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

March 7, 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 2.02 Results of Operations and Financial Condition.

On March 7, 2024, ARS Pharmaceuticals, Inc. (the "Company") announced in its corporate presentation that as of December 31, 2023, it had approximately $228 million in cash and short-term investments.

The information in this Item 2.02 of this Current Report on 8-K is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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 "Securities Act"). 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 7.01. Regulation FD Disclosure.

On March 7, 2024, 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 in 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 Exchange Act, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act. 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, dated March 7, 2024.
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: March 7, 2024

ARS Pharmaceuticals, Inc.

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

Exhibit 99.1

neffy Investor Day

March 7, 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: ARS Pharma's plan to file its NDA early in the second quarter of 2024, with an anticipated PDUFA action date and launch of ***neffy***, if approved, in the second half of 2024; the timing of the EMA's decision and submissions to other foreign regulatory authorities; 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 September 30, 2023, filed with the Securities and Exchange Commission ("SEC") on November 9, 2023. 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

Today's Speakers

ARS Management

Richard Lowenthal, M.S., MSEL
Chief Executive Officer, Co-Founder
Led FDA approvals for multiple nasal spray products
25+ years of experience

NARCAN® NASAL SPRAY · VALTOCO® · tosymra® · OPVEE® (nalmefene) NASAL SPRAY

Eric Karas
Chief Commercial Officer
Led Narcan® commercial ops at Emergent/Adapt, and Auxilium specialty
25+ years of experience

NARCAN® NASAL SPRAY · Testim® (testosterone gel) · XIAFLEX®

Key Opinion Leaders

Jonathan Spergel, M.D., Ph.D.
Chief of Allergy Program
Children's Hospital of Philadelphia

Thomas B. Casale, M.D.
Professor of Medicine & Pediatrics
Chief, Allergy & Immunology
University of South Florida

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
- **Completed repeat dose NAC study requested by FDA in Sept 2023 CRL**
- **NDA on track to respond to FDA CRL by early Q2 2024, with FDA action date and potential US launch in H2 2024**
- **Potential multi-billion-dollar market** driven by HCP and consumer preference and adoption
- **NCE-like IP exclusivity** potential until at least 2038
- **$228 million in cash and short-term investments** as of 12/31/2023 with an anticipated $195 million at anticipated FDA action in H2 2024

ARS PHARMA

What We Will Cover Today

Unmet need in type I allergic reactions including anaphylaxis
Dr. Jonathan Spergel

neffy clinical profile, registrational studies
Richard Lowenthal

neffy benefit-risk for type I allergic reactions including anaphylaxis
Dr. Thomas Casale

US market opportunity and commercialization strategy
Eric Karas

Unmet Need / Current Challenges

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

PROBLEM	NO TREATMENT AVAILABLE	REFUSAL OF TREATMENT	DELAY IN TREATMENT	USER ERROR IN TREATMENT
ONLY 10% - 20% of patients with active Rx use as indicated[7]	~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]
neffy **SOLUTIONS**	**SMALL**	**NO NEEDLE NO INJECTION**	**EASIER AND MORE CONSISTENT DOSING**	**RELIABLE**
	• Fits in your pocket; can carry more than 1 • ~10% of cases require repeat doses of epinephrine[1]	• Rapid administration without a needle • No risk of needle-related injuries; lacerations[2] or cardiotoxic blood vessel injections • Less hesitation to dose	• 0% critical dosing errors in registration self-administration study • High bioavailability, low 2 mg dose of *neffy* achieves comparable PK without overexposure risk	• 99.999% delivery of effective dose in reliability testing; 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.

