UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

May 10, 2024
Date of Report (Date of earliest event reported)

ARS Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39756**	**81-1489190**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

11682 El Camino Real, Suite 120	
San Diego, California	**92130**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 771-9307

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	SPRY	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On May 10, 2024, ARS Pharmaceuticals, Inc. (the "Company") updated its corporate presentation for use in meetings with investors, analysts and others. The presentation is available through the Company's website and a copy is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

The information under this Item 7.01 of this Current Report on 8-K, including Exhibit 99.1, is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Company Presentation.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 10, 2024

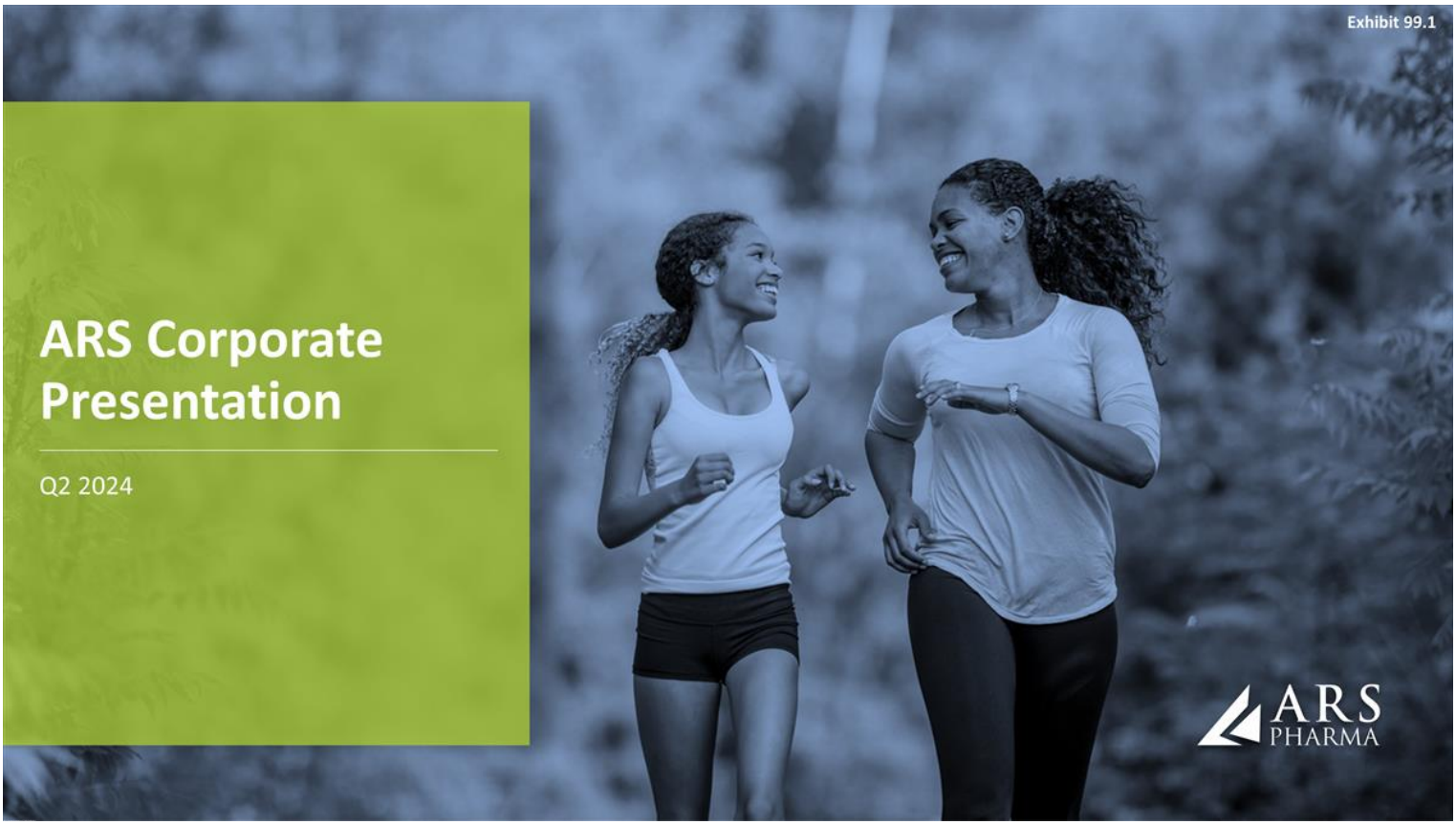
ARS Pharmaceuticals, Inc.

By: /s/ Richard Lowenthal, M.S., MSEL
Name: Richard Lowenthal, M.S., MSEL
Title: President and Chief Executive Officer

Exhibit 99.1

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 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.

ARS PHARMA

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

ARS PHARMA

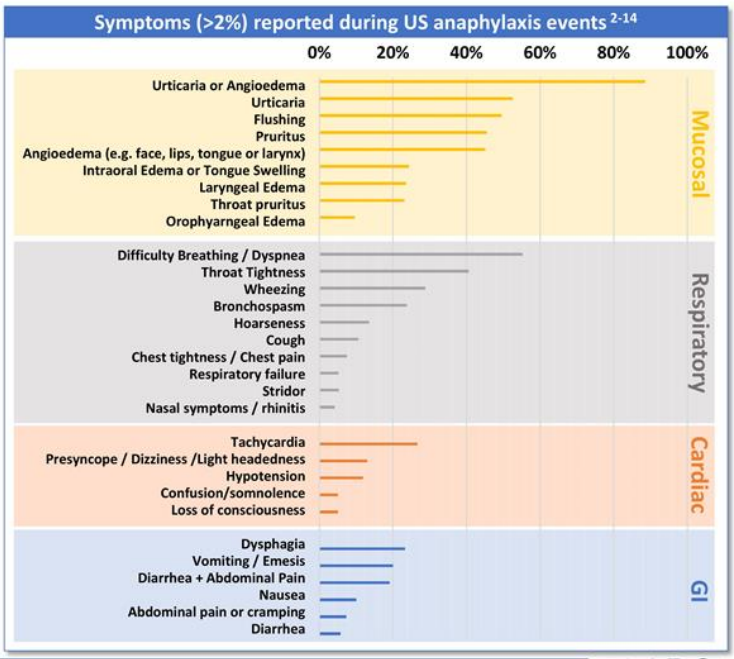
Anaphylaxis is Accompanied by Many Frequent Symptoms

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)



References: **1.** Shaker MS, et al. *J Allergy Clin Immunol*. 2020. **2.** Pistiner M, et al. *J Allergy Clin Immunol Pract*. 2021. **3.** Jalil M, et al. Abstract at *AAAAI* 2020 Virtual Meeting. **4.** Gonzelez-Estrada A, et al. *Ann Allergy Asthma Immunol*. 2018. **5.** Lee S, et al. *J Allergy Clin Immunol*. 2017. **6.** Lee S, et al. *J Allergy Clin Immunol Pract*. 2014. **7.** Manivannan V, et al. *Am J Emerg Med*. 2014. **8.** Wood RA, et al. *J Allergy Clin Immunol* 2014. **9.** Walsh KE, et al. *Pharmacoepidemiol Drug Saf* 2013. **10.** Decker WW, et al. *J Allergy Clin Immunol*. 2008. **11.** Ross MP, et al. *J Allergy Clin Immunol*. 2008. **12.** Webb LM & Lieberman P. *Ann Allergy Asthma Immunol*. 2006. **13.** Ditto AM, et al. *Ann Allergy Asthma Immunol*. 1996. **14.** Rudders SA, et al. *Pediatrics*. 2010. Note that some publications do not specify angioedema symptom subtype. Angioedema subtype frequency aggregated when reported.

