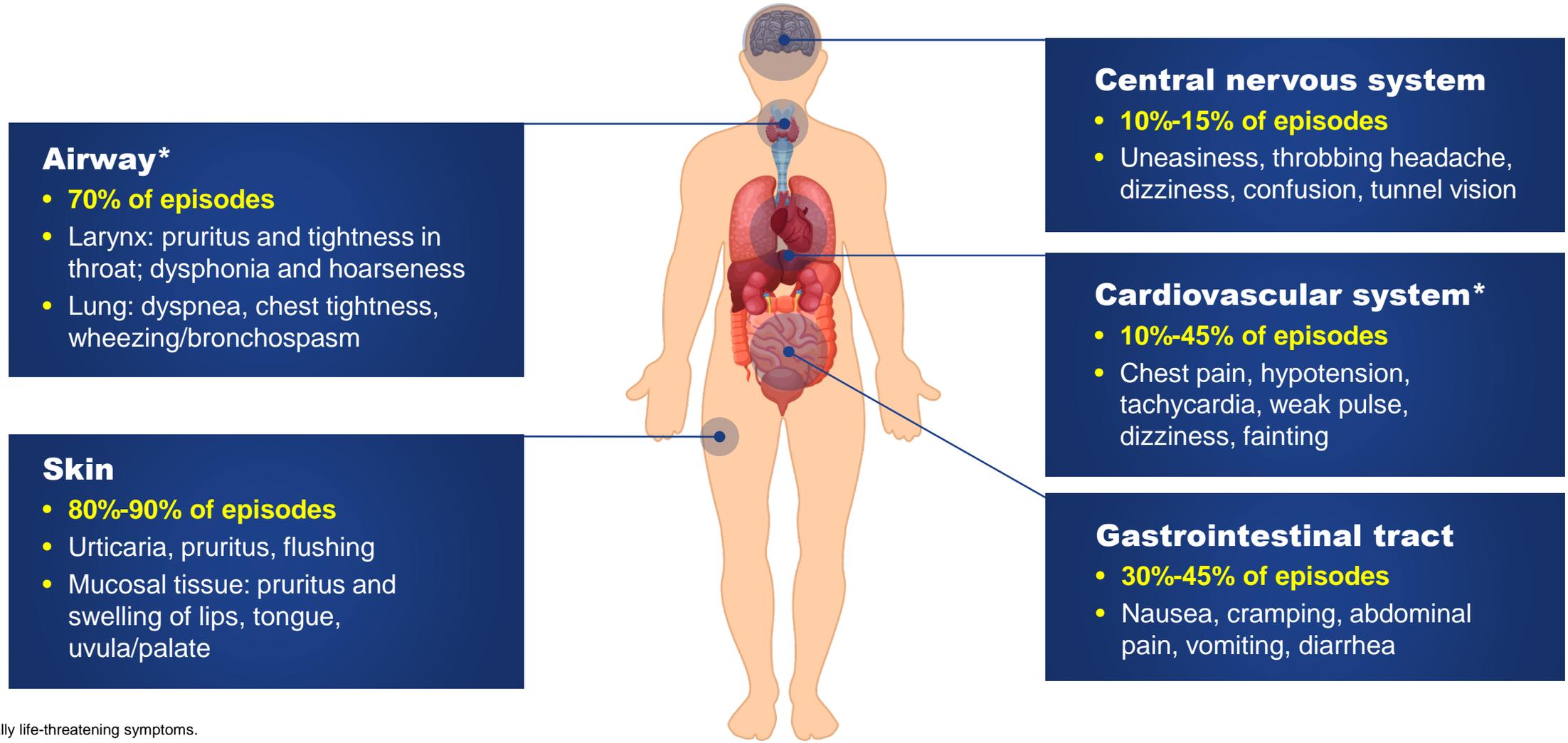
Demonstrated successful absorption of a second dose of AQST-109 in all subjects

Second dose¹ had an observed median T_{max} of 18 minutes (8 minutes after second dose administration)

