

# ARS Corporate Presentation

---

Q2 2024



# Forward Looking Statements

Statements in this presentation that are not purely historical in nature are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this presentation include, without limitation, statements regarding: the anticipated timing for regulatory review decisions on the **neffy** NDA and MAA; ARS Pharma’s belief that **neffy** will be approved for the treatment of Type I allergic reactions; the timing for the potential U.S. launch of **neffy**, if approved; the potential market, demand and expansion opportunities for **neffy**; ARS Pharma’s expected competitive position; whether the results will be sufficient to demonstrate that **neffy** is at least as effective as injectable epinephrine; the timelines for potential regulatory filings, approvals and commercialization of **neffy** in ex-US regions; ARS Pharma’s marketing and commercialization strategies, including potential partnerships in foreign jurisdictions; potential benefits of **neffy**, if approved, including the likelihood that doctors will prescribe **neffy** and that allergy patients and caregivers will choose to carry and dose **neffy** compared to needle-bearing options; the expectation of **neffy** attaining coverage, including without restriction for 80% of commercial lives within a year of launch; ARS Pharma’s anticipated cash, cash equivalents and short-term investments on hand upon any future approval and launch of **neffy**; the expected size, composition and reach of ARS Pharma’s sales force; the availability and functionality of **neffy**Experience and **neffy**Connect; the anticipated pricing and co-pay buydown; the anticipated timing and costs of future studies and commercialization efforts, and their impact on operating runway; ARS Pharma’s projected operating runway; expected intellectual property protection; and any statements of assumptions underlying any of the foregoing. These forward-looking statements are subject to the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as “anticipate,” “could,” “demonstrate,” “expect,” “indicate,” “may,” “plan,” “potential,” “will” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon ARS Pharma’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation: the PDUFA target action date may be further delayed due to various factors outside ARS Pharma’s control; the ability to obtain and maintain regulatory approval for **neffy**; the results of the new clinical trial may not support the approval of **neffy**; results from clinical trials may not be indicative of results that may be observed in the future; potential safety and other complications from **neffy**; the labelling for **neffy**, if approved; the scope, progress and expansion of developing and commercializing **neffy**; potential for payers to delay, limit, or deny coverage for **neffy**; the size and growth of the market therefor and the rate and degree of market acceptance thereof vis-à-vis intramuscular injectable products; ARS Pharma’s ability to protect its intellectual property position; uncertainties related to capital requirements; and the impact of government laws and regulations. Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption “Risk Factors” in ARS Pharma’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, filed with the Securities and Exchange Commission (“SEC”) on May 9, 2024. This and other documents ARS Pharma files with the SEC can also be accessed on ARS Pharma’s website at [ir.ars-pharma.com](http://ir.ars-pharma.com) by clicking on the link “Financials & Filings” under the “Investors & Media” tab.

The forward-looking statements included in this presentation are made only as of the date hereof. ARS Pharma assumes no obligation and does not intend to update these forward-looking statements, except as required by law.





# Potential to Transform the Treatment of Type I Allergic Reactions

- **neffy®**: first potential “no needle, no injection” solution for Type I allergic reactions to address an unmet market need
- **Registration program** demonstrates comparable PK and PD, without risk of needle-related safety concerns, fear and hesitation
- **Rapid and statistically significant response on PD surrogates for efficacy (SBP, HR)** observed even 1 minute after dosing with *neffy* vs. injection
- **Significant opportunity to disrupt** current epinephrine injectables market
- **Response to CRL including positive data submitted April 2, 2024 - up to 6 months FDA review; CHMP opinion in Europe by June 2024**
- **Potential multi-billion-dollar market** driven by HCP and consumer preference and adoption
- **NCE-like IP exclusivity** potential until at least 2038
- **\$223.6 million in cash and short-term investments** as of 3/31/2023 with an anticipated >\$200 million at anticipated FDA approval in H2 2024

# Anaphylaxis is Accompanied by Many Frequent Symptoms

## Common Anaphylaxis Symptoms Include:

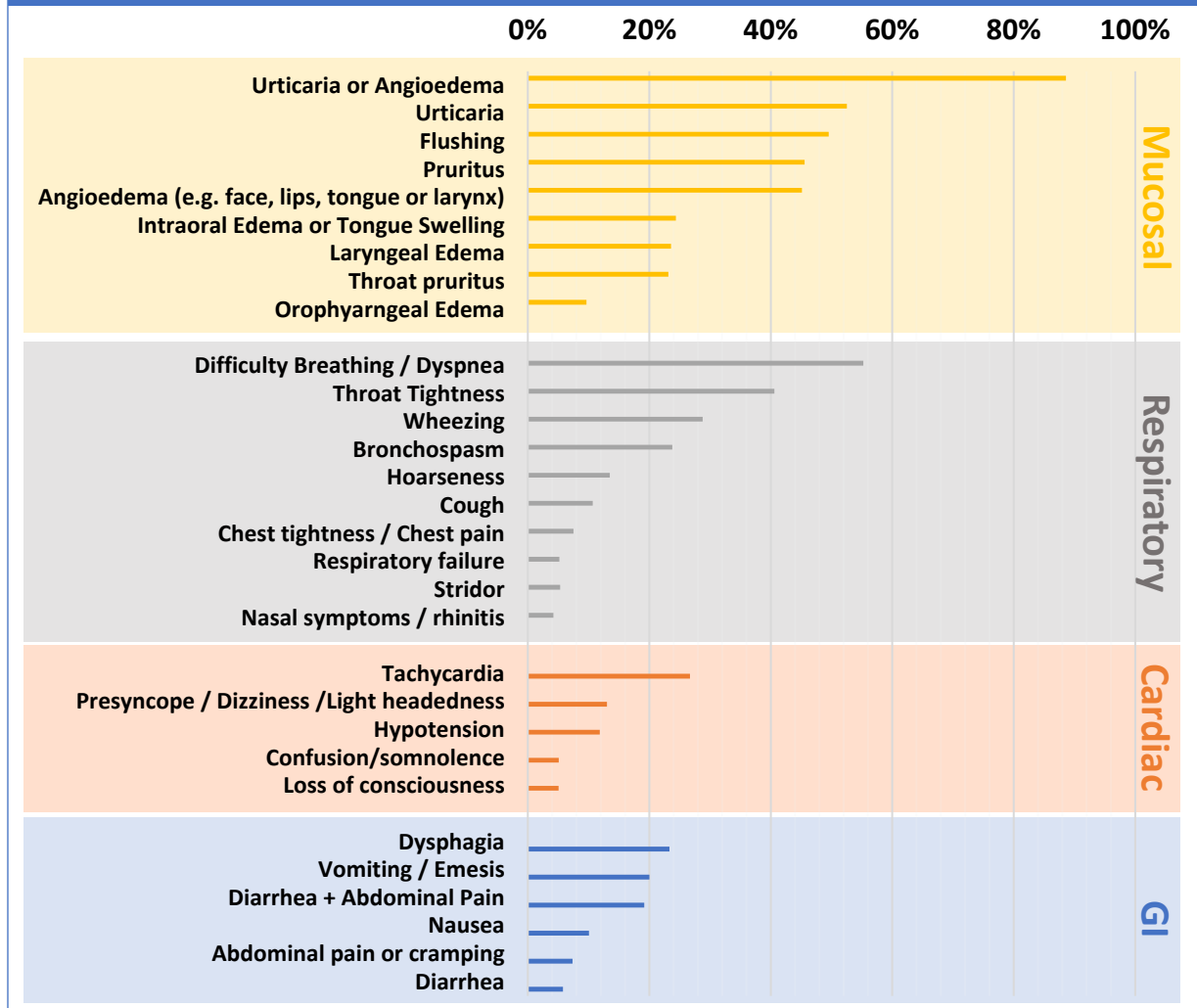
**>85%** urticaria (hives, erythema) or angioedema (swelling of the face, lips, tongue or larynx)

**>55%** difficult breathing

**>40%** gastrointestinal (eg, vomiting, nausea)



## Symptoms (>2%) reported during US anaphylaxis events<sup>2-14</sup>



# Epinephrine: The First Line of Defense Against Anaphylaxis

## Patients with Type 1 Severe Allergic Reactions are prescribed epinephrine to use at symptom onset

- Used for over 100 years
- Well-known mechanism of action, and only drug known to reverse a systemic allergic reaction
- Well-established efficacy and safety profile

## Products approved based on pharmacologic properties, not clinical efficacy studies

- All approved products demonstrate efficacy (90% response on a single dose) despite different pharmacokinetic (PK) properties
- Clinical studies are considered unethical/unfeasible

## All approved products are needle-based

- High unmet need for needle-free, easy-to-carry epinephrine remains

***neffy*** is the first potential “no needle, no injection” solution for Type I allergic reactions to address an unmet market need



**Rapid, reliable delivery**



**Small and easy to carry**



**Place and Press administration**



**Well-tolerated in extensive trials**

# Unmet Need / Current Challenges

## Vast Majority of Type I Allergy Patients Face Significant Limitations with Current Treatment Options





### PROBLEM:

ONLY 10% - 20% of patients with active Rx use as indicated<sup>7</sup>

### SOLUTION:

**neffy**



 NO TREATMENT AVAILABLE	 REFUSAL OF TREATMENT	 DELAY IN TREATMENT	 USER ERROR IN TREATMENT
~50% of patients carry <sup>1</sup> (<20% carry two)	~25% - 60% do not administer <sup>1,3 5, 6</sup>	~40% - 60% of patients delay <sup>2</sup>	23% - 35% fail to dose correctly <sup>4</sup>
<b>SMALL</b> <ul style="list-style-type: none"><li>Fits in your pocket; easy to carry the recommended 2 devices</li><li>~10% of cases require repeat doses of epinephrine<sup>1</sup></li></ul>	<b>NO NEEDLE NO INJECTION</b> <ul style="list-style-type: none"><li>Rapid administration without a needle</li><li>No risk of needle-related injuries; lacerations<sup>2</sup> or cardiotoxic blood vessel injections</li><li>Less hesitation to dose</li></ul>	<b>EASIER AND MORE CONSISTENT DOSING</b> <ul style="list-style-type: none"><li>100% of untrained adults and children can dose <i>neffy</i> successfully<sup>7</sup></li><li>High bioavailability, low 2 mg dose of <i>neffy</i> achieves comparable PK without overexposure risk including any side effects that mimic anaphylaxis</li></ul>	<b>RELIABLE</b> <ul style="list-style-type: none"><li>99.999% delivery of effective dose in reliability testing; not obstructed by any anaphylaxis symptoms; no inhalation required</li><li>24-month shelf-life at room temperature, with up to 3 months at high temperatures (122°F)</li></ul>



# neffy Designed for Ease of Use and Easy Carry

For epinephrine to be effective, patients must:



Case holds **two** neffy 2mg devices

Regularly have their device on hand

Not hesitate to dose immediately after symptom onset

Have a second device on hand if needed (~10% of cases)

Administer the device as intended

- **neffy** has a simple place and press administration (no hold time)
- **100% of adults and children** able to use **neffy** successfully without any training

Relative Size of **neffy** two pack Compared to iPhone 15 and EpiPen



# Development Program Centers on Pharmacology Studies

- Efficacy studies not ethical / feasible in severe Type I allergy patients
- **neffy** clinical studies developed in agreement with FDA and EMA to allow reference to historic efficacy and safety data of epinephrine injection
  - Bracketed pharmacokinetic (PK) exposures
  - Comparable pharmacodynamic (PD) responses
- > 1,200 administrations of **neffy** in > 700 subjects

Primary Studies (2 mg dose)	Patient Population
EPI 15	Adult: Healthy volunteer (HCP administration) – single and repeat dosing
EPI 16	Adult: Type 1 allergy patients (NAC induced rhinitis) – single dosing
EPI 17	Adult: Type 1 allergy patients (self-administration) – single dosing
EPI 18	Adult: Type 1 allergy patients (NAC induced rhinitis) – repeat dosing
EPI 10	Pediatric: Type 1 allergy patients: $\geq 30\text{kg}$ (NDA), $15 \leq 30\text{kg}$ (sNDA) – single dosing



# Registrational studies demonstrate comparability on both PD surrogates for efficacy and PK with *neffy*

## PD and PK Data

- 2 mg *neffy* met all clinical endpoints
- PD surrogates for efficacy comparable to approved products (SBP/HR  $\geq$  approved injection products)
- Rapid and significant response on PD surrogates for efficacy observed even 1 minute after dosing
- PK bracketed by approved products (exposures  $\geq$  IM/SC for efficacy,  $<$  EpiPen for safety)
- Repeat doses (including during rhinitis) within range of approved injection products