ARS PHARMA

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[7]

NO TREATMENT AVAILABLE	REFUSAL OF TREATMENT	DELAY IN TREATMENT	USER ERROR IN TREATMENT
~50% of patients carry[1] (<20% carry two)	~25% - 60% do not administer[1,3 5, 6]	~40% - 60% of patients delay[2]	23% - 35% fail to dose correctly[4]

SOLUTION:

neffy

SMALL

- Fits in your pocket; easy to carry the recommended 2 devices
- ~10% of cases require repeat doses of epinephrine[1]

NO NEEDLE NO INJECTION

- Rapid administration without a needle
- No risk of needle-related injuries; lacerations[2] or cardiotoxic blood vessel injections
- Less hesitation to dose

EASIER AND MORE CONSISTENT DOSING

- 100% of untrained adults and children can dose *neffy* successfully[7]
- High bioavailability, low 2 mg dose of *neffy* achieves comparable PK without overexposure risk including any side effects that mimic anaphylaxis

RELIABLE

- 99.999% delivery of effective dose in reliability testing; not obstructed by any anaphylaxis symptoms; no inhalation required
- 24-month shelf-life at room temperature, with up to 3 months at high temperatures (122°F)

References: 1. Warren CM, et al. *Ann Allergy Asthma Immunol.* 2018. **2.** Rooney E, et al. Poster Presentation at *ACAAI* 2022 (Louisville, KY). **3.** Brooks C, et al. *Ann Allergy Asthma Immunol.* 2017. **4.** El Turki A, et al. *Emerg Med J.* 2017. **5.** Asthma and Allergy Foundation of American Patient Survey Report 2019. **6.** Mehta GD, et al. *Expert Rev Clin Immunol.* 2023. **7.** ARS company estimates based on IQVIA data and references 1 through 6. **4.** Data on file from *neffy* human factors studies.

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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 <u>without any training</u>

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

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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: ≥ 30kg (NDA), 15 ≤ 30kg (sNDA) – single dosing**

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

PD and PK Data

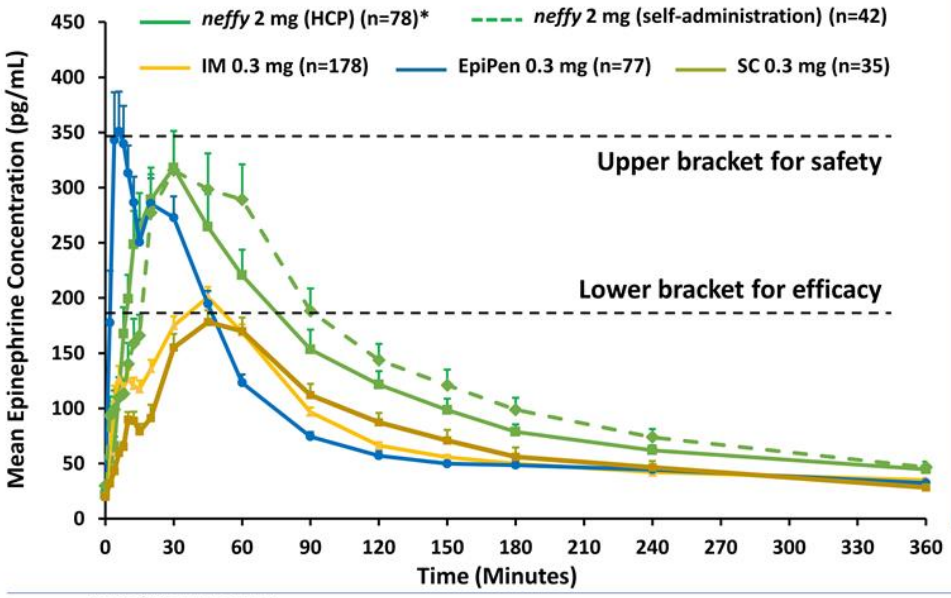
- 2 mg *neffy* met all clinical endpoints
- PD surrogates for efficacy comparable to approved products (SBP/HR ≥ approved injection products)
- Rapid and significant response on PD surrogates for efficacy observed even 1 minute after dosing
- PK bracketed by approved products (exposures ≥ IM/SC for efficacy, < 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 ≥ 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

*Includes Studies EPI-15 and EPI-16

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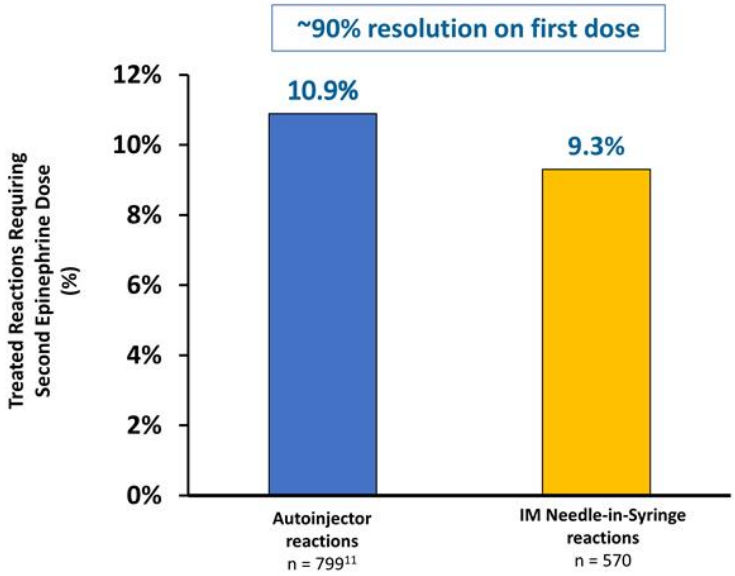
Second Dose Frequency Demonstrates Similar Efficacy Between IM and Autoinjectors (the only FDA approved products today)