ARS PHARMA

Significant Catalysts for *neffy* in 2024

- **US NDA response to CRL** by early Q2 2024
- **PDUFA action date** anticipated in H2 2024

- **EMA decision (CHMP Opinion)** expected by mid-2024

- **China NDA filing** expected by YE 2024
- **Japan NDA filing** expected by YE 2024
- **Planning in progress for filing in other major ex-US regions** including Canada

- **Expansion opportunities**
  - Positive data from Phase 2 chronic urticaria study reported in Feb 2024
  - **Initiation of Phase 2b outpatient urticaria study**

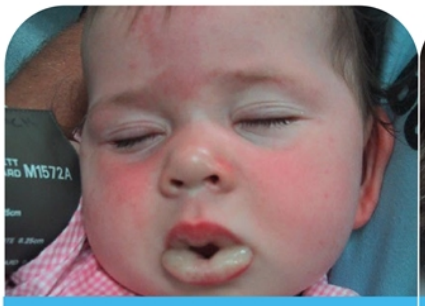
Type I Allergies & Unmet Needs

Jonathan M. Spergel, M.D., Ph.D.
Professor of Pediatrics
Chief of the Allergy Program
Children's Hospital of Philadelphia

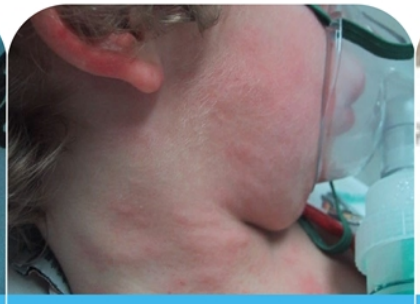
Type I Allergic Reactions: Systemic Hypersensitivity Reaction

~40 Million people in **US** with systemic Type I allergic reaction to allergens

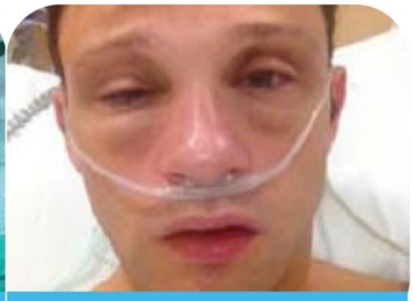
More than **500,000** ER visits **each year** due to systemic Type I allergic reactions[1], costing an average of $1600+ per visit[2]



Caused by exposure to a **specific allergen**, most commonly **food, venom, drugs**



Significant co-morbidities and symptomatic impact on quality of life.



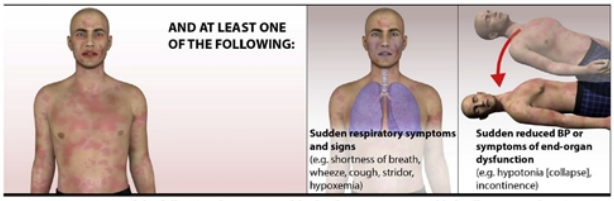
Other Type I allergy indications (e.g. urticaria flares)

References: 1. Carillo-Martin I, et al. *J Allergy Clin Immunol Pract* 2020. **2.** BlueCross BlueShield of America. Childhood Allergies in America 2018

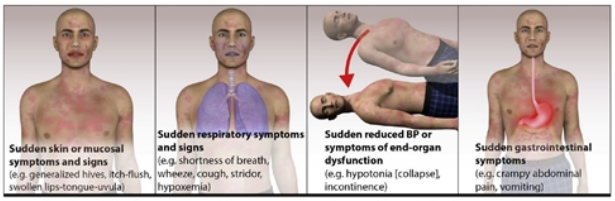
Anaphylaxis Diagnosis Criteria and Symptoms

Anaphylaxis is highly likely when any one of the following three criteria is fulfilled

1 Sudden onset of an illness (minutes to several hours), with involvement of the skin, mucosal tissue, or both (e.g. generalized hives, itching or flushing, swollen lips-tongue-uvula)