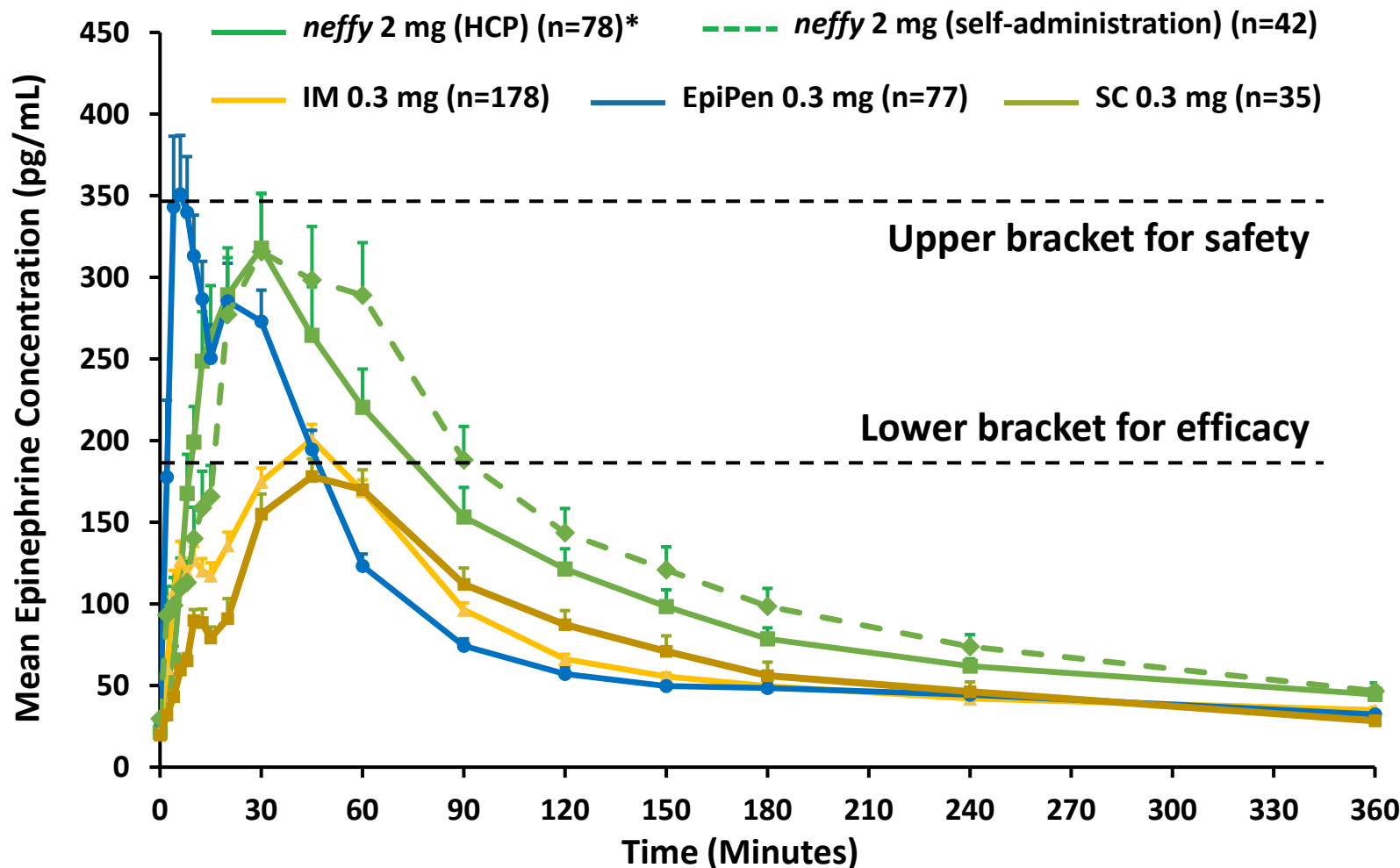


## Safety Data

- Adverse events generally mild in nature with no meaningful nasal irritation or pain up to 4 mg dose
- Most common adverse events ( $>5\%$ ) were mild nasal discomfort (9.7%) and mild headache (6%), with no correlation of nasal discomfort to pain or irritation
  - Mean VAS pain scores between 5 to 8 out of 100
  - No irritation based on formal assessment
- No serious adverse events in any clinical study
- No risk of needle-related injuries or blood vessel injections with *neffy*

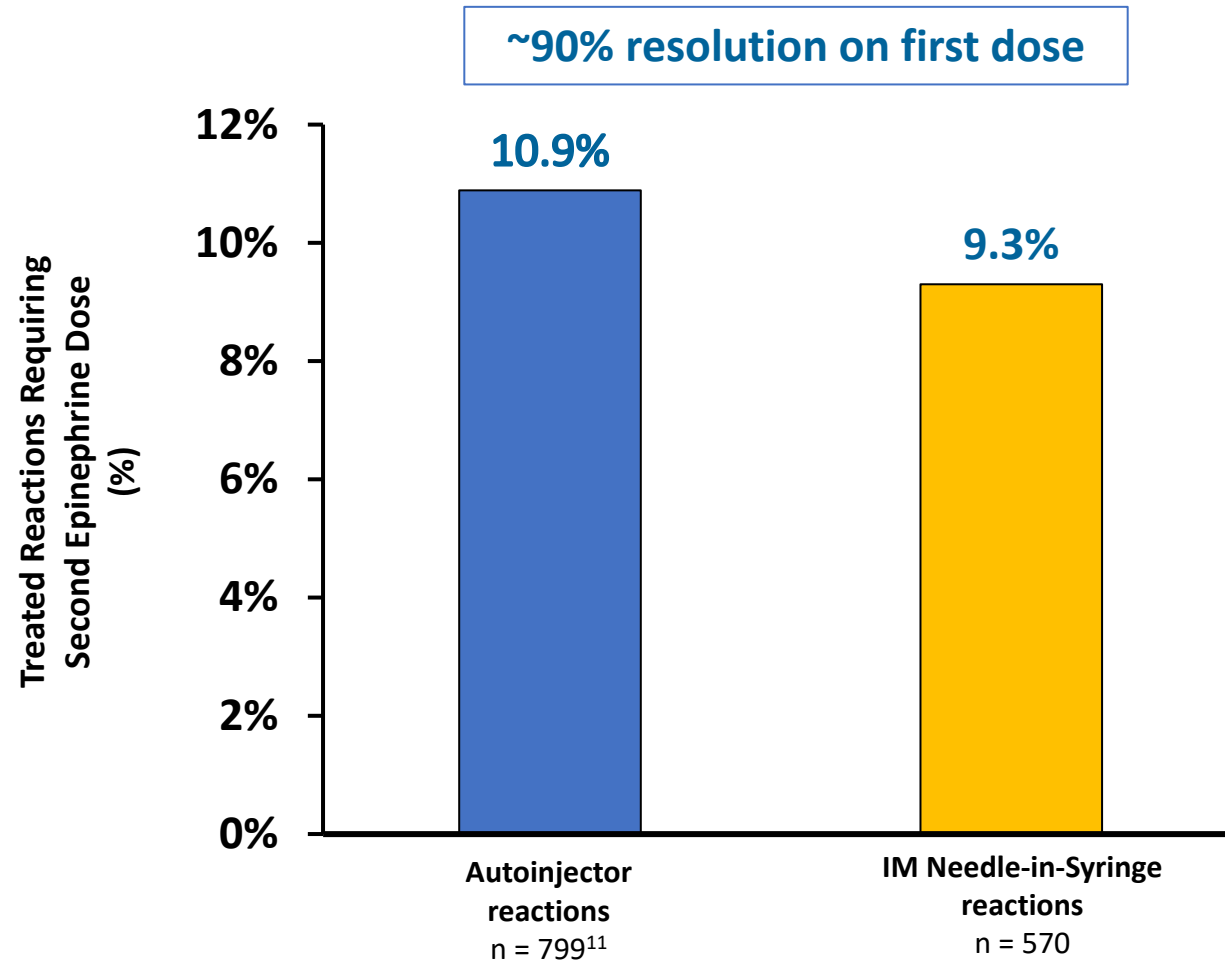
**Response to FDA submitted on April 2, 2024 followed by up to 6-month FDA review**

# Pharmacokinetic Results from *neffy* 2 mg Studies Satisfies Bracketing Approach agreed with by FDA



- FDA focused on PK properties to ensure efficacious and safe epinephrine exposures within range of approved products (“Bracketing”)
- Minimum exposure must be  $\geq$  IM/SC (efficacy)
- Maximum exposures must be  $<$  EpiPen (safety)
- No difference in efficacy between all injection products
- 90% response to single dose irrespective of device

# Second Dose Frequency Demonstrates Similar Efficacy Between IM and Autoinjectors (the only FDA approved products today)

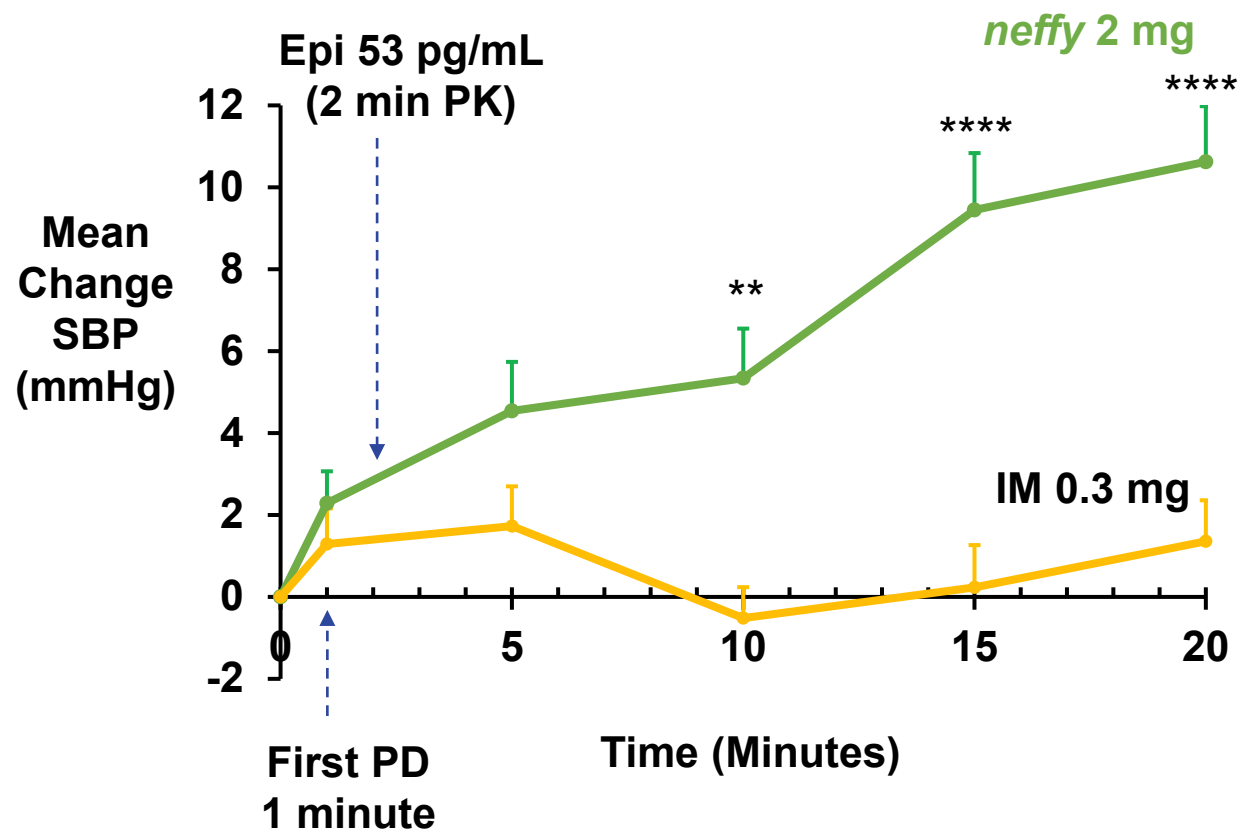


- Analysis of 12 studies with 100% autoinjector ( $\geq 80\%$  EpiPen) or 100% IM-needle-and-syringe use in community or ED setting<sup>1-11</sup>
- Differences in PK profile across products do not impact efficacy based on need for repeat dosing to resolve symptoms