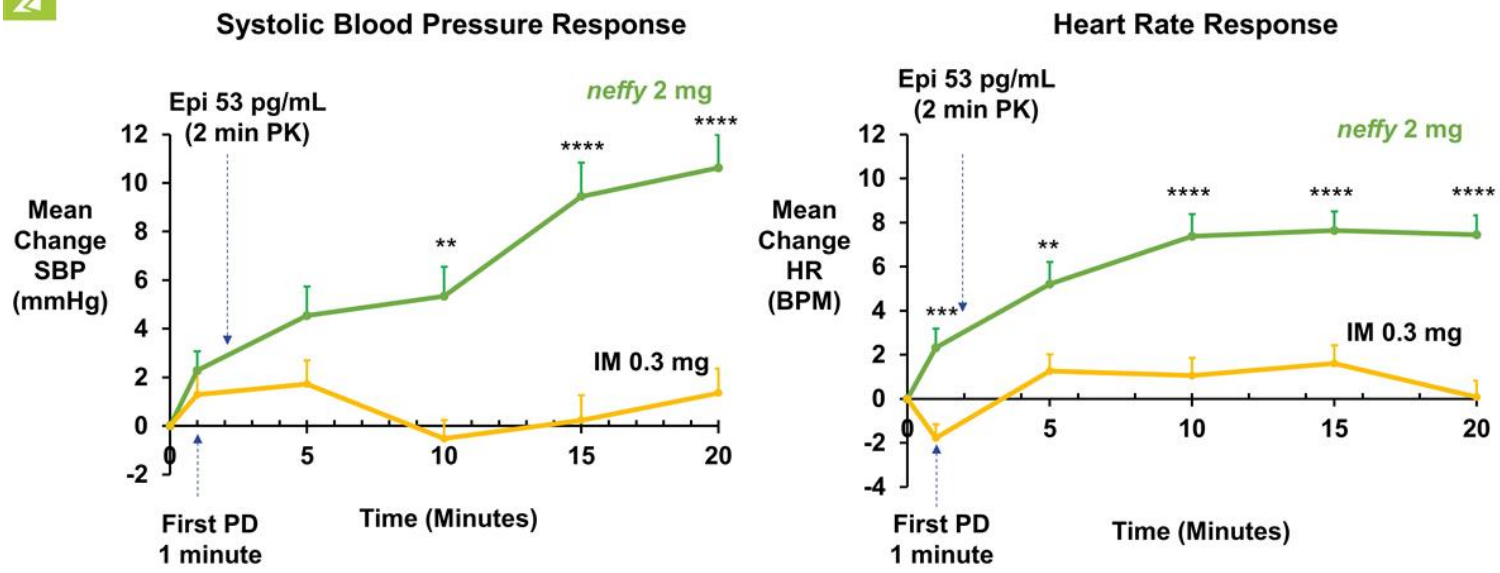


- Analysis of 12 studies with 100% autoinjector (≥ 80% EpiPen) or 100% IM-needle-and-syringe use in community or ED setting[1-11]
- Differences in PK profile across products do not impact efficacy based on need for repeat dosing to resolve symptoms

References: 1. Patel N, et al. *J Allergy Clin Immunol.* 2021. **2.** Kahveci M, et al. *Pediatr Allergy Immunol.* 2020. **3.** Oya S, et al. *J Emerg Med.* 2020. **4.** Kondo A, et al. *Air Med J.* 2018. **5.** Cardona V, et al. *Int Arch Allergy Immunol.* 2017. **6.** Arkwright PD. *J Allergy Clin Immunol.* 2008. **7.** Gold MS & Sainsbury R. *J Allergy Clin Immunol.* 2020. **8.** Noimark L, et al. *Clin Exp Allergy.* 2011. **9.** Soller L, et al. *J Allergy Clin Immunol Pract.* 2019. **10.** Webb LM & Lieberman P. *Ann Allergy Asthma Immunol.* 2006. **11.** White MV, et al. *Allergy Asthm Proc.* 2015; note that this publication reports data on 636 reactions treated exclusively with EpiPen

ARS PHARMA

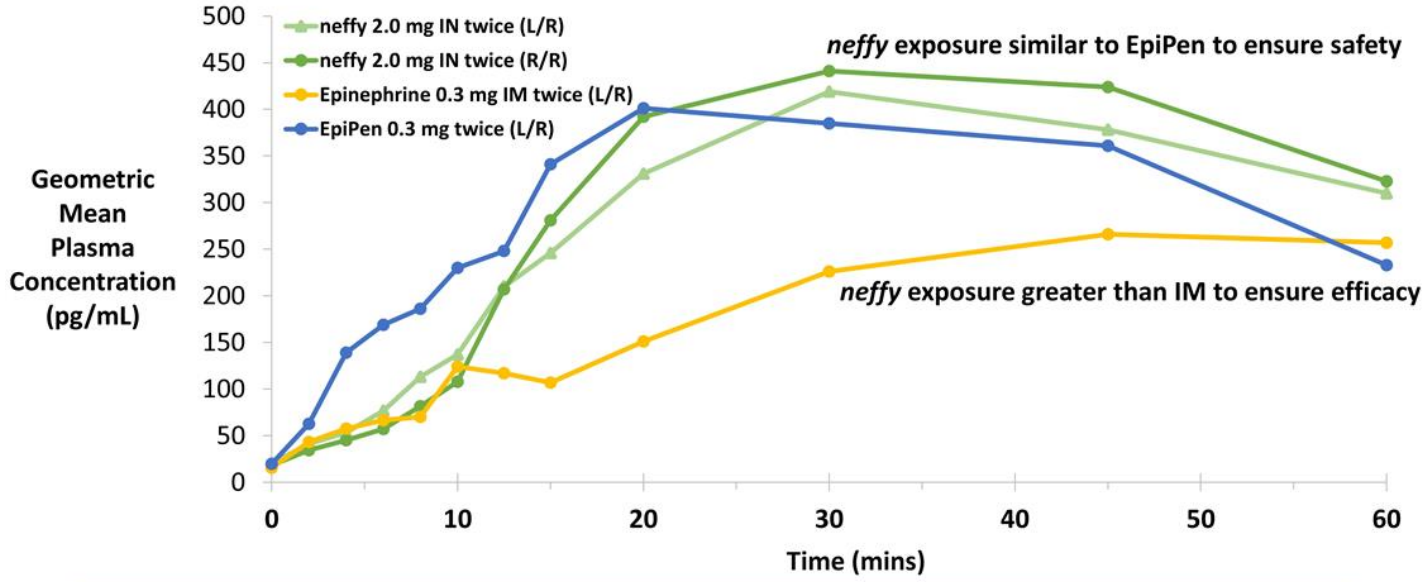
Robust response on PD surrogate markers for efficacy shows engagement of receptors that reverse anaphylaxis symptoms



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



13 Integrated data from ARS clinical studies, FDA Briefing Document May 2023 PADAC for NDA/BLA# 214697 (*neffy*)

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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)[1-12]
- ARS successfully evaluated patients with rhinitis in response to FDA CRL, which responded positively to single and repeat doses of *neffy*

Potential effect on <u>ability to dose or absorption profile</u> 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

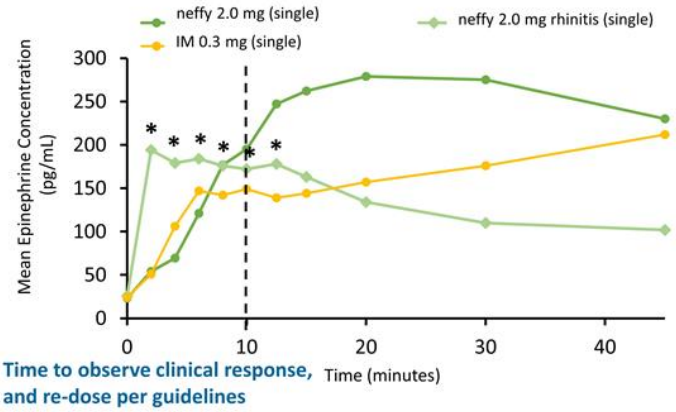
*** insufficient oral and inhalation systemic absorption due to rapid conjugation and oxidation in GI tract or difficulty taking in enough puffs[14]**