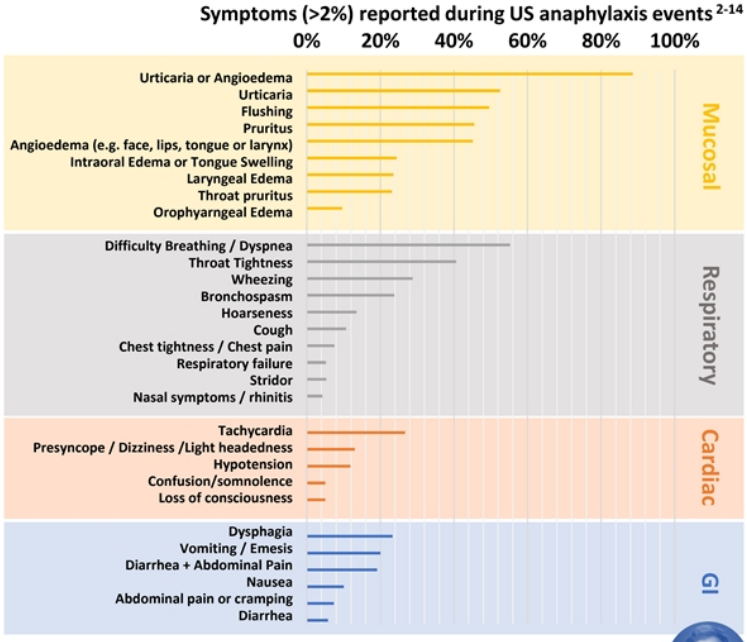


OR **2** Two or more of the following that occur suddenly after exposure to a *likely allergen or other trigger* for that patient* (minutes to several hours)



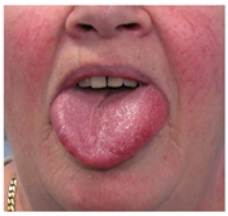
OR **3** Reduced blood pressure (BP) after exposure to a *known allergen** for that patient* (minutes to several hours)

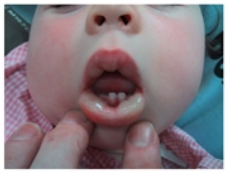
Symptoms (>2%) reported during US anaphylaxis events [2-14]

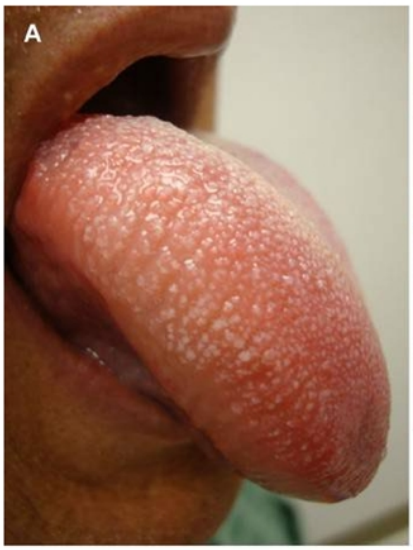


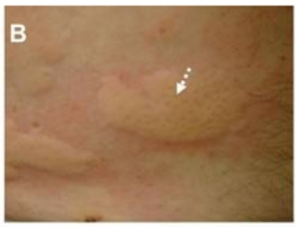
References: 1. Shaker MS, et al. *J Allergy Clin Immunol.* 2020. **2.** Pistiner M, et al. *J Allergy Clin Immunol Pract.* 2021. **3.** Jalil M, et al. Abstract at *AAAAI* 2020 Virtual Meeting. **4.** Gonzelez-Estrada A, et al. *Ann Allergy Asthma Immunol.* 2018. **5.** Lee S, et al. *J Allergy Clin 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.