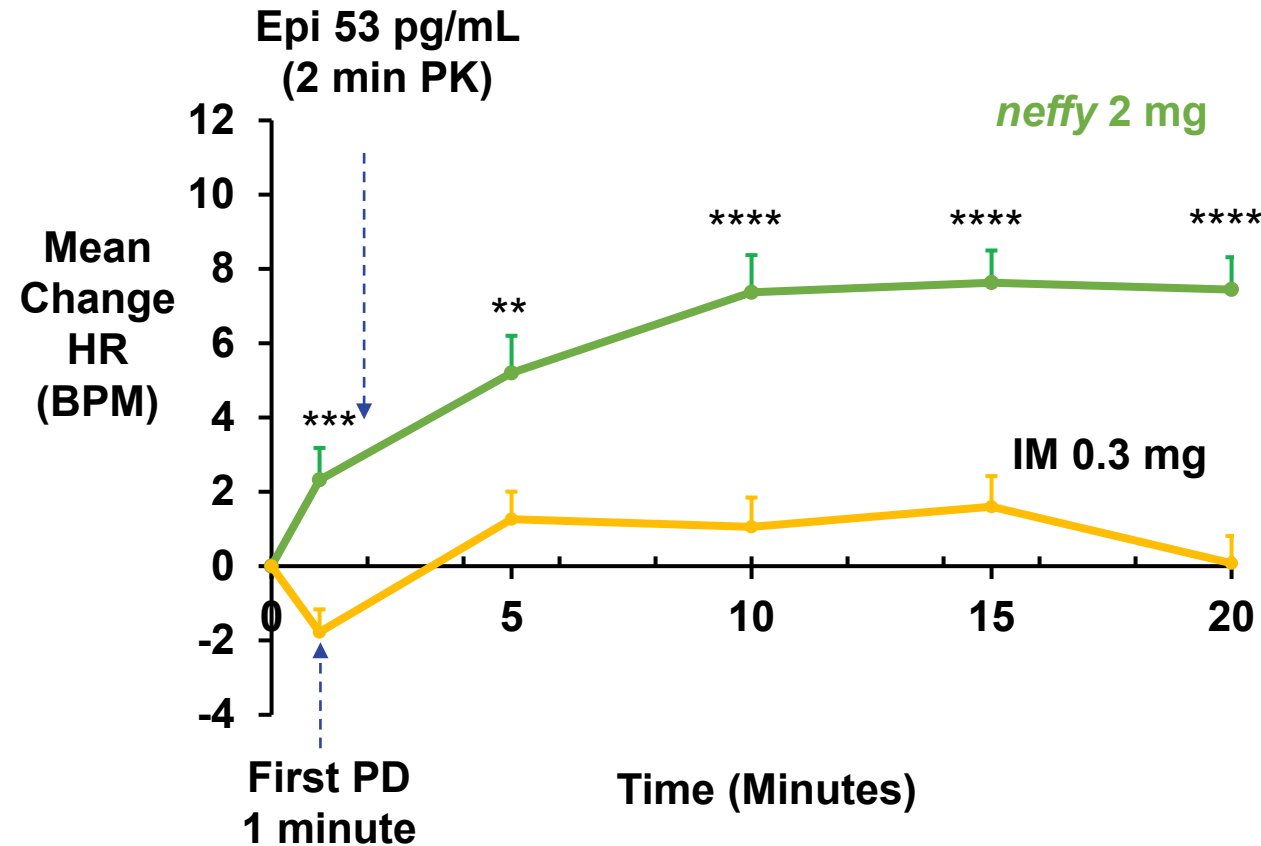


# Robust response on PD surrogate markers for efficacy shows engagement of receptors that reverse anaphylaxis symptoms

## Systolic Blood Pressure Response



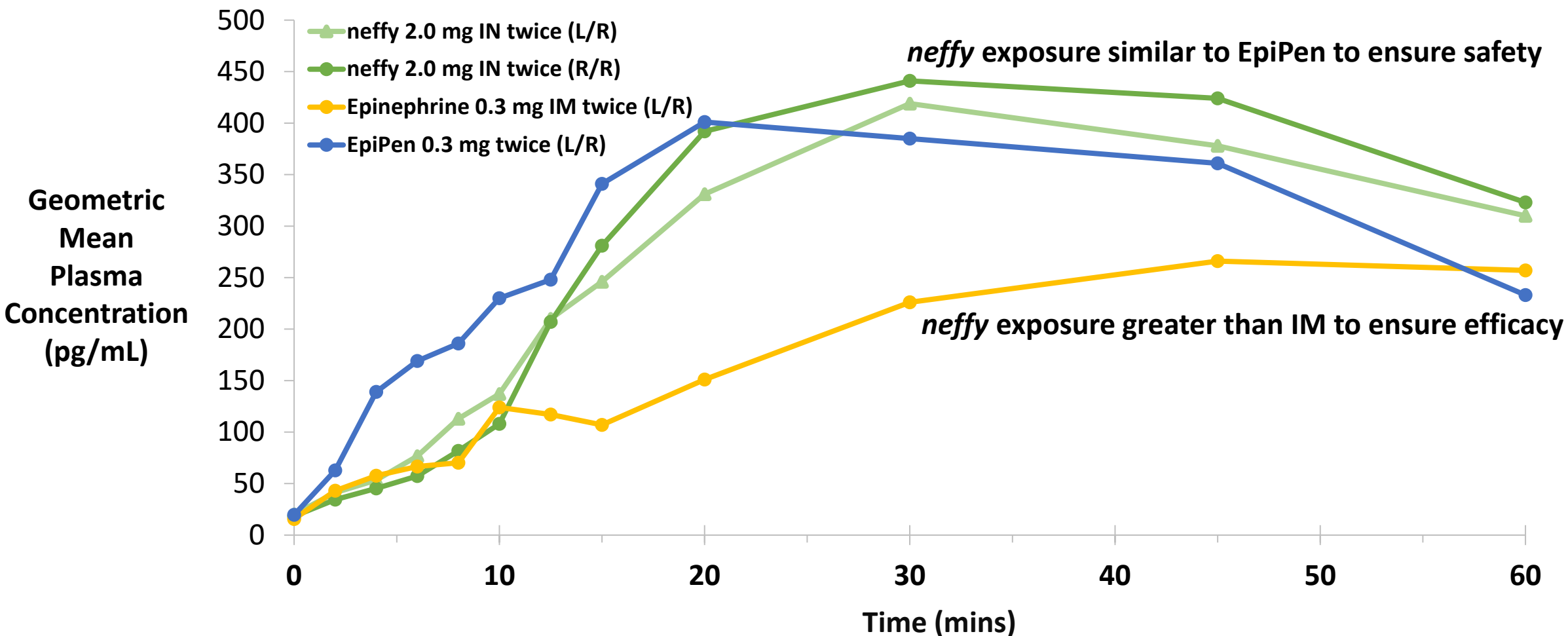
## Heart Rate Response



Significance level: \*\*  $p < 0.01$ , \*\*\*  $p < 0.001$ , \*\*\*\*  $p < 0.0001$

# Exposures of repeat doses of *neffy* in healthy subjects are also in the range of FDA approved epinephrine injection products

Repeat-dosing (10 min apart) results in healthy subjects



# PK/PD profile and ability to dose may be influenced by anaphylaxis itself, so FDA asked ARS to evaluate rhinitis in clinical studies



- Intranasal formulation least impacted by anaphylaxis symptoms compared to alternate non-injectable routes
- Nasal symptoms or rhinitis only impact only 4% of cases (analysis of 4,805 US anaphylaxis events)<sup>1-12</sup>
- ARS successfully evaluated patients with rhinitis in response to FDA CRL, which responded positively to single and repeat doses of *neffy*

Potential effect on ability to dose or absorption profile by theoretical route of administration for epinephrine

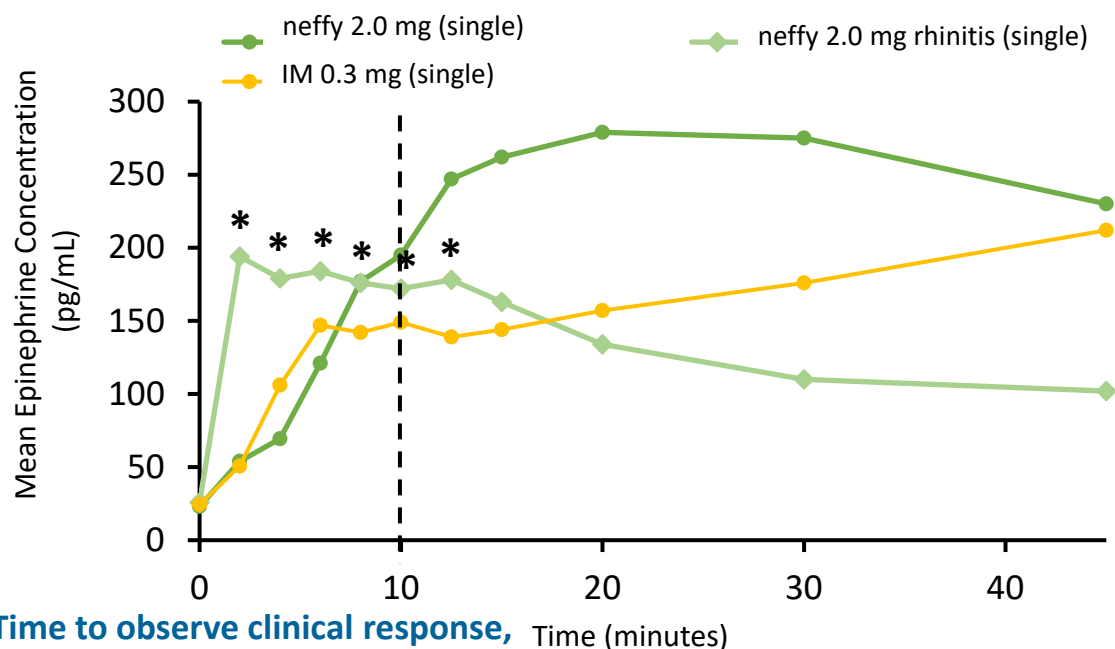
Anaphylaxis Symptom	US %	Intranasal	Sublingual	Oral*	Inhalation*
Nasal symptoms or rhinitis	4%	X			X
Oropharyngeal edema	10%		X	X	X
Vomiting / Emesis	20%		X	X	X
Dysphagia	23%			X	X
Laryngeal Edema	24%			X	X
Bronchospasm	24%				X
Intraoral Edema or Tongue Swelling	24%		X	X	X
Angioedema (e.g. face, lips, tongue or larynx)	45%		X	X	X
Difficulty Breathing / Dyspnea	55%				X

\* insufficient oral and inhalation systemic absorption due to rapid conjugation and oxidation in GI tract or difficulty taking in enough puffs<sup>14</sup>