No severe or serious safety or tolerability events were observed

1. Second dose administered 10 minutes after the first.

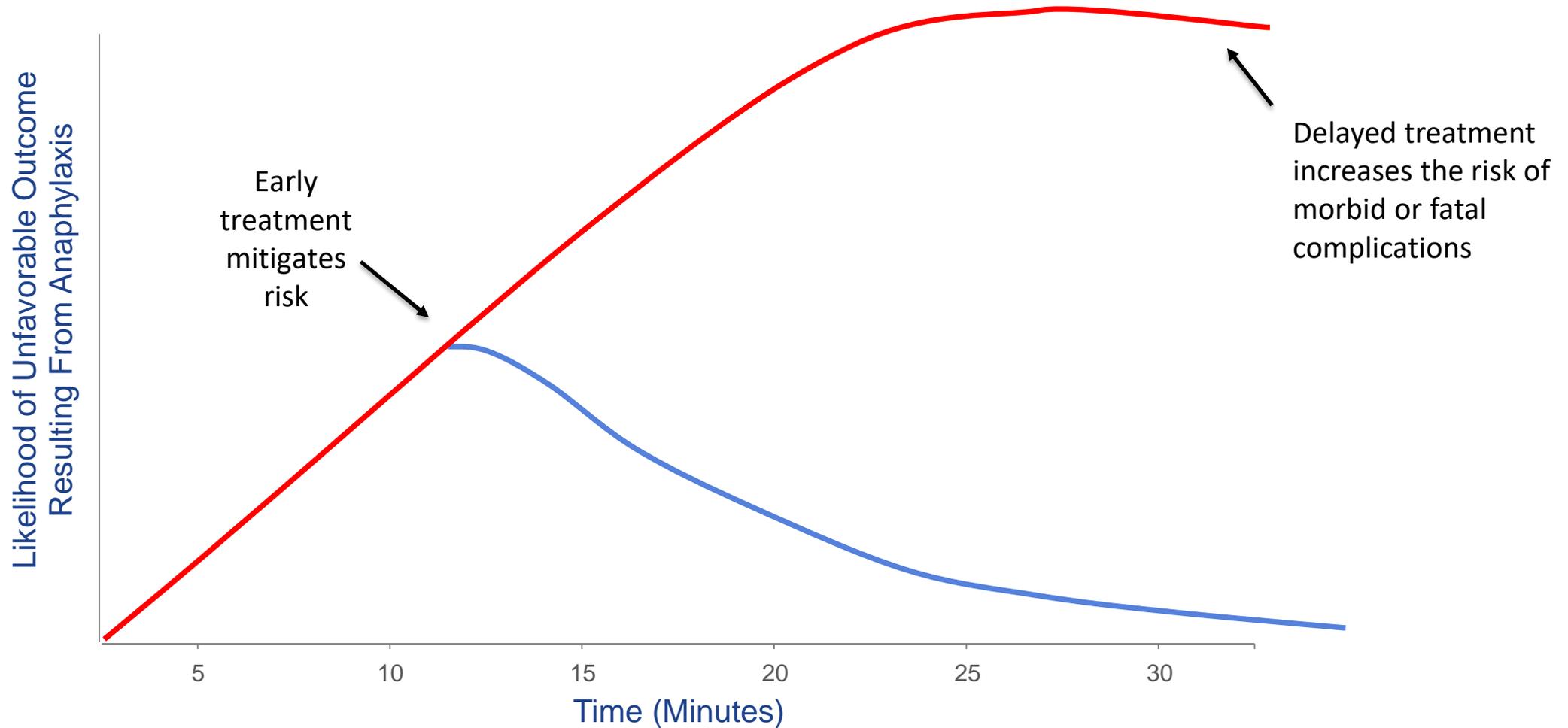
Symptoms of Anaphylactic Shock



*Potentially life-threatening symptoms.

Simons FE. *J Allergy Clin Immunol.* 2009;124(4):625-636.