References: 1. Pistiner M, et al. *J Allergy Clin Immunol Pract.* 2021. **2.** Jalil M, et al. Abstract at *AAAAI* 2020 Virtual Meeting. **3.** Gonzelez-Estrada A, et al. *Ann Allergy Asthma Immunol.* 2018. **4.** Lee S, et al. *J Allergy Clin Immunol.* 2017. **5.** Lee S, et al. *J Allergy Clin Immunol Pract.* 2014. **6.** Manivannan V, et al. *Am J Emerg Med.* 2014. **7.** Wood RA, et al. *J Allergy Clin Immunol* 2014. **8.** Walsh KE, et al. *Pharmacoepidemiol Drug Saf* 2013. **9.** Decker WW, et al. *J Allergy Clin Immunol.* 2008. **10.** Ross MP, et al. *J Allergy Clin Immunol.* 2008. **11.** Webb LM & Lieberman P. *Ann Allergy Asthma Immunol.* 2006. **12.** Ditto AM, et al. *Ann Allergy Asthma Immunol.* 1996. **13.** Rudders SA, et al. *Pediatrics.* 2010.**14.** Simons KJ, et al. *J Allergy Clin Immunol.* 2004. Note that some publications do not specify angioedema symptom subtype. Angioedema subtype frequency aggregated when reported.

ARS PHARMA

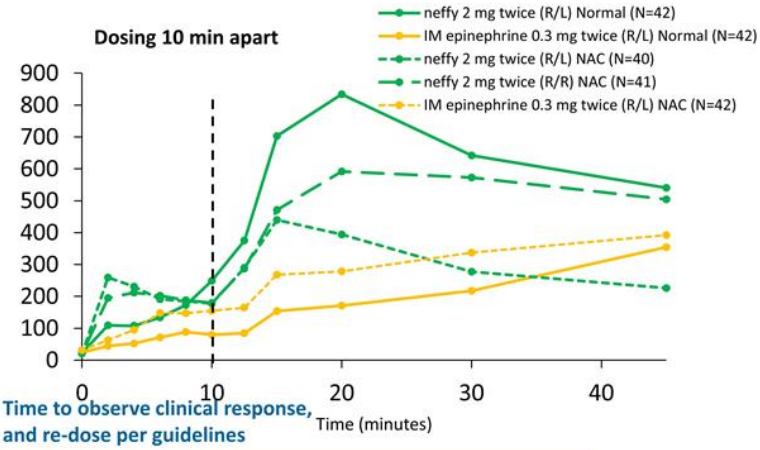
Experimental Nasal Allergen Challenge (NAC)-Induced Rhinitis Does Not Negatively Impact *neffy*'s PK Profile (allergic rhinitis subjects)

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

* Statistically significant differences between *neffy* with rhinitis compared to IM injection ($p < 0.05$)

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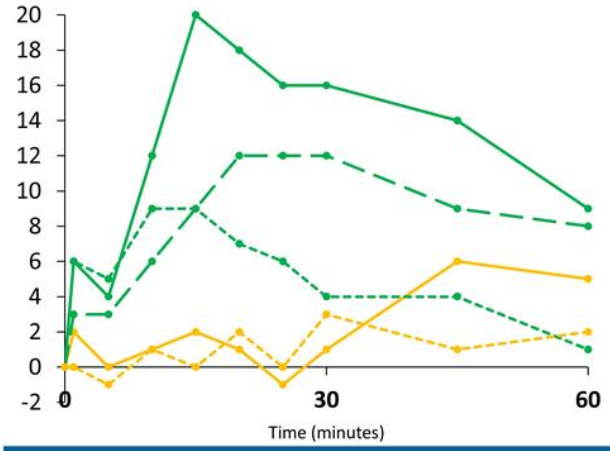
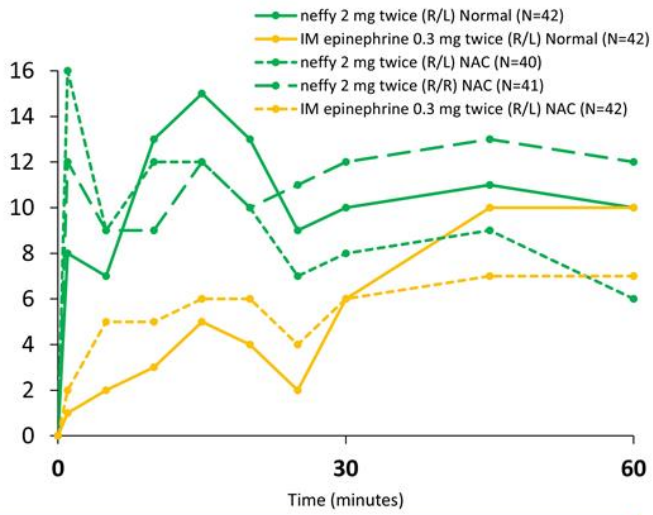
Experimental NAC-Induced Rhinitis Does Not Negatively Impact *neffy*'s PD Profile (Repeat Doses 10 min Apart)