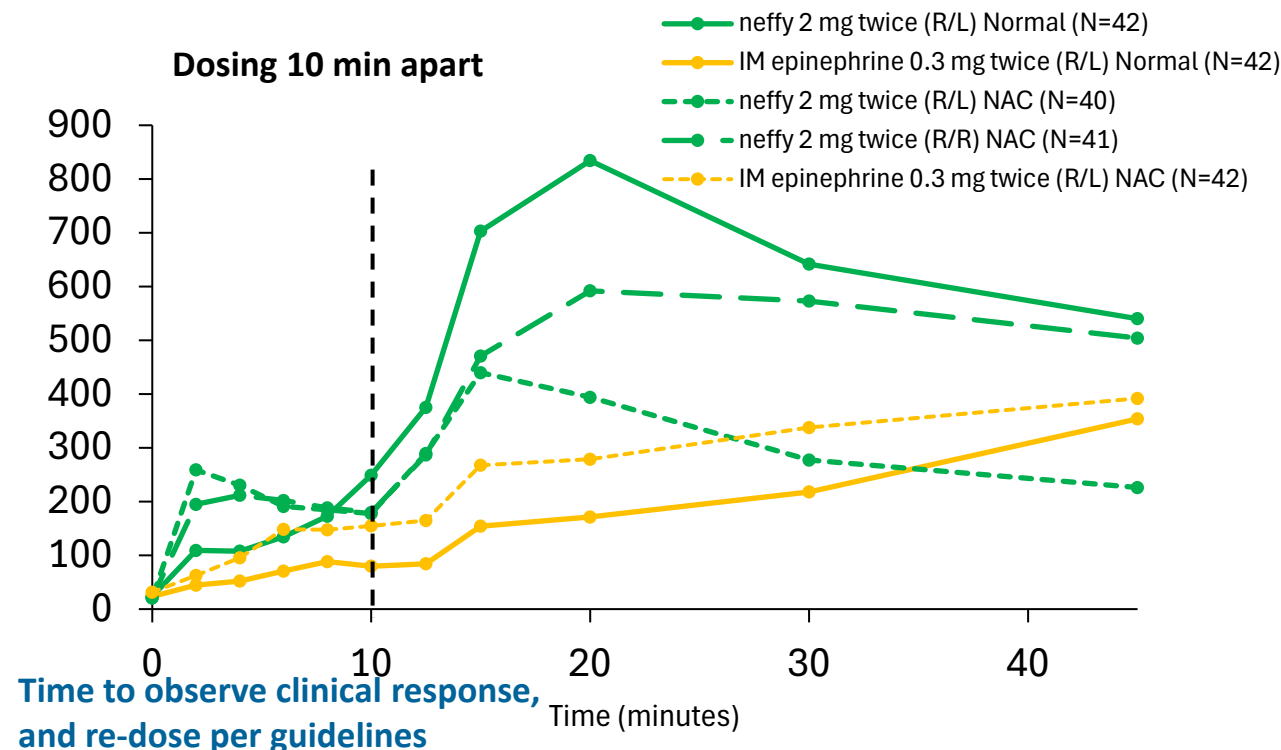
# Experimental Nasal Allergen Challenge (NAC)-Induced Rhinitis Does Not Negatively Impact *neffy*'s PK Profile (allergic rhinitis subjects)

NAC-induced rhinitis accelerates absorption of single dose *neffy*, but within the range of injection



Time to observe clinical response, and re-dose per guidelines

Repeat doses of *neffy* under NAC-induced rhinitis supports similarity to injection for more severe cases of anaphylaxis

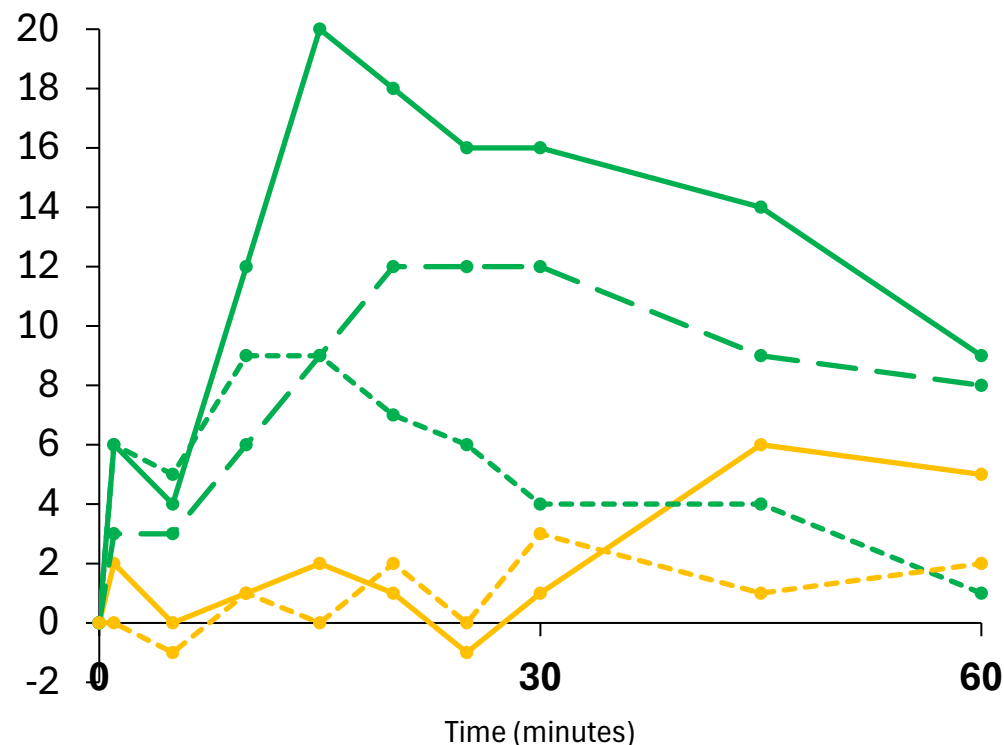


Time to observe clinical response, and re-dose per guidelines

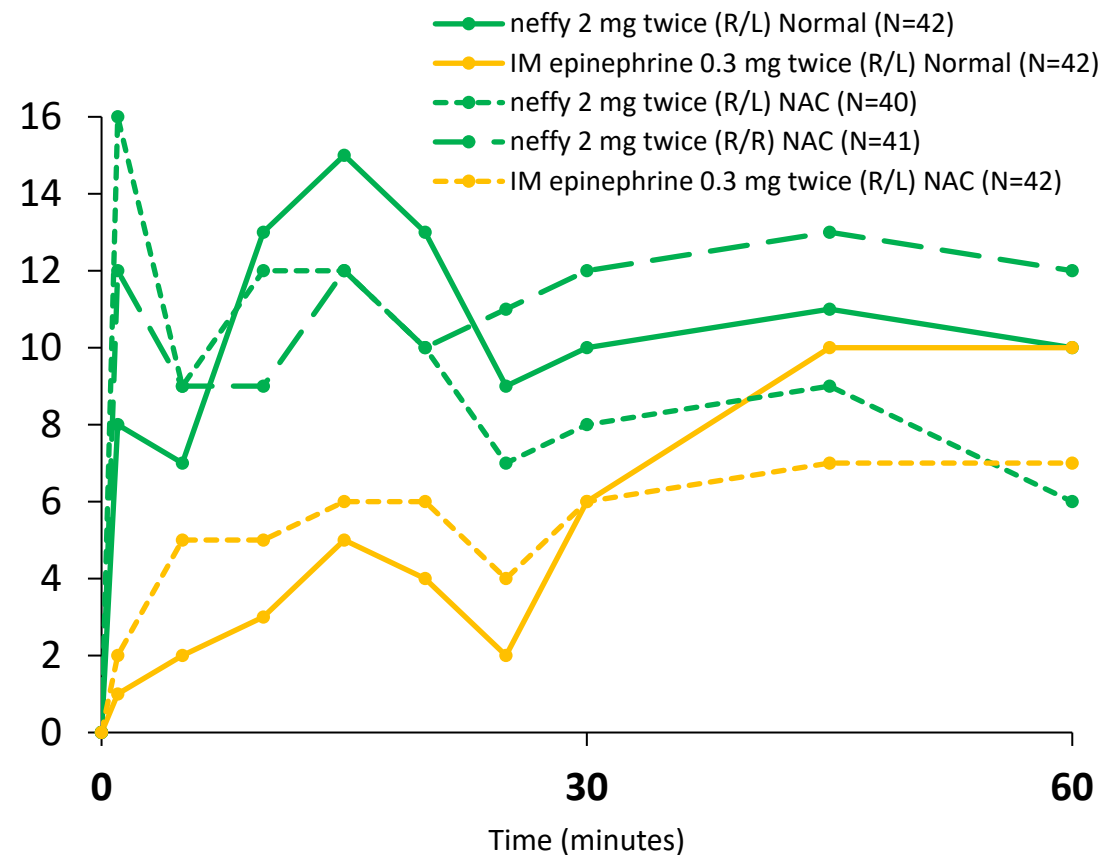
FDA Advisory Committee viewed single dose *neffy* NAC data as “encouraging” and “favorable”, but FDA’s CRL requested, and ARS successfully completed repeat dose *neffy* NAC study

# Experimental NAC-Induced Rhinitis Does Not Negatively Impact *neffy*'s PD Profile (Repeat Doses 10 min Apart)

Mean Change in Systolic Blood Pressure (mmHg)



Mean Change in Heart Rate (bpm)

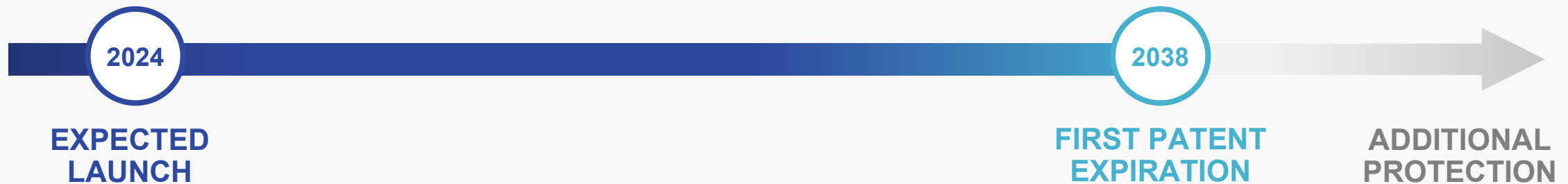


Response to FDA's CRL submitted April 2, 2024 followed by up to 6-month FDA review

# neffy on track for potential US launch in H2 2024 with market exclusivity potential until at least 2038

**Extensive studies in the lab and clinic completed to develop a proprietary product with expected NCE-like exclusivity**

- ✓ Issued composition of matter patent (US10,576,156) on Intravail® + epinephrine provides foundational exclusivity blocking any generic products. **Method of treatment patents (US11,173,209; US11,191,838)** block other alkyl glycosides.
- ✓ Issued method of treatment patent (US10,682,414, US11,744,895, US11,717,571, US11,191,655) also blocks intranasal epinephrine product using a different technology using a low dose (<4 mg)
- ✓ PCT patent granted in Europe (EP19751807), UK (GB2583051), Japan (JP6941224), Canada (3088909), Australia (AUS2019217643), Korea (10-2375232), China (2019800010042), with same claims as the US





# Commercialization Strategy

---





PHYSICIAN

# Significant Opportunity to Address Unmet Needs in Current US Severe Allergic Reaction Market



**Epidemiology prevalence data estimates**  
**~40M patients with type 1 allergic reactions<sup>2-10</sup>**



**~20M diagnosed and under physician care over the last 3 years<sup>11</sup>**



**Consistent Market Growth (Units)**

+6.5% CAGR since 2010, +12.7% YoY in 2023<sup>1</sup>



**Promotional Responsiveness**

~50% increase over market growth trend with consumer promotion (2010 to 2015<sup>1</sup>)



**~3.2M patients filled Rx in 2023, but ~80-90% do not use as indicated<sup>11</sup>**

(1) do not carry (~50%), (2) do not inject (25-60%), (3) wait to inject (40-60%) or (4) dose incorrectly (23-35%)

~\$1 billion net today based on generic autoinjector pricing<sup>1</sup>

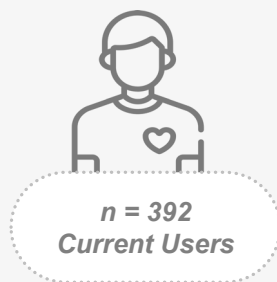
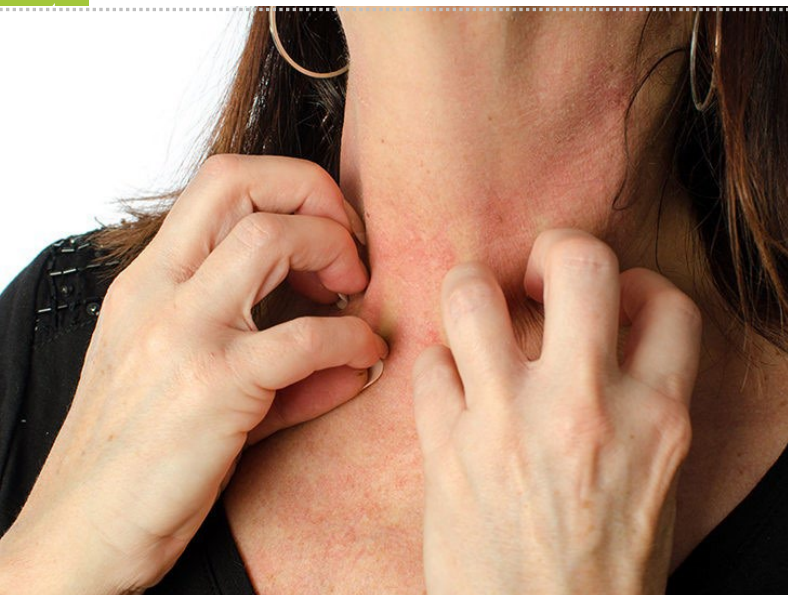