Importance of Speed in Treating a Systemic Allergic Reaction

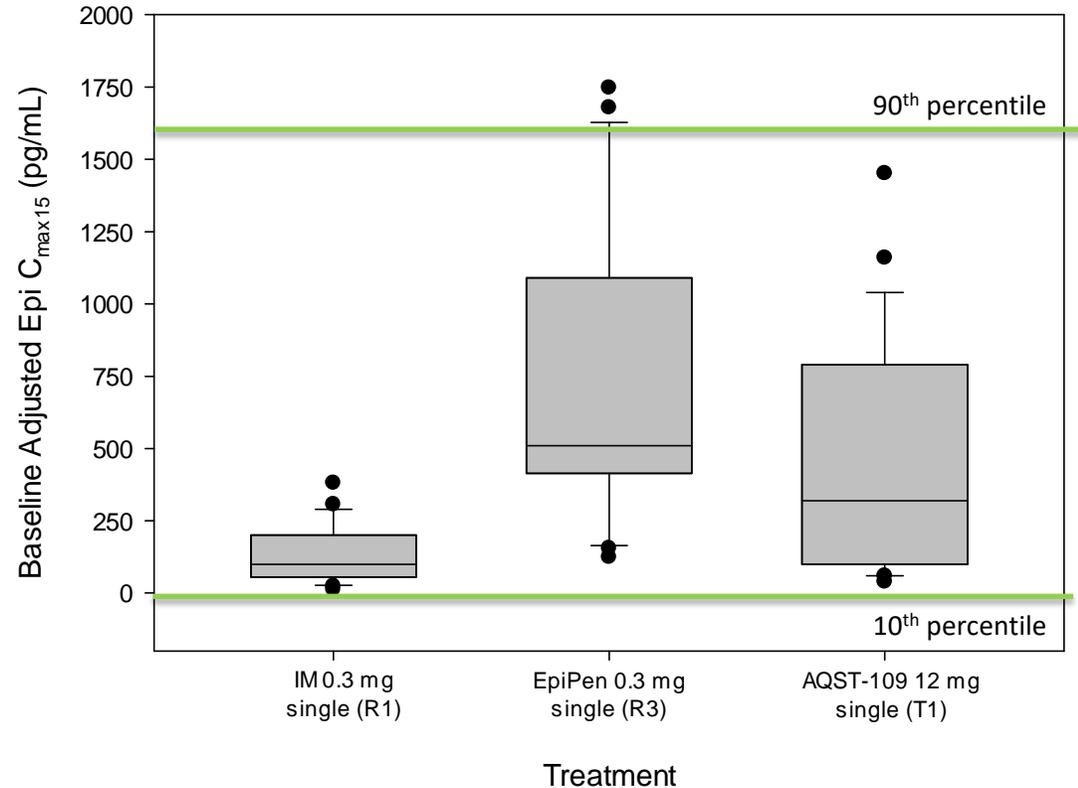


EPIPHAST II: Trial Design and Objectives

- **Healthy volunteers, randomized, open-label, 5-period trial**
- **Designed to compare pharmacokinetics and pharmacodynamics of:**
 - Single doses of AQST-109 to single doses of EpiPen® 0.3mg and epi 0.3mg IM injection
 - Repeat doses of AQST-109 to repeat doses of epi 0.3mg IM injection
- **Assessed continued safety and tolerability**