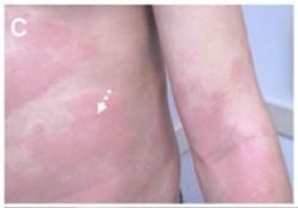
Most frequently reported symptoms are difficulty breathing, angioedema (face, lips, tongue, larynx) and urticaria (hives)

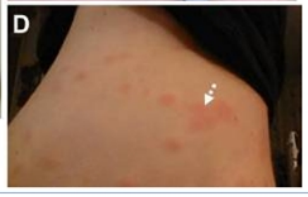


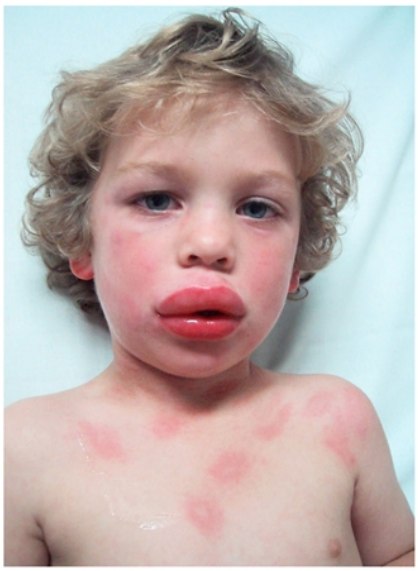












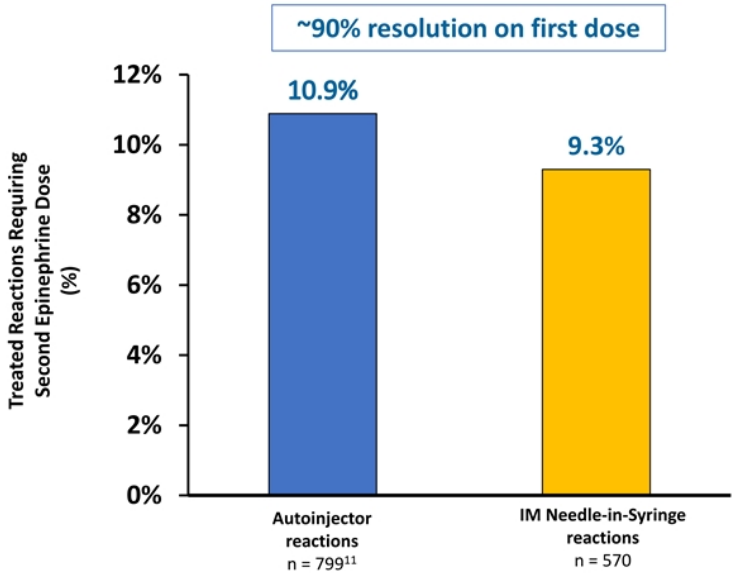
References: 1. LoVerde D, et al. *Chest*. 2018. **2.** Images reproduced with permission

Epinephrine: Well Known Mechanism of Action

Adrenergic Receptor	Pharmacological Effect of Epinephrine	Clinical Effect of Epinephrine
β_2	• **Stabilizes mast cells and basophils - Inhibits inflammatory mediators** • Relaxation of bronchial smooth muscles • Vasodilation in skeletal vasculature	• **Reverses pathological histamine cascade** • Increase in bronchial airflow • Increases blood to skeletal muscle
β_1	• Increases blood pressure and heart rate	• Relieves hypotension and shock
α_1	• Increases systolic blood pressure • Causes blood vessel constriction • Decreases mucosal edema	• Relieves hypotension and shock • Relieves upper airway obstruction

Receptor Sensitivity

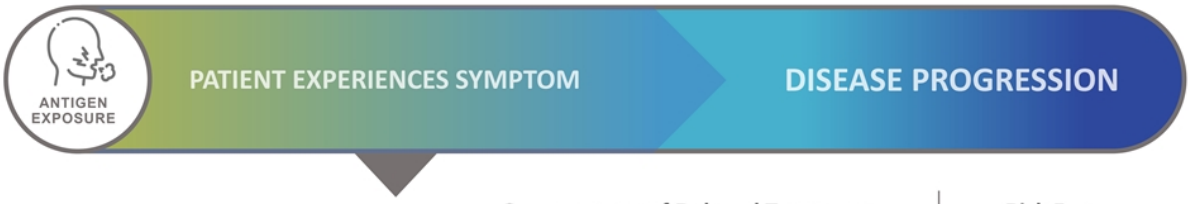
Second Dose Demonstrates Similar Efficacy Between IM and Autoinjectors (the only FDA approved products today)