**~3.3M don't fill regularly, haven't refilled or haven't filled a written Rx in 2022<sup>11</sup>**



**~13.5M Type 1 diagnosed but not prescribed Rx (past 3 years)<sup>11</sup>**

# *neffy* has the ability to address the unmet need and is aligned with what healthcare providers, patients and parents want<sup>1</sup>



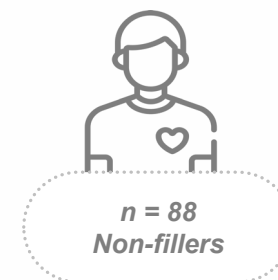
**88%**

OF PATIENTS LIKELY TO  
VERY LIKELY TO ASK THEIR  
PHYSICIAN ABOUT *neffy* Rx<sup>1</sup>



**89%**

OF NON-FILLING PATIENTS  
STATED THEY WOULD ASK THEIR  
PHYSICIAN ABOUT *neffy* RX<sup>1</sup>



**72%**

OF THE TIME,  
PEOPLE WHO  
USE AN OTC WOULD  
USE *neffy* FIRST<sup>2</sup>

**81%**

OF PEOPLE  
WOULD USE *neffy*  
SOONER THAN CURRENT  
NEEDLE INJECTORS<sup>3</sup>





PHYSICIAN

# Physicians supportive of adopting *neffy* into practice



*n* = 75  
Physicians

**8.5 out of 10 rating<sup>1</sup>**

viewed as a major advance in therapy

10 = MAJOR ADVANCE / 1 = NOT AN ADVANCE AT ALL

**99%**

*n* = 185  
Physicians

**Would prescribe *neffy* if their patients asked for it<sup>1</sup>**

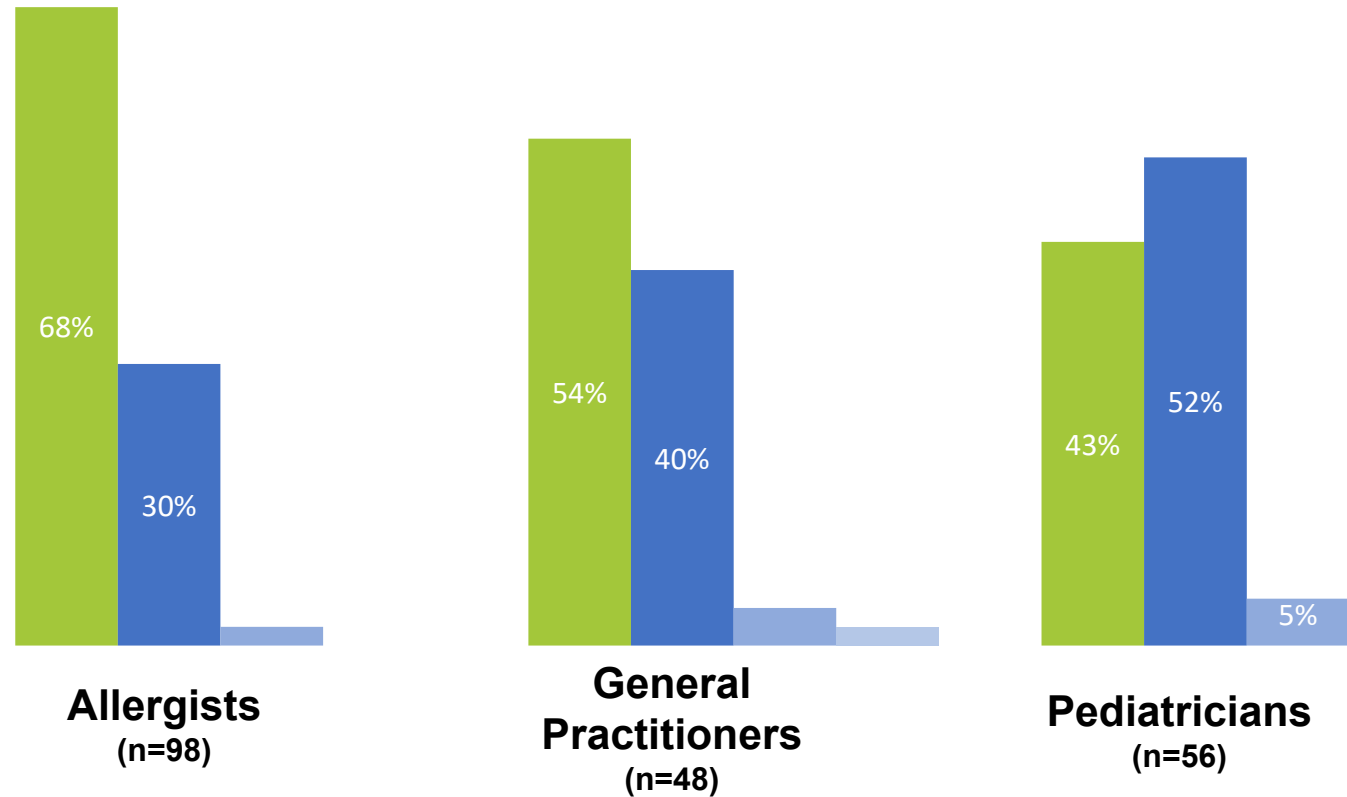


PHYSICIAN

# Two-Thirds of Allergists and Half of GPs Ready to Prescribe *neffy* as Soon as Possible; Majority of Pediatricians Expected to Prescribe within One Year

## Timeline for Prescribing *neffy* – % of physicians

- As soon as possible
- Within one year of its approval
- 1-3 years of it being on the market
- After it is on the market for more than 3 years



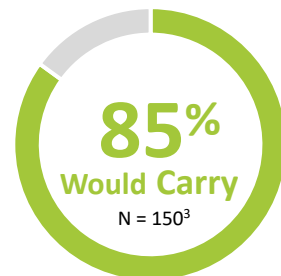
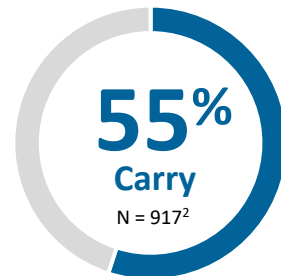


# *neffy*: Innovative Treatment to Overcome Known Challenges with Needle-Injectors for SAR Patients

## Benefits of needle-free alternative to address major unmet needs

- More allergy patients and caregivers are likely to carry *neffy* compared to current needle-bearing options
- Patients are likely to dose *neffy* more rapidly with a needle-free device

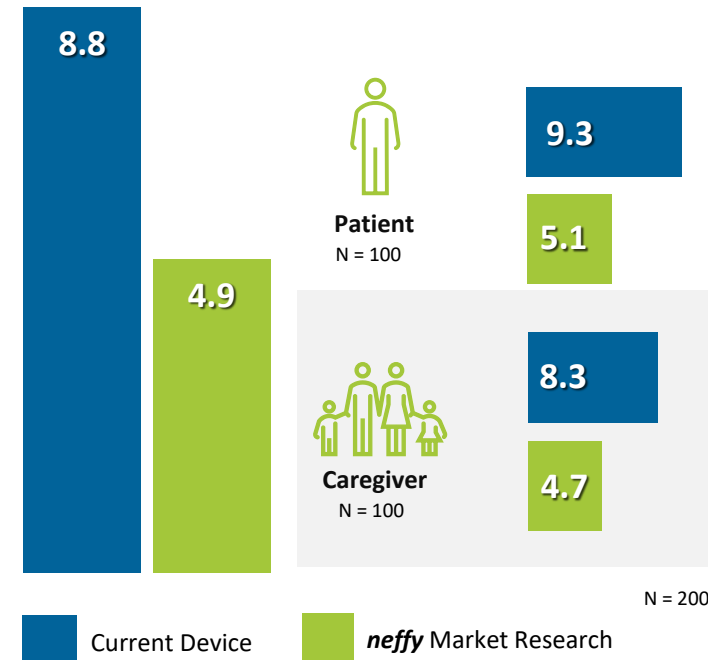
 % of Time Carrying at least One Epinephrine Device<sup>2,3</sup>



↓ 45% REDUCTION IN TIME TO USE



**Average Time** (minutes)  
from Symptom Start to Device Use<sup>1</sup>

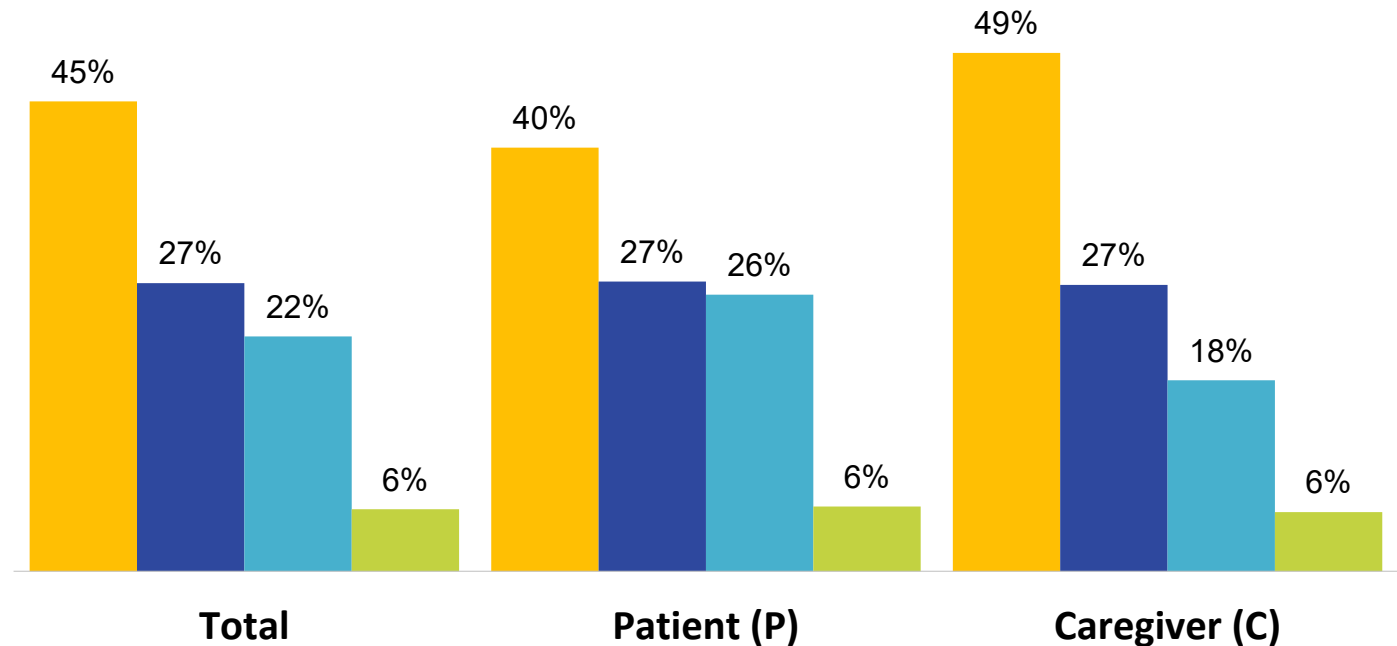




# ~ 72% of Respondents would Make a Special Appointment to Discuss *neffy* with their HCP

## Action Taken to Discuss *neffy* with HCP

- Make a special in-person appointment to discuss *neffy*
- Make a special telehealth appointment to discuss *neffy*
- Wait until my next regular appointment to discuss *neffy*
- Wait to see if my doctor wanted to discuss *neffy* with me



Respondents who may ask their HCP about *neffy*, Aug-23: Total (n=476), Patient (n=244), Caregiver (n=232) % of respondents

# neffy Strategic Objectives



## EDUCATE PRESCRIBERS

Drive adoption within specialty and high decile prescribers on the compelling value-proposition of **neffy**



## FACILITATE ACCESS

**neffy** access, affordability and support services



## ACTIVATE PATIENTS

Create awareness and motivate patients and caregivers to seek **neffy**





EDUCATE

# Drive Adoption within Specialty and High Decile Prescribers

## Healthcare Provider Launch Objectives

- Commercial force of **110** Sales and Virtual Representatives and Area Sales Managers
- Education, awareness, and resources to drive adoption (**neffy** Experience)
- Calling on **12,500** Allergy Specialists and High Decile Prescribers
  - **Reaching 40-45%** of Prescriptions from all HCPs -> 55% of Prescriptions including co-located HCPs (~50,000 HCPs)
  - **Reaching >80%** of Prescriptions from Allergists and Pediatricians





EDUCATE

# *neffy* experience program allows allergists to gain firsthand experience and increased patient awareness of *neffy*

- The **neffy Experience Program** is a proposed product trial program to enable HCP real-world experience with *neffy*
- Targeting allergist offices who conduct in-office allergy skin and food challenge testing where epinephrine is currently used to reverse anaphylactic reactions when they occur in-office
- By using *neffy* in office as a rescue therapy during allergy challenge/testing, HCPs will have the ability to gain first-hand knowledge of *neffy*'s effectiveness
- Patients undergoing allergy challenge/testing will also be exposed to *neffy* since the HCP will offer it as an option (e.g. patient asked at beginning if they prefer rescue therapy by epinephrine injection or nasal spray)



**Thank you for enrolling in the  
*neffy* Experience Program!**



The *neffy* Experience Program enables healthcare professionals to gain real-world experience with *neffy*, a nasal spray for Type 1 allergic reactions, including anaphylaxis. This kit includes 3 professional courtesy packs, each containing 2 *neffy* epinephrine nasal spray devices. Administering *neffy*, if needed during anaphylaxis, can provide you an opportunity to observe how your patients respond to *neffy* firsthand.