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

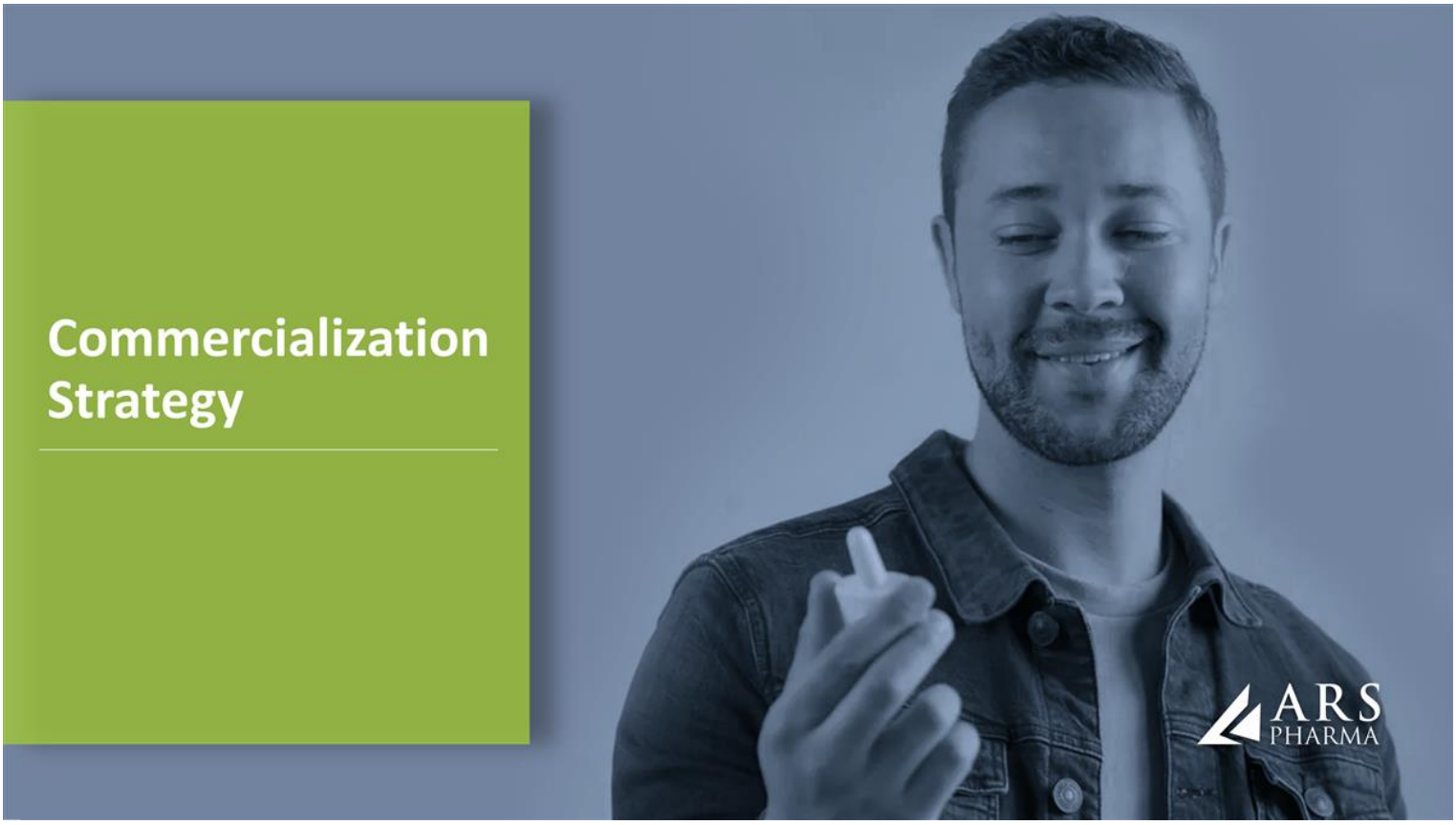
ARS PHARMA

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[2-10]

~20M diagnosed and under physician care over the last 3 years[11]

Consistent Market Growth (Units)
+6.5% CAGR since 2010, +12.7% YoY in 2023[1]

Promotional Responsiveness
~50% increase over market growth trend with consumer promotion (2010 to 2015[1])

~3.2M patients filled Rx in 2023, but ~80-90% do not use as indicated[11]

(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[1]

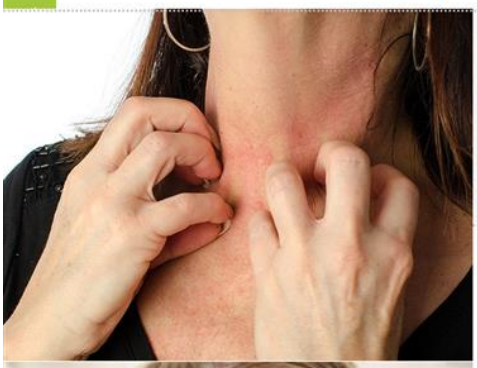
~3.3M don't fill regularly, haven't refilled or haven't filled a written Rx in 2022[11]

~13.5M Type 1 diagnosed but not prescribed Rx (past 3 years)[11]

References: 1. Based on IQVIA prescription data (~5.2 million two-packs sold in 2023) and weighted average generic/branded epinephrine auto-injector net pricing. **2.** Gupta RS, et al. *Pediatrics*. 2011. **4.** Gupta RS, et al. *Pediatrics* 2018. **5.** McGowan EC, et al. *J Clin Allergy Immunol*. 2013. **6.** Jackson KD, et al. *NCHS Data Brief*. 2013. **7.** Black LI, et al. CDC National Center for Health Statistics Data Brief. 2019. **8.** Gupta RS, et al. *JAMA Netw Open*. 2019. **9.** Verrill L, et al. *Allergy Asthma Pro*. 2015. **10.** Bilo BM, et al. *Current Opin Allergy Clin Immunol*. 2008. **11.** IQVIA Claims Data, 2023

ARS PHARMA

neffy has the ability to address the unmet need and is aligned with what healthcare providers, patients and parents want[1]



n = 392
Current Users

88% OF PATIENTS LIKELY TO VERY LIKELY TO ASK THEIR PHYSICIAN ABOUT *neffy* Rx[1]

89% OF NON-FILLING PATIENTS STATED THEY WOULD ASK THEIR PHYSICIAN ABOUT *neffy* RX[1]

n = 88
Non-fillers

72%
OF THE TIME,
PEOPLE WHO USE AN OTC WOULD USE *neffy* FIRST[2]

81%
OF PEOPLE
WOULD USE *neffy* SOONER THAN CURRENT NEEDLE INJECTORS[3]

References: 1. ARS market research on file. **2.** Lowenthal R, et al. Presentation at AAAAI 2023 (San Antonio, Texas). **3.** Kaplan H, et al. Presentation at ACAAI 2022 (Louisville, Kentucky).

PHYSICIAN

Physicians supportive of adopting *neffy* into practice

n = 75 Physicians

8.5 out of 10 rating[1]

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[1]

References: 1. ARS market research on file.

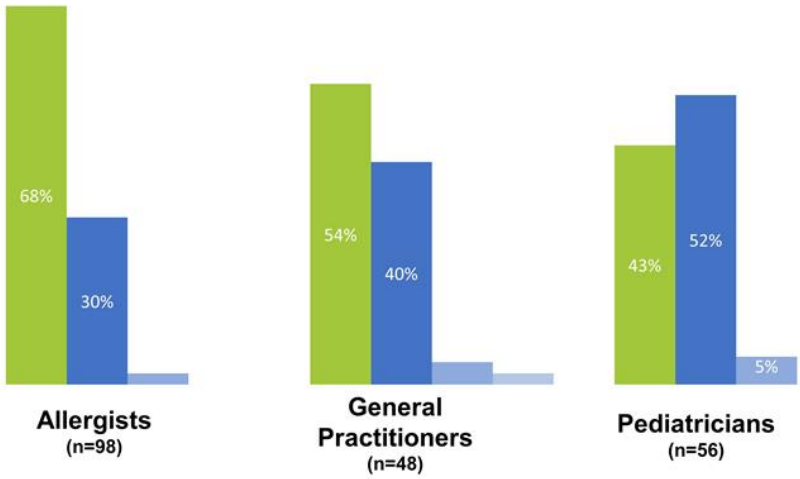
ARS PHARMA

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



References: ARS market research on file.

PATIENT

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

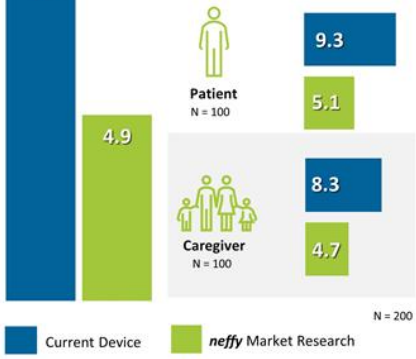
Benefits of needle-free alternative to address major unmet needs

- 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[2,3]

45% REDUCTION IN TIME TO USE

Average Time (minutes)
from Symptom Start to Device Use[1]



References: 1. Kaplan H, et al. Presentation at ACAAI 2022 (Louisville, Kentucky). **2.** Warren CM, et al. *Ann Allergy Asthma Immunol.* 2018. **3.** ARS market research on file.