- 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 Ashm Proc.* 2015; note that this publication reports data on 636 reactions treated exclusively with EpiPen

Prompt Treatment with Epinephrine is Critical

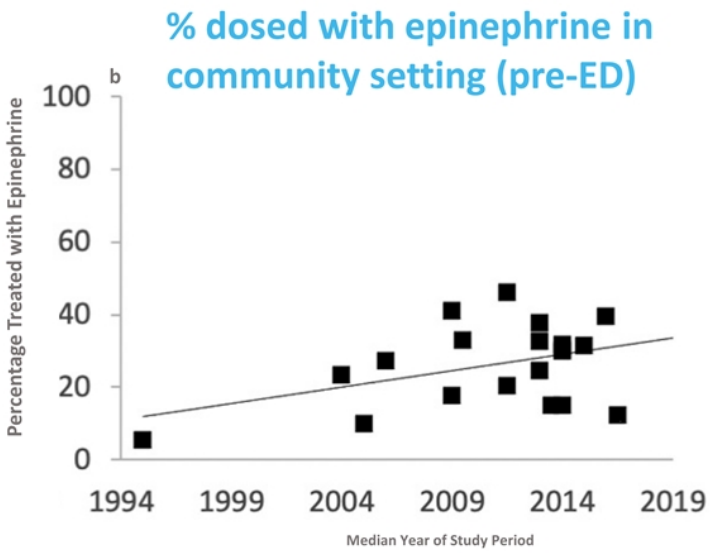


Patients / Caregivers wait up to **18 minutes** to dose epinephrine

Consequence of Delayed Treatment	Risk Factor
Abnormal vitals (HR, SBP, Respiration)[1]	p<0.001
Repeat Epinephrine Doses[2]	OR = 5.0
Hospitalization (500,000 ER visits / yr)[3]	HR = 4.0
Biphasic anaphylaxis[4]	OR = 3.4
Fatality[5]	

References: 1. Andrew E, et al. *Prehosp Emerg Care*. 2018. **2.** Hochstadter E, et al. *J Allergy Clin Immunol*. 2016. **3.** Fleming JT, et al. *J Allergy Clin Immunol Pract. 2015.* **4.** Liu X, et al. *J Allergy Clin Immunol Pract*. 2020. **5.** Turner PJ, et al. *J Allergy Clin Immunol*. 2017.

Only ~40%
of ER Anaphylaxis Patients are Dosed with Epinephrine Pre-Arrival in the Community Setting



References: 1. Mehta GD, et al. *Expert Rev Clin Immunol.* 2023.

Delays in Treatment with Epinephrine are Principally Due to Autoinjector Limitations and Accompanying Patient Reluctance

>40% of patients **do not fill or refill** their epinephrine prescription[1]

~40% of patients **do not administer** epinephrine at all[2]

55%-60% don't consistently carry epinephrine[2-4]

>50% of parents are **afraid or somewhat afraid to administer** their child's epinephrine[5]