Each device contains a one-time emergency dose of epinephrine. Because these devices were designed for one-time use, DO NOT TEST the devices.



**SEE THE ADMINISTRATION VIDEO FOR THIS DEVICE.**

**Contact your ARS representative to request any of the following materials for your practice:**

#### DEVICE TRAINING KIT

A kit containing guides for administering and disposing of *neffy* demonstration devices for training patients/caregivers in your office



#### PATIENT BROCHURE

Information for patients and caregivers about treating severe allergic reactions



#### PATIENT IN-OFFICE QUESTIONNAIRE

A resource designed to help create an open dialogue between patients and HCPs on carrying and using traditional epinephrine



#### INDICATION

*neffy* is indicated for the immediate and emergency treatment of allergic reactions (Type I), including anaphylaxis, which may result from allergens, as well as idiopathic and exercise-induced anaphylaxis in adults and children  $\geq 30$ kg (66 lbs.).

#### IMPORTANT SAFETY INFORMATION

##### Warnings

**Emergency treatment:** After use of *neffy*, if symptoms subside, the patient should contact a medical professional to determine if more medical care is needed. If symptoms continue to progress after approximately 5-15 minutes, the patient should give a second dose using a new *neffy* device and seek immediate medical or hospital care.

Please see the full Prescribing Information for *neffy*<sup>®</sup> (epinephrine nasal spray).



# *neffy* Shows Robust and Rapid Clinical Resolution of Oral Food Challenge Anaphylaxis Symptoms

## Efficacy Study of *neffy* in Oral Food Challenge Induced Anaphylaxis (EPI-JP-03)<sup>1</sup>

**Study Design:** single arm, open-label study

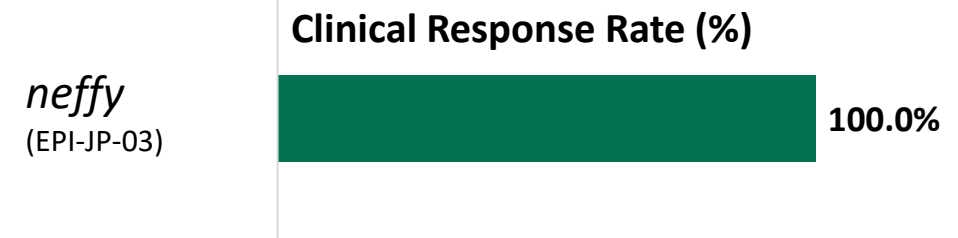
**Participants:** 15 pediatric subjects (aged 6 to 17):

- 9 subjects (30 kg+)
- 6 subjects (15-30 kg)

Patients experiencing Grade 2 (moderate) or higher anaphylaxis symptoms (out of 3 grade scale)<sup>3</sup> following oral food challenge dosed with a single dose of either 2 mg or 1 mg *neffy*:

- **Mucosal:** generalized urticaria/exanthema/wheal pruritus, swollen face, throat pain
- **GI:** moderate abdominal pain, recurrent emesis/diarrhea,
- **Respiratory:** repetitive cough, chest tightness/wheezing detectable via auscultation
- **Circulatory:** pale face/mild hypotension/tachycardia (>15 beats/min), light-headedness/feeling of “pending doom”/somnolence/headache

## Study Outcomes



**100%** of patients responded to a single dose of *neffy* in the first 15 minutes, and did not require a second dose of epinephrine per treatment guidelines

**100%** of patients experienced complete resolution of the anaphylaxis symptoms with single dose of *neffy*<sup>2</sup>

**16 min** median time to complete resolution of anaphylaxis following single dose of *neffy*



FACILITATE

# Committed to ensuring *neffy* access for all patients

## Key findings from discussions with the major payers and PBMs:

- High degree of interest in *neffy* and positive receptivity in early conversations; proactively requesting clinical presentations prior to approval
- Epinephrine is covered as a pharmacy benefit, and we expect to achieve coverage without restriction for 80% of commercial lives within a year of launch
- ARS is committed to access and affordability – we will offer a co-pay buydown to \$25 for commercial patients, a cash price of \$199, and a Patient Assistance Program for uninsured or underinsured
- *neffy*connect will assist in managing coverage by providing patients, caregivers and healthcare providers with information regarding support programs and financial aid

*“If this is priced properly, this could be a ‘**state-of-the-art therapy**’ for patients.”*

– PBM

*“This is a **game-changer**; it really addresses the unmet needs we currently have in this space, specifically the safety and tolerability issues.”*

– Payer

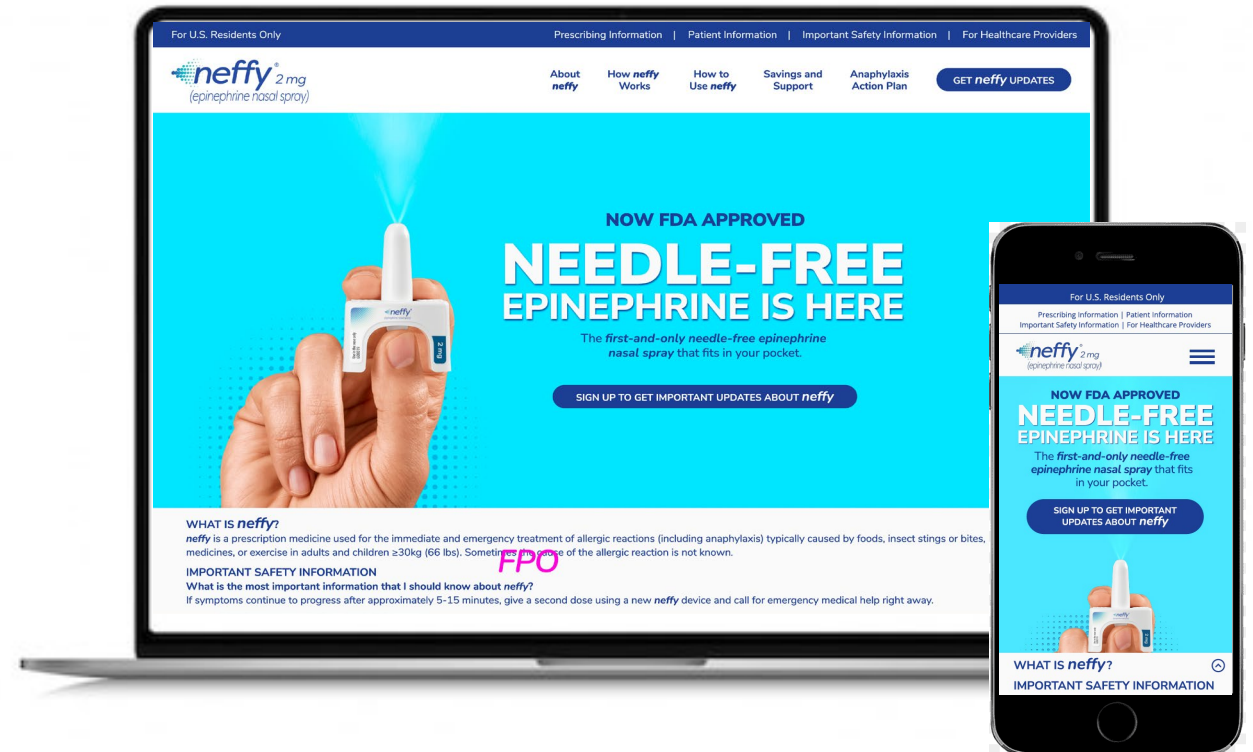
*“There is no value in delaying access to a product like this and nothing to prior authorize (PA). We can’t PA if the patient needs it.”*

– PBM

# Create Awareness & Motivate Patients and Caregivers to Request *neffy*

## Consumer Launch Objectives

- Drive awareness & motivate patients and caregivers to request *neffy* by name
- Enable patients and caregivers to feel fully prepared to act during a potential crisis moment
- Activate patients and caregivers to share their *neffy* story to encourage peer uptake