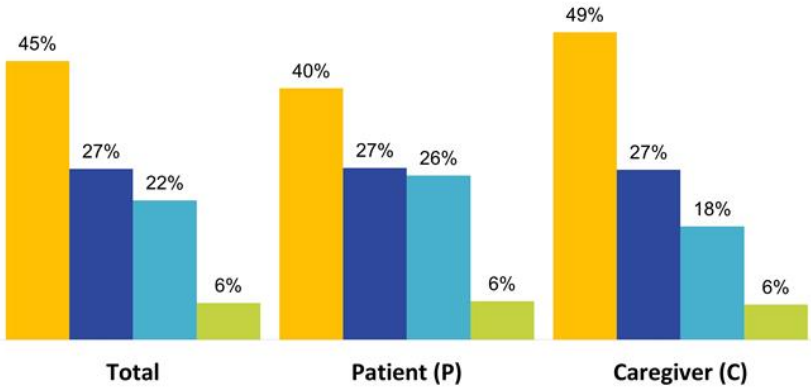
ARS PHARMA

PATIENT

~ 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

References: ARS market research on file.

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

ARS PHARMA

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

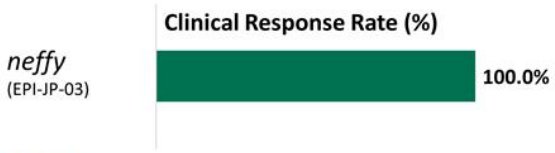
Efficacy Study of *neffy* in Oral Food Challenge Induced Anaphylaxis (EPI-JP-03)[1]

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)[3] 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*[2]**

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

References: 1. Ebisawa M, et al. Presentation at AAAAI 2024 (Washington DC). **2.** 100% of EPI-JP-03 patients dosed with *neffy* did not require a second dose in the first 15 minutes per guidelines because a response was not being observed, and 100% of patients achieved complete resolution of symptoms. 1 of the 16 subjects (6.7%) challenged with egg experienced a biphasic reaction 2h 45 min after being dosed with a single dose of *neffy* and achieving complete resolution of symptoms. This is consistent with the 12.8% frequency of biphasic reactions reported in children with food-induced anaphylaxis.(Gupta RS, et al. *J Allergy Clin Immunol Pract.* 2021).

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

ARS PHARMA

ACTIVATE

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

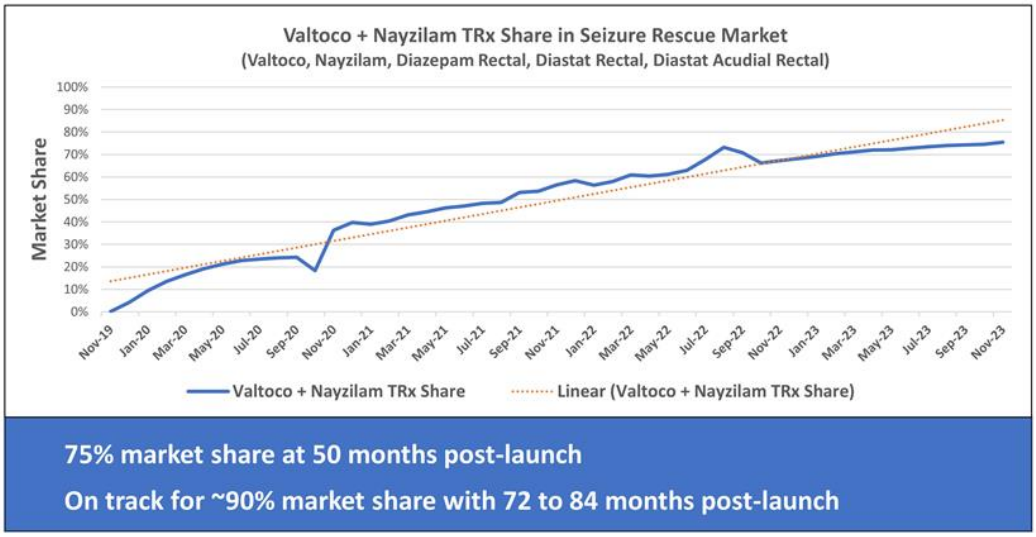
Consumer Launch Objectives

- 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®



75% market share at 50 months post-launch

On track for ~90% market share with 72 to 84 months post-launch

References: 1. IQVIA prescription data (2023)

US Epinephrine Market Evolution Due to the Availability of *neffy* Supports Significant Revenue Opportunity[1]

Millions of epinephrine 2-pack devices sold in US

1. ~$1B+ net sales US market based on generic epinephrine pricing in 2023[3]
   (~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***)

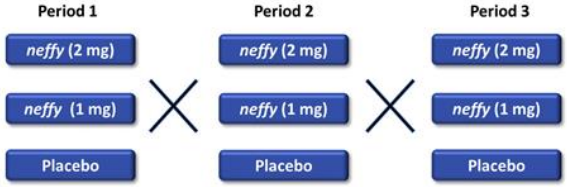
References: 1. ARS company estimates and market research on file. **2.** Market estimates based only on prescription volume from community use epinephrine autoinjector products, not intramuscular injection vials and syringes, **3.** Net sales estimate are based on current autoinjector pricing (90%+ of current volume is generic), not branded epinephrine product pricing

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

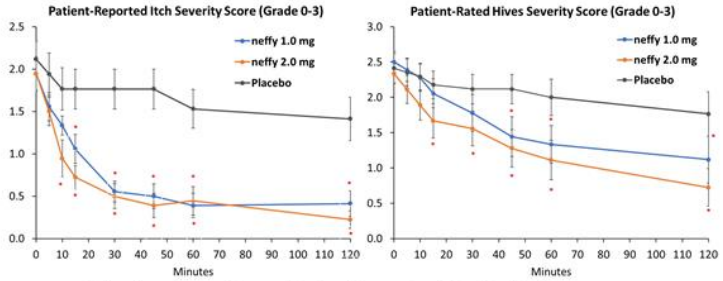
Randomized, Placebo-Controlled Efficacy Data in Treatment Refractory Chronic Urticaria (EPI-U01)[1]

Study Design

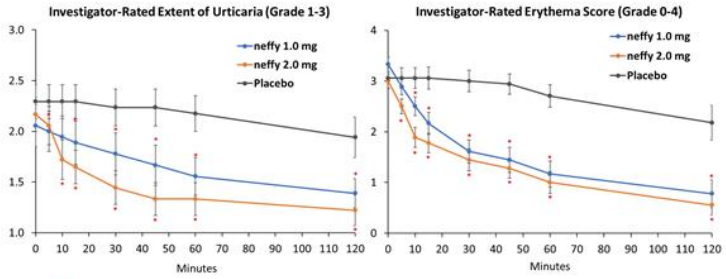
randomized, placebo-controlled crossover trial study



- 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



* p<0.05 based on pair t-test of 1 mg vs. placebo and 2 mg vs. placebo (n = 17 subjects)



* p<0.05 based on pair t-test of 1 mg vs. placebo and 2 mg vs. placebo (n = 17 subjects)

References: 1. Bernstein D, et al. Presentation at AAAAI 2024 (Washington DC).