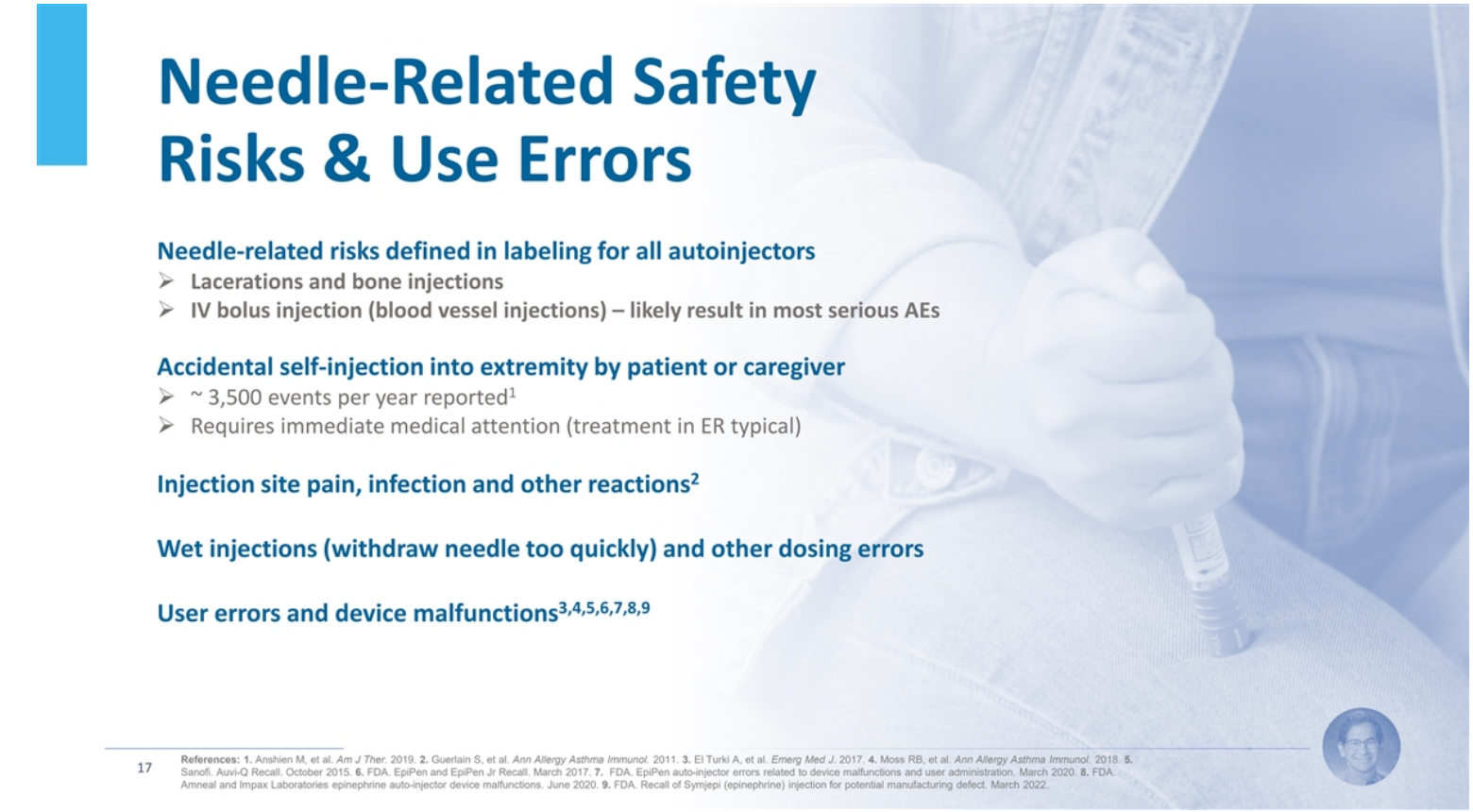
Patients that Do Not Administer Correctly[7]

~70% of patients **Without Training**

~20% of patients **with Training**

References: 1. Data on File. ARS Pharmaceuticals. 2023. **2.** Warren CM, et al. *Ann Allergy Asthma Immunol*. 2018. **3.** Brooks C, et al. *Ann Allergy Asthma Immunol*. 2017. **4.** Curtis C, et al. *Ann Allergy Asthma Immunol*. 2014. **5.** Chad L, et al. *Eur J Allergy Clin Immunol*. 2013. **6.** Sicherer SH, et al. *Pediatrics*. 2000. **7.** El Turki A, et al. *Emerg Med J*. 2017.