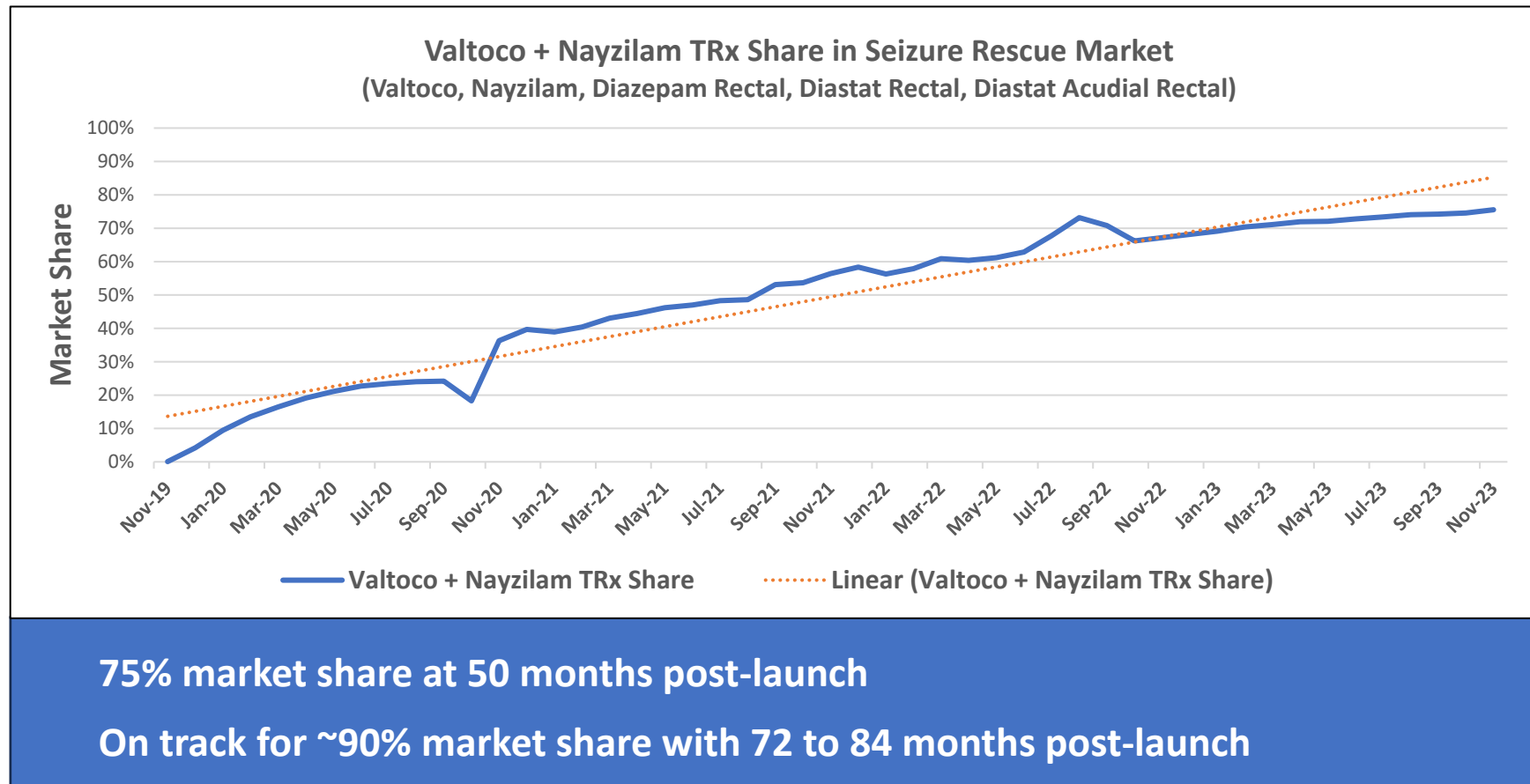


# Intranasal Analog Comparison: Seizure Rescue Market Valtoco and Nayzilam Share Growth

**VALTOCO®**

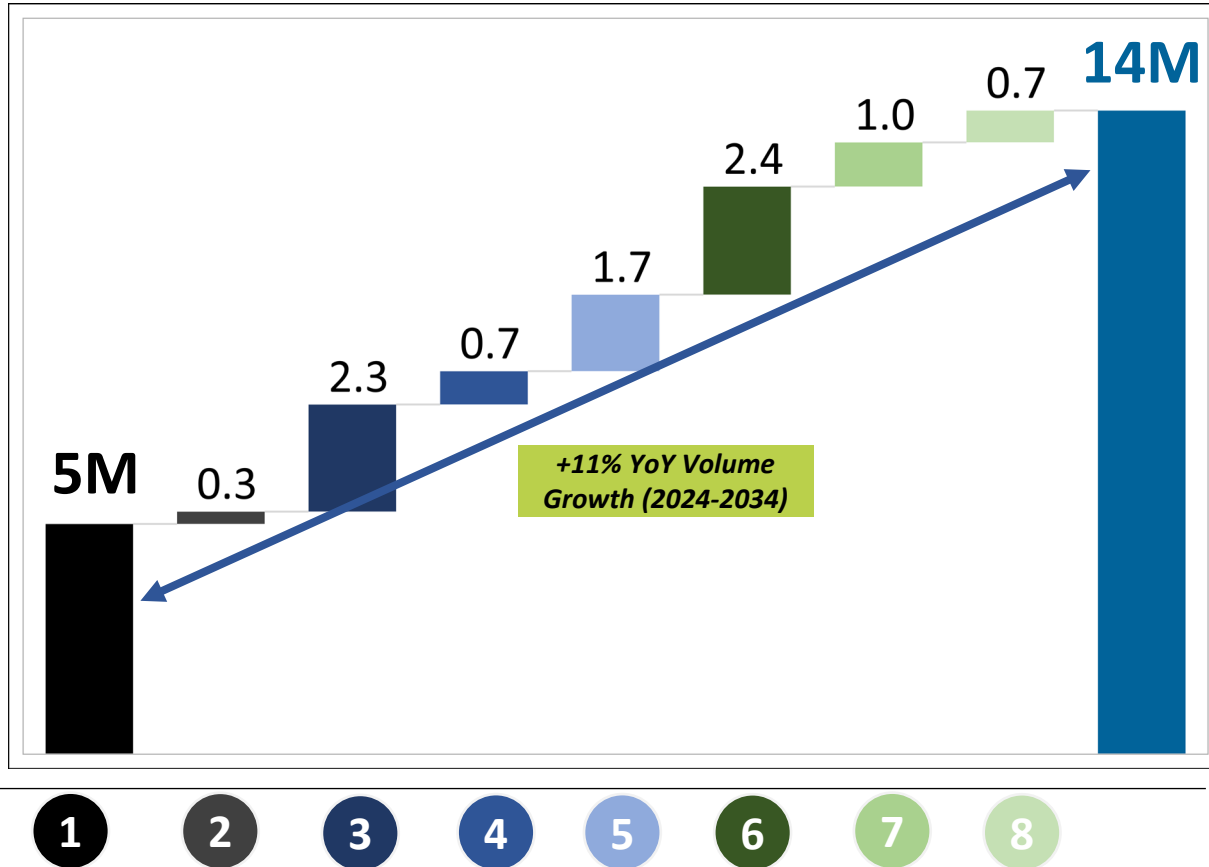


**NAYZILAM®**



# US Epinephrine Market Evolution Due to the Availability of *neffy* Supports Significant Revenue Opportunity<sup>1</sup>

## Millions of epinephrine 2-pack devices sold in US



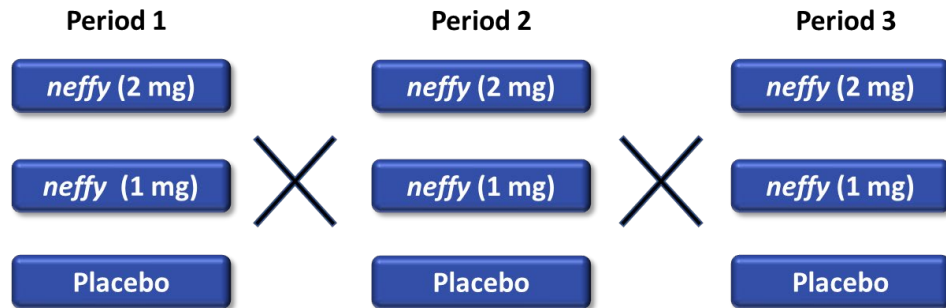
- 1 ~\$1B+ net sales US market based on generic epinephrine pricing in 2023<sup>3</sup>  
(~5M 2-packs, ~3.2M active patients)
- 2 Natural population growth (~0.6% YoY growth)
- 3 Conversion of some lapsed Rx patients
- 4 Conversion of some never filled Rx patients
- 5 Conversion of some never Rx'ed patients
- 6 Growth in diagnosed population due to branding, marketing and DTC
- 7 Increased Rx/year (improved persistency)
- 8 Increased devices/Rx (patient demand for *neffy*)

# neffy Shows Robust and Rapid Clinical Responses in Treatment-Resistant Urticaria; Phase 2 outpatient study to initiate in 2024

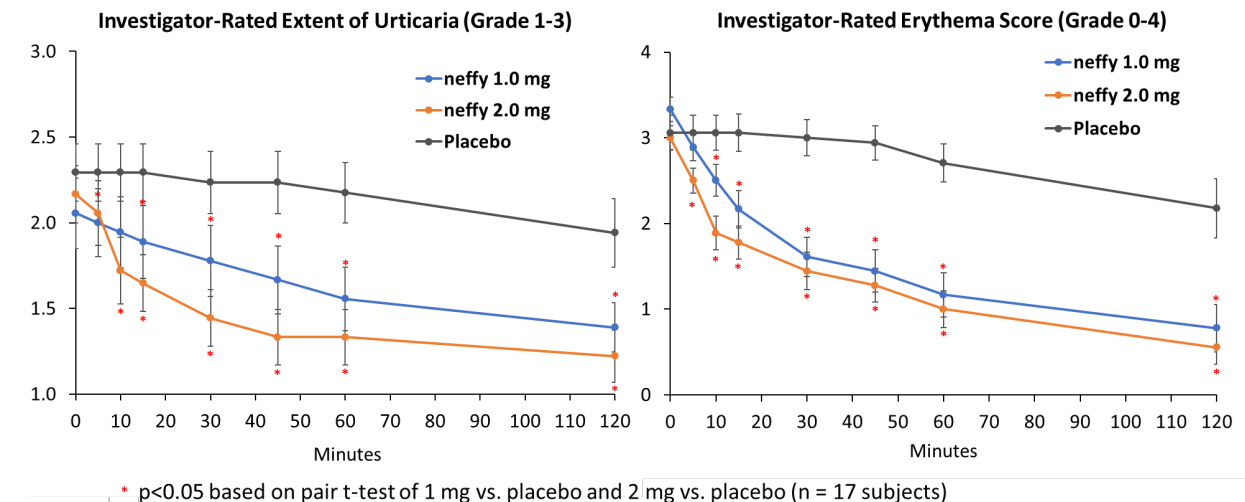
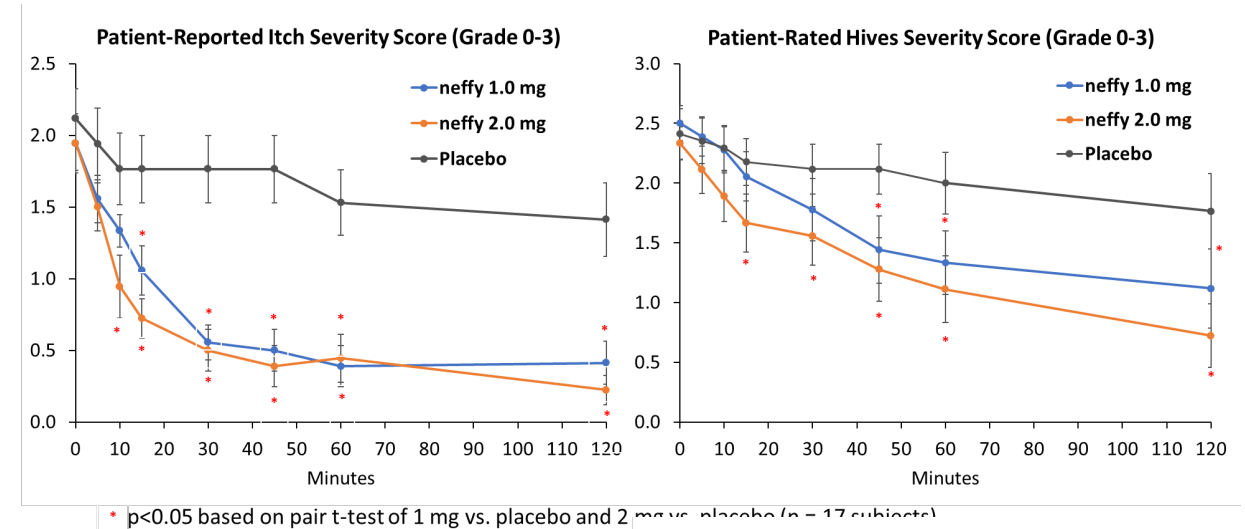
## Randomized, Placebo-Controlled Efficacy Data in Treatment Refractory Chronic Urticaria (EPI-U01)<sup>1</sup>

### Study Design

randomized, placebo-controlled crossover trial study



- 18 chronic urticaria subjects who experience flares at least two times a week while on chronic treatment (antihistamines +/- Xolair)
- Patients come to clinic when experiencing a flare and are treated with 2 mg, 1 mg or placebo



# Significant Ex-US opportunity for *neffy*

<10% TYPE I ALLERGY  
MARKET PENETRATION  
(LESS THAN HALF OF US  
ADOPTION RATES)

Canada EAI Market:  
**~\$67M TODAY**

Europe EAI Market:  
**~\$219M TODAY**

Japan EAI Market:  
**~\$12M TODAY**

China EAI market:  
no approved products  
**Significant Potential**

AUS/NZ EAI market:  
**~\$18M TODAY**



*alfresa*

**CSL™**

# Multiple Attributes Contribute to *neffy*'s Potential Best-in-Class Epinephrine Product Profile



## Does it work?

- PK/PD response shows onset within 1 minute after dosing
- Rapid efficacy profile in OFC anaphylaxis (100% response rate in first 15 min), as well as treatment-resistant urticaria
- Predictable dose-proportional PK/PD profile within range of approved injection products even under real-world co-morbidities (e.g. rhinitis)
- Only anaphylaxis symptom that may alter PK/dosing is rhinitis, and for *neffy*, no negative impact on PK/PD
- 99.999% reliable sprayer device – tens of millions of units sold annually in US



## Is it safe?

- Benign safety profile – mild nasal discomfort (9.7%) and mild headache (6%)
- No risk of injury (no needle) and minimal risk of overdose even with population variability (high bioavailability, low dose)
- No side effects (GI, vomiting, erythema) that could confound clinical monitoring and treatment



## Will patients use it?

- Benign safety profile – mild nasal discomfort and headache
- Palatable – no meaningful pain/irritation, no taste/smell
- Small – fits in pocket
- Easy to use – 100% of adults and children can use without training (even passerby's); ability to dose not obstructed by anaphylaxis symptoms