Significant Ex-US opportunity for *neffy*

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

References:: 2023 IQVIA MIDAS (USD MNF)

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

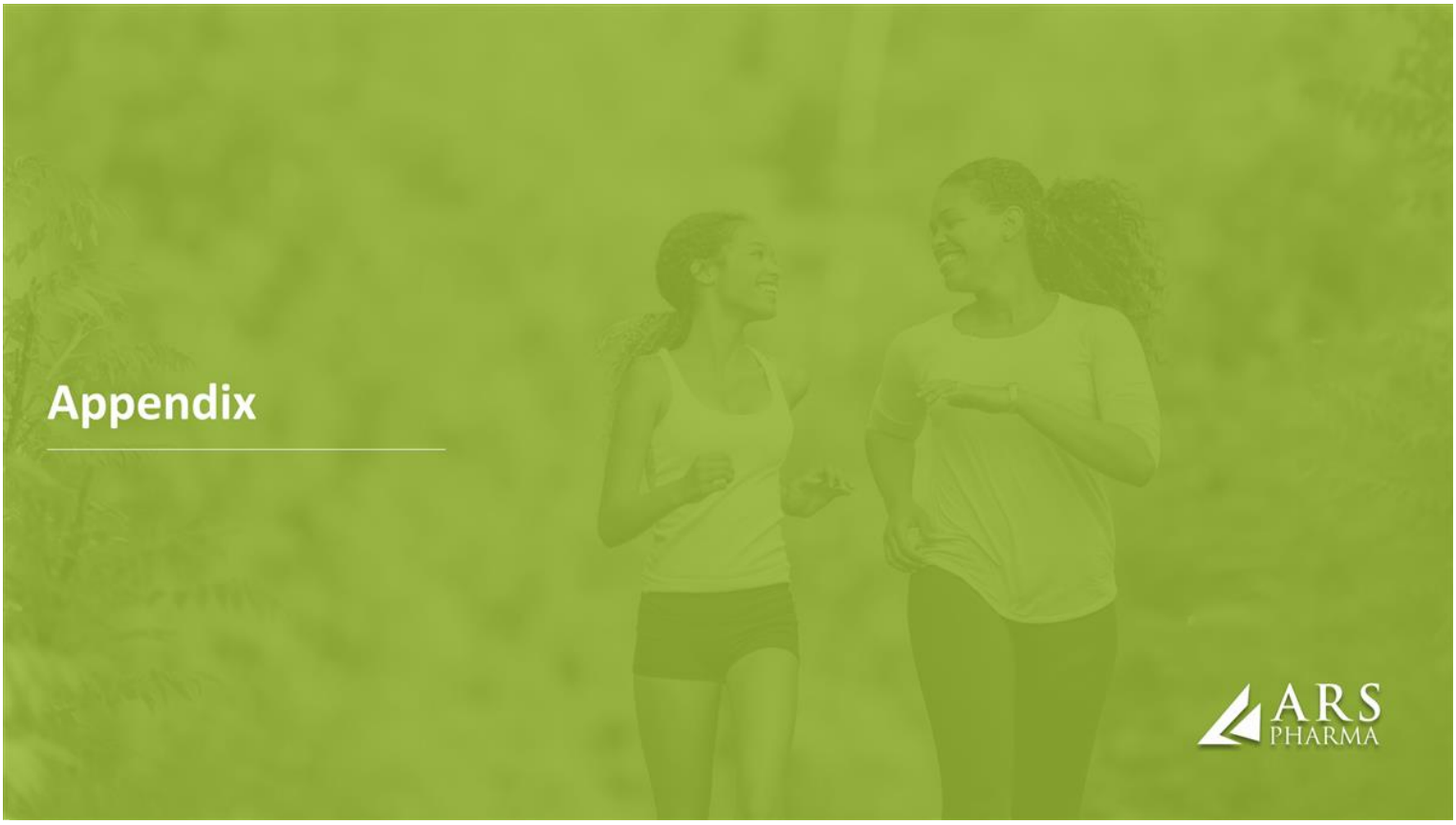
ARS PHARMA

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

ARS PHARMA

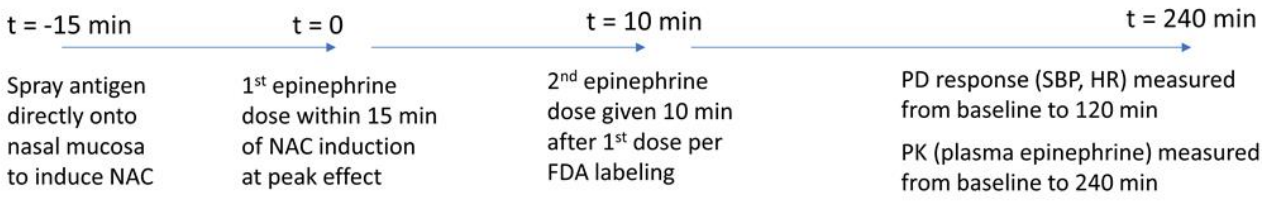


Appendix

EPI-18 Repeat Dose NAC Study Design

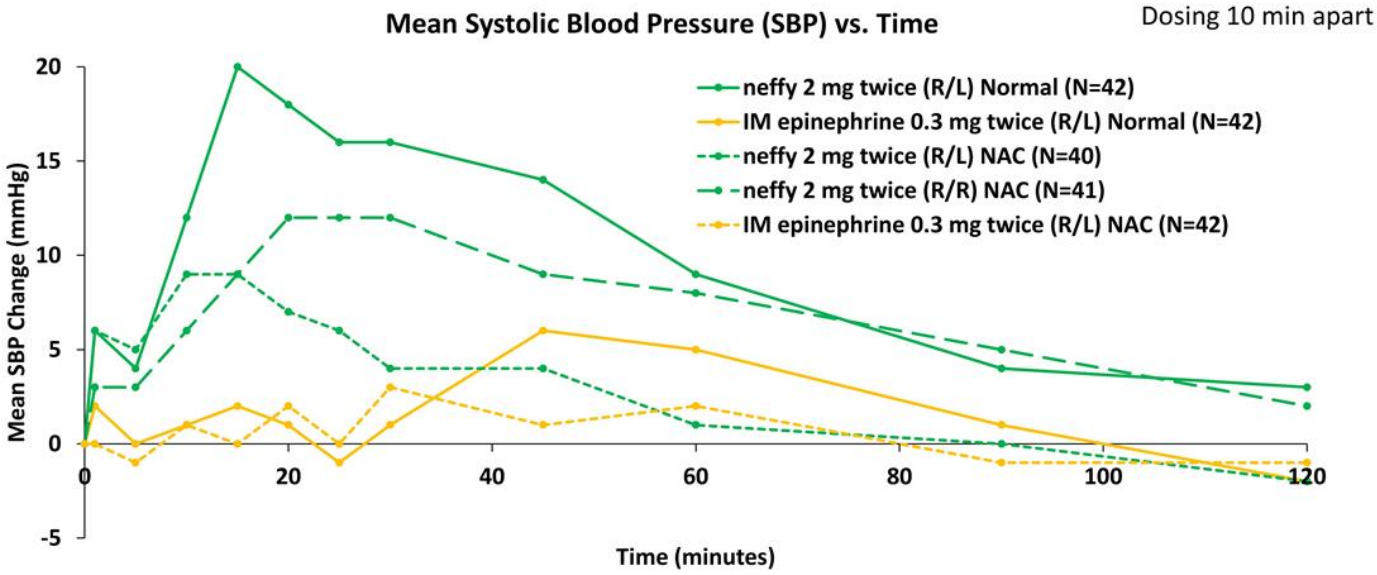
- **Rationale**: Study designed together with FDA to generate data on ***neffy's*** PK/PD profile if NAC-like conditions occurred during the 10% of anaphylaxis events that require a second dose
- **Comparator**: FDA explicitly requested ARS include 0.3 mg intramuscular (IM) injection via manual syringe 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 ≥5 out of 12 and a congestion score of ≥2 out of 3 during the screening NAC