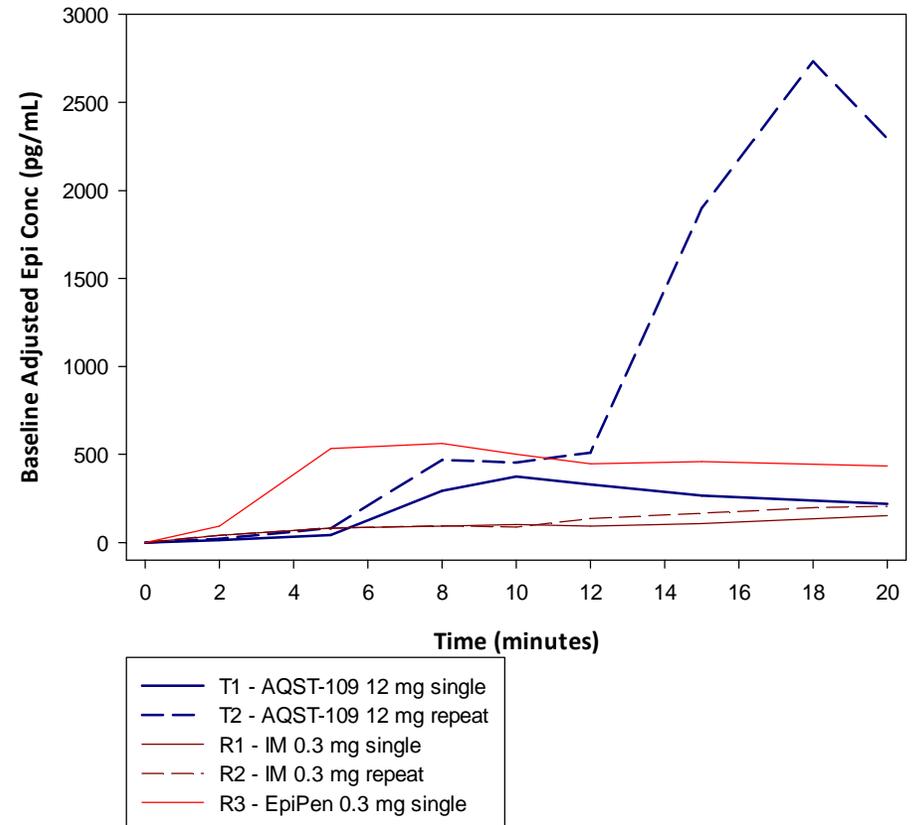
EPIPHAST II: Topline Results

AQST-109 C_{max} values within the timeframe critical to abate the cascade of anaphylaxis are comparable to and well bracketed by the 0.3mg IM and the EpiPen®

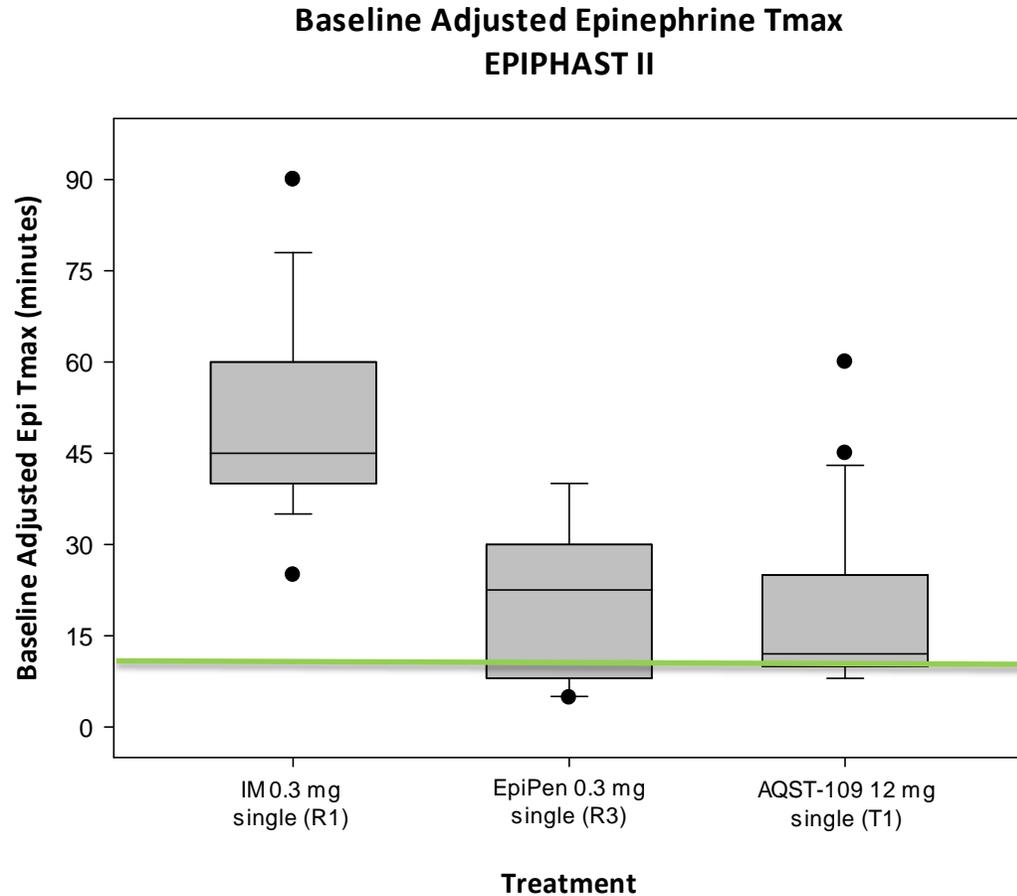


Represents data from top-line results. Geometric means presented for C_{max}. EPIPHAST II study was conducted with a 4-minute administration hold time. Administration instructions for future studies may vary.