# *neffy*: the first needle-free way to administer epinephrine



**Rapid, reliable delivery**



**Small and easy to carry**



**Place and Press administration**



**Well-tolerated in extensive trials**

**AVOIDS ALL NEEDLE-RELATED ADVERSE EVENTS**

# Appendix

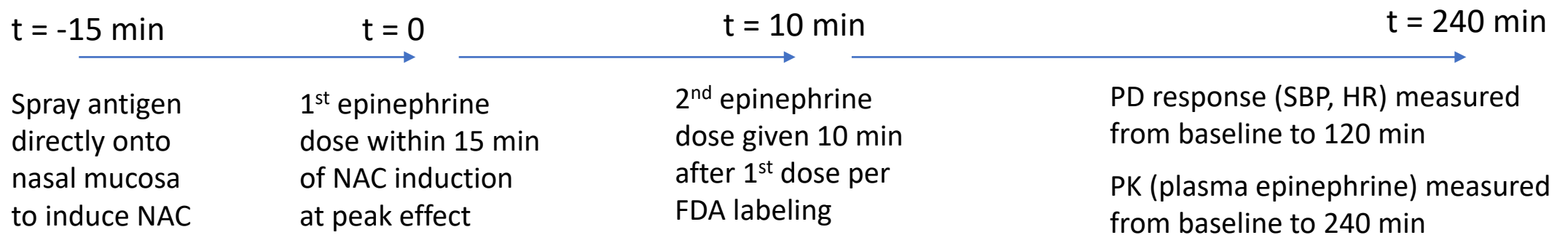
---



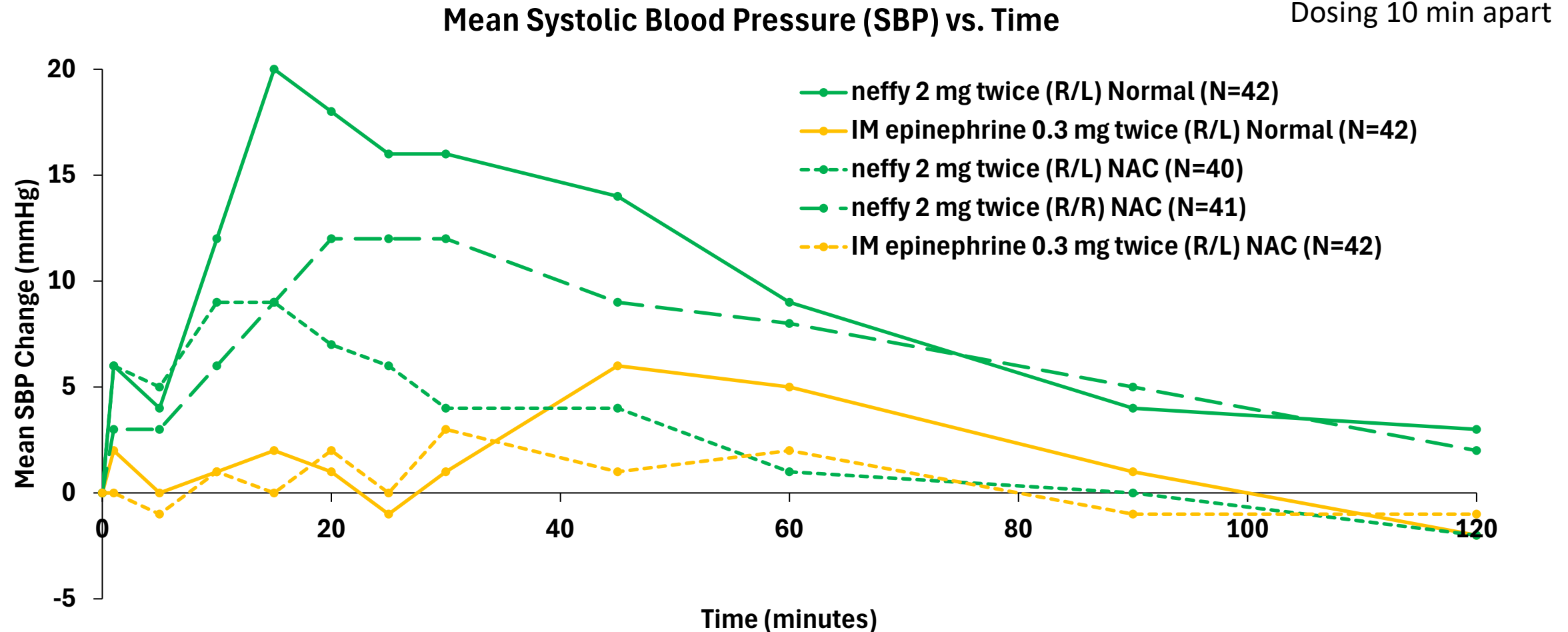
# EPI-18 Repeat Dose NAC Study Design

- **Rationale:** Study designed together with FDA to generate data on *neffy's* PK/PD profile if NAC-like conditions occurred during the 10% of anaphylaxis events that require a second dose
- **Comparator:** FDA explicitly requested ARS include 0.3 mg intramuscular (IM) injection via manual syringe as the reference, and not an autoinjector, as IM is the basis for efficacy of all products
- **Treatments:** repeat doses of **2 mg *neffy*** (normal R/L, NAC R/L – opposite nostril, NAC R/R – same nostril), repeat doses of **0.3 mg IM injection** (rhinitis and normal)
- **Population:** 43 patients with seasonal allergic rhinitis who test positive with a Total Nasal Symptom Score (TNSS) of  $\geq 5$  out of 12 and a congestion score of  $\geq 2$  out of 3 during the screening NAC

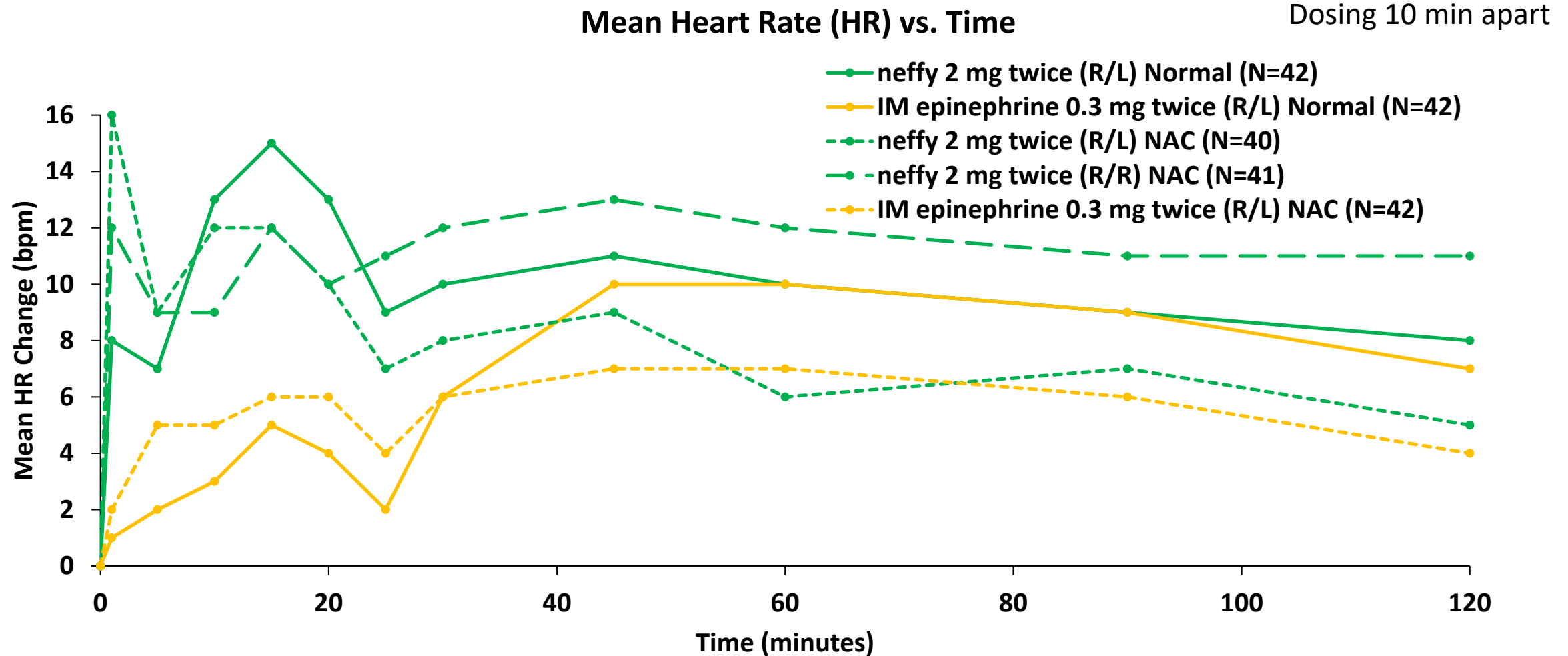
## Repeat Dose NAC PK/PD Methodology (5 treatment periods, randomized, crossover)



# PD response (SBP) with repeat doses of *neffy* with or without NAC greater or similar to repeat doses of injection



# PD response (HR) with repeat doses of *neffy* with or without NAC greater or similar to repeat doses of injection

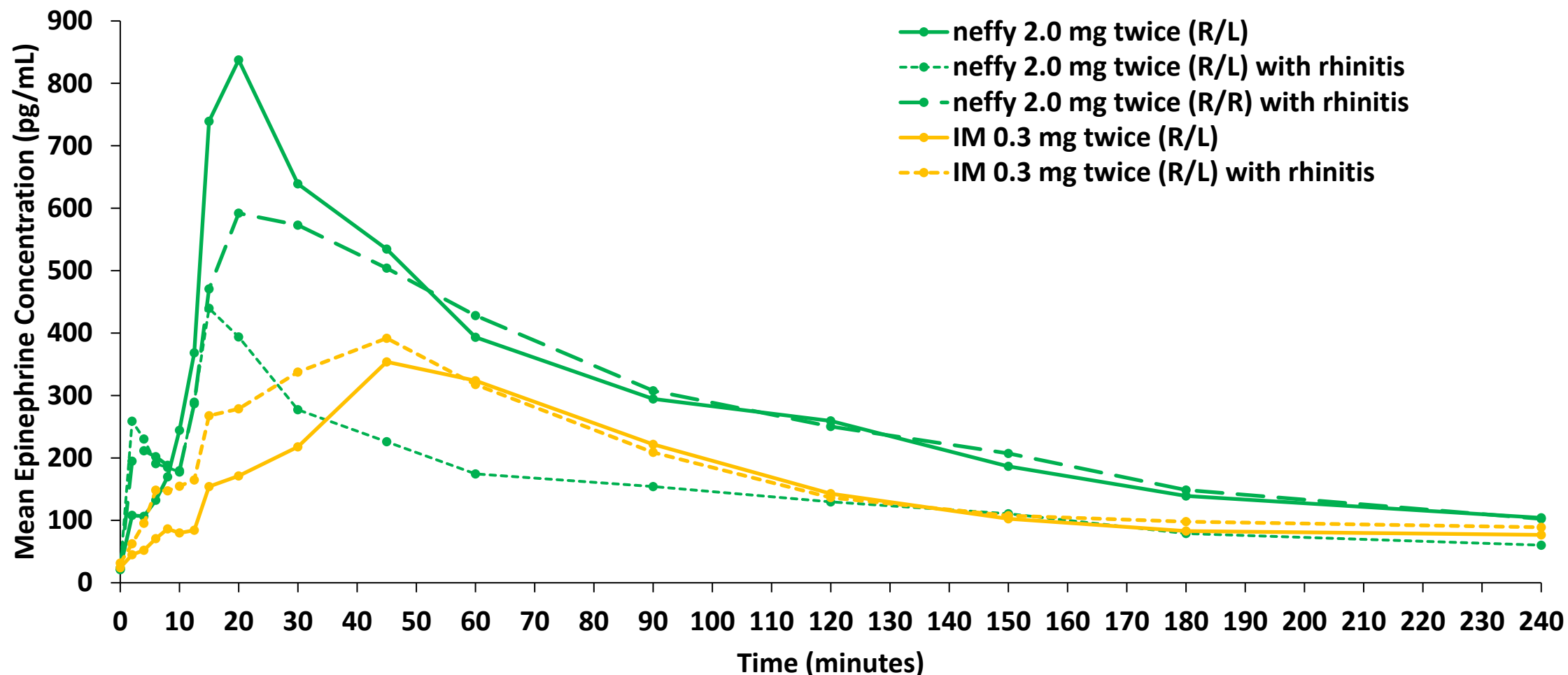




# Exposures with repeat doses of *neffy* with or without NAC greater or similar to repeat doses of injection

Mean Epinephrine Concentration vs. time

Dosing 10 min apart



# Exposures with repeat doses of *neffy* with or without NAC greater or similar to repeat doses of injection (first 60 min)