Needle-Related Safety Risks & Use Errors



Needle-related risks defined in labeling for all autoinjectors

- Lacerations and bone injections
- IV bolus injection (blood vessel injections) – likely result in most serious AEs

Accidental self-injection into extremity by patient or caregiver

- ~ 3,500 events per year reported[1]
- Requires immediate medical attention (treatment in ER typical)

Injection site pain, infection and other reactions[2]

Wet injections (withdraw needle too quickly) and other dosing errors

User errors and device malfunctions[3,4,5,6,7,8,9]

References: 1. Anshien M, et al. *Am J Ther.* 2019. **2.** Guerlain S, et al. *Ann Allergy Asthma Immunol.* 2011. **3.** El Turki A, et al. *Emerg Med J.* 2017. **4.** Moss RB, et al. *Ann Allergy Asthma Immunol.* 2018. **5.** Sanofi. Auvi-Q Recall. October 2015. **6.** FDA. EpiPen and EpiPen Jr Recall. March 2017. **7.** FDA. EpiPen auto-injector errors related to device malfunctions and user administration. March 2020. **8.** FDA. Amneal and Impax Laboratories epinephrine auto-injector device malfunctions. June 2020. **9.** FDA. Recall of Symjepi (epinephrine) injection for potential manufacturing defect. March 2022.

2023 AAAAI guidelines updated so that EMS activation not required for 90% of events that resolve with single dose

Practice Parameters

Anaphylaxis: A 2023 practice parameter update

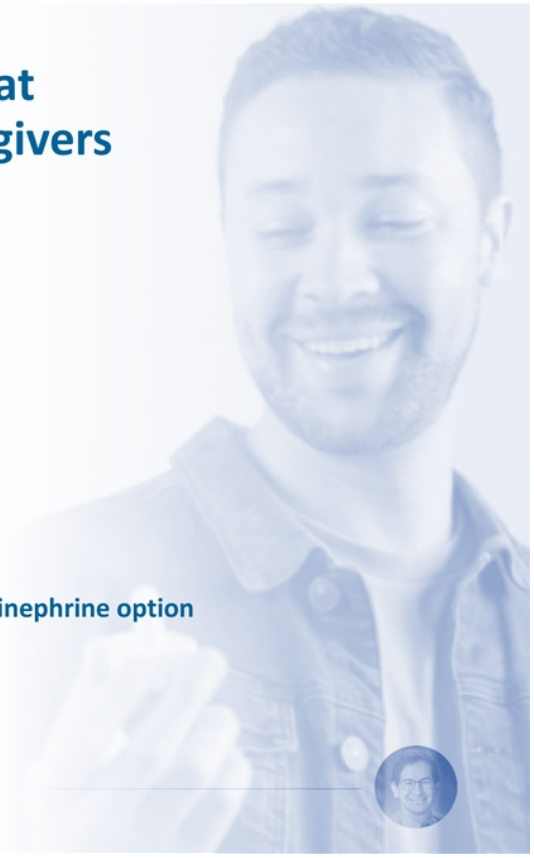
Historic guidelines recommended ED visit following use of epinephrine for anaphylaxis, which may result in families not giving epinephrine to avoid ED visits

Based on outcomes of anaphylaxis in EDs and the COVID-19 pandemic, data indicates treatment and monitoring of anaphylaxis can occur at home

- If signs and symptoms resolve within minutes of dosing, monitor at home after first dose
- If signs and symptoms improve within minutes of dosing, monitor at home if comfortable, while considering EMS activation and possible second dose of epinephrine
- If signs and symptoms are not resolving, activate EMS immediately, and consider second dose of epinephrine

Prompt use of epinephrine and monitoring at home will decrease healthcare utilization

neffy (epinephrine nasal spray) Can Fill Great Unmet Medical Need for Patients and Caregivers



Epinephrine has a well-established efficacy and safety profile

- Efficacy same across epinephrine injection products