Mean Baseline Adjusted Epi Concentrations over Time by Treatment
EPIPHAST II



EPIPHAST II: Time to Maximum Concentration (Tmax)



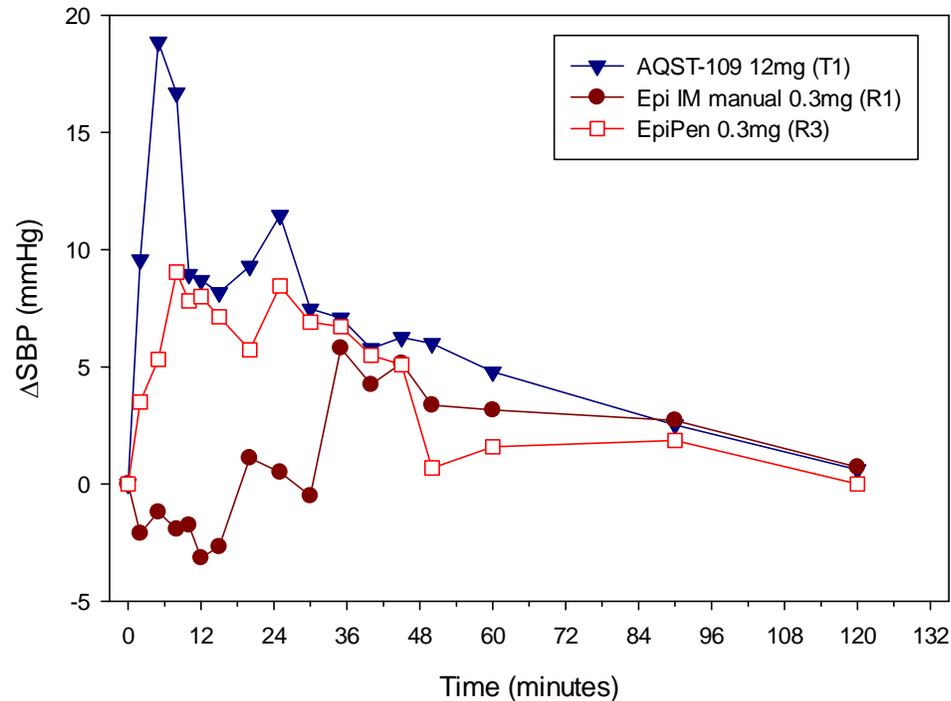
- AQST-109 showed a shorter median Tmax than both 0.3 mg IM and 0.3 mg EpiPen[®]
- Range of Tmax values across study is consistent with EpiPen[®]
- Both EpiPen[®] and AQST-109 provide faster median Tmax values than 0.3 mg IM

Fastest Median Tmax

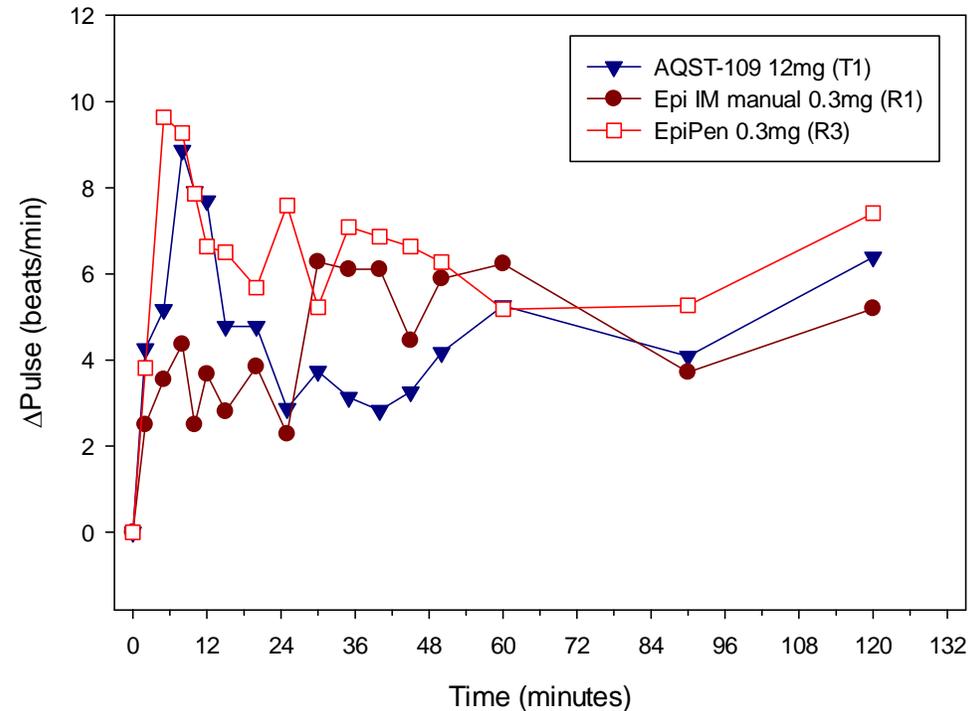
EPIPHAST II: Pharmacodynamic (PD) Results