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



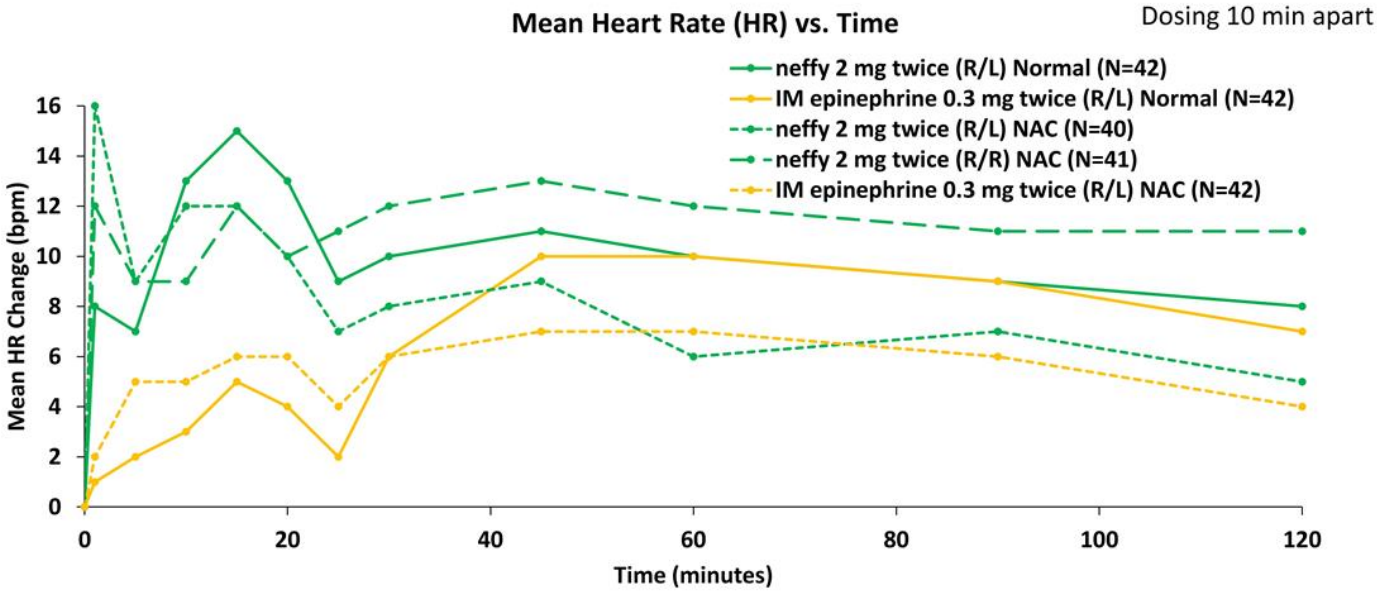
PD response (SBP) with repeat doses of *neffy* with or without NAC greater or similar to repeat doses of injection

Dosing 10 min apart

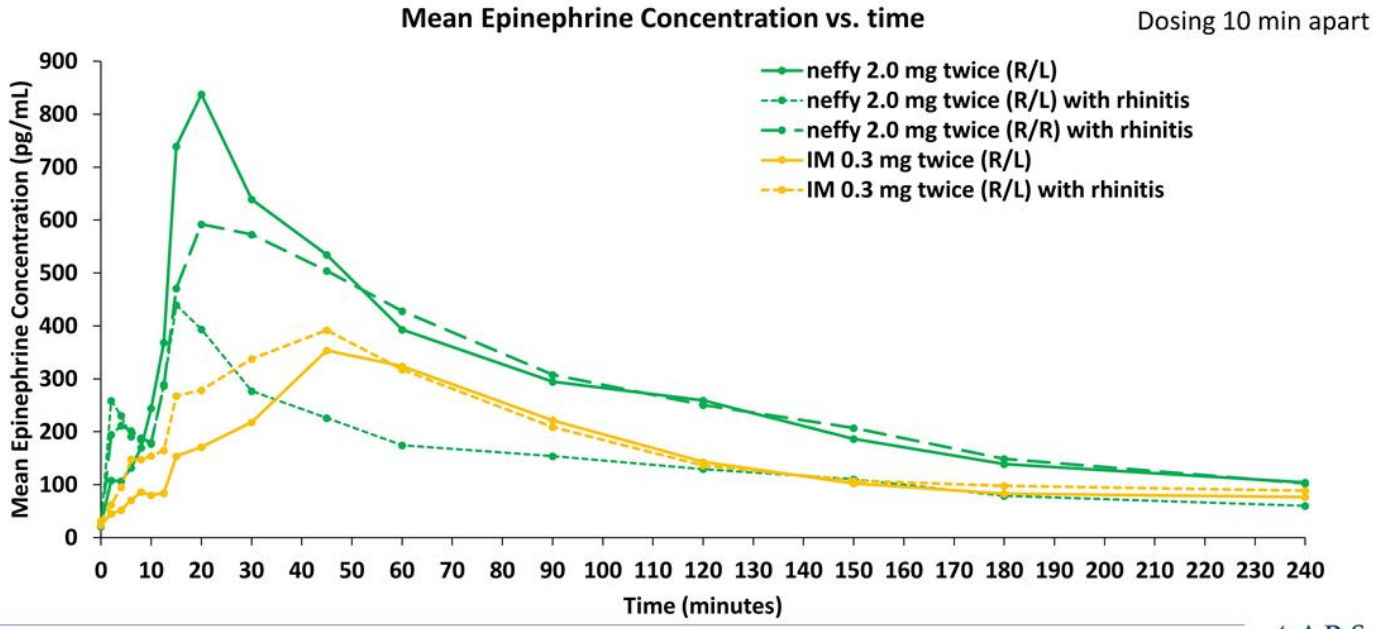


PD response (HR) with repeat doses of *neffy* with or without NAC greater or similar to repeat doses of injection

Dosing 10 min apart



Exposures 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 (first 60 min)