- AQST-109 demonstrates a pharmacodynamic response for Systolic Blood Pressure (SBP) and Pulse consistent with that of EpiPen[®]
- Pronounced early peak in PD implies rapid and robust onset of therapeutic benefits

Mean Baseline Adjusted SBP over 130 minutes by Treatment
EPIPHAST II, Single Administration Treatments



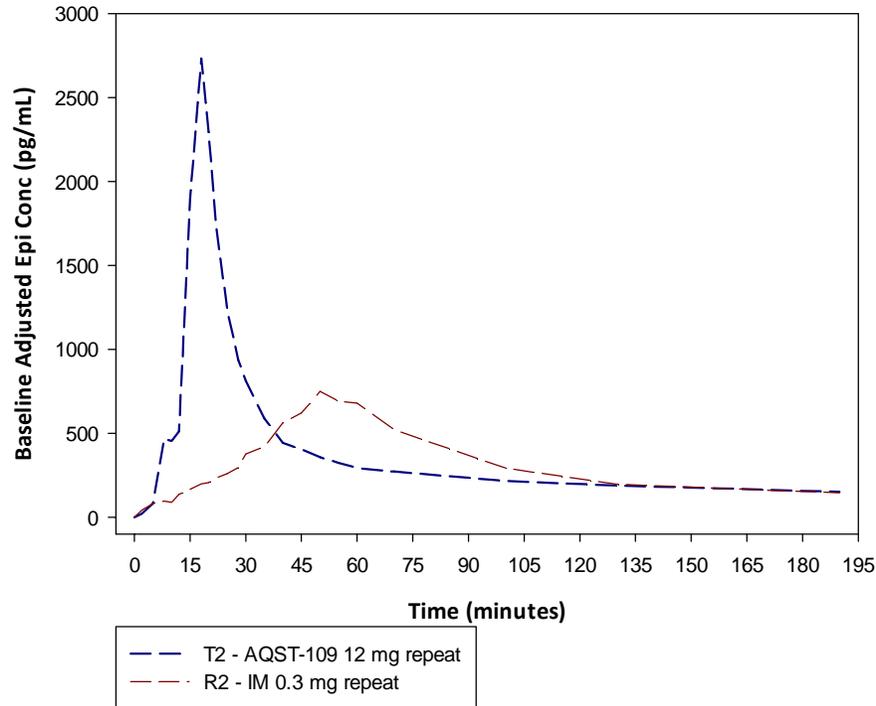
Mean Baseline Adjusted Pulse over 130 minutes by Treatment
EPIPHAST II, Single Administration Treatments



EPIPHAST II: Repeat Dose Topline Results

- AQST-109 performed favorably against the IM injection
- All subjects receiving a second dose showed absorption of the dose and lack of local epinephrine effects
- Plasma drug levels showed rapid absorption of the second dose with a median Tmax of 18 minutes (8 minutes post second dose administration)

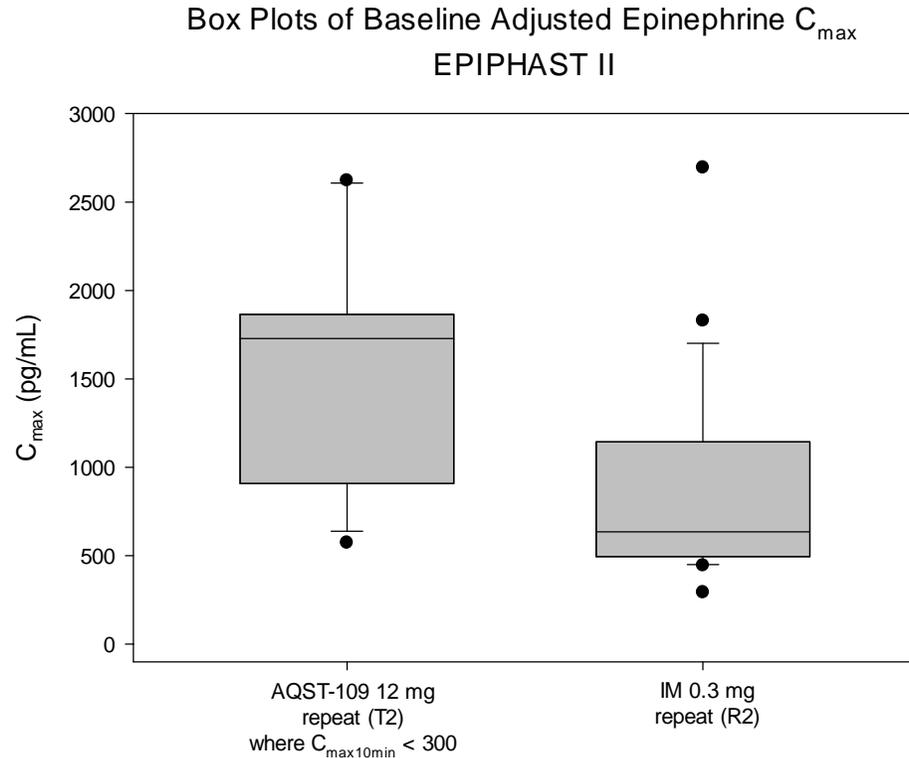
Mean Baseline Adjusted Epi Concentrations over 3 hours
EPIPHAST II, Repeat dose IM vs Repeat dose AQST-109



Description	AQST-109 Repeat Dose	0.3mg IM Repeat Dose
# Subjects/#Dosings	23/24	23/24
Cmax (pg/ml) (ISCV%)	2134	755
AUC 0-t (hr*pg/ml)	1469	1300
AUC 0-30min (hr*pg/ml)	402	67
Tmax (min)	18	50
Tmax Range (min)	8 - 30	30 - 70

Represents data from top-line results. Geometric means presented for Cmax and AUC0-t, Median Tmax.

EPIPHAST II: Repeat Dosing Post-Hoc Analysis



- Subjects with high C_{max} levels were significantly above therapeutic thresholds and mean C_{max} levels of the Reference Listed Drug (RLD) at time of second dosing
- These subjects represent patients unlikely to require a second dose
- For those with lower C_{max} levels, a repeat dose increased drug levels adequately, but not excessively
- Speed to onset of effects with AQST-109 will better inform both clinicians and patients about the need for a second dose, limiting unnecessary exposure

EPIPHAST II: Safety and Tolerability

PT Adverse Event Term	EPIPHAST II				
	12 mg (N=23) n (%)	24 mg (N=23) n (%)	0.3 mg (N=23) n (%)	0.6 mg (N=23) n (%)	EpiPen (N=22) n (%)
Cardiac Disorders	2 (8.7)	9 (39.1)	1 (4.3)	1 (4.3)	7 (31.8)
Palpitations	2 (8.7)	9 (39.1)	1 (4.3)	1 (4.3)	7 (31.8)
Ventricular Extrasystoles	0	0	0	1 (4.3)	0

- AQST-109's single dose safety profile had a lower incidence of palpitations than that of the 0.3 mg EpiPen®
- AQST-109's repeat dose safety profile had a similar incidence of palpitations to that of the single administration of 0.3 mg EpiPen®
- Local tolerability of both single and repeat doses of AQST-109 remains favorable with AE's mild to moderate and self resolving

AQST-109 was safe and well tolerated in both single and repeat administrations in the EPIPHAST II study

EPIPHAST II: Trial Summary

AQST-109 compared to EpiPen® 0.3mg (single dose)

- ❖ Confirmation of 12-minute median time to maximum concentration (T_{max})
- ❖ Faster observed median T_{max} than either EpiPen (22 minutes) or 0.3mg IM injection (45 minutes)
- ❖ Safety profile in line with previous studies – no SAE's

AQST-109 compared to epi 0.3mg IM injection (repeat dose)

- ❖ Demonstrated successful absorption of a second dose of AQST-109 in all subjects
- ❖ Second dose had an observed median T_{max} of 18 minutes (8 minutes after second dose administration)
- ❖ No severe or serious safety or tolerability events were reported

Regulatory Pathway

- ❖ End-of-Phase 2 meeting with FDA Division of Pulmonology, Allergy, and Critical Care scheduled during fourth quarter 2022
- ❖ Anticipate FDA meeting minutes before the end of the year

Q & A Session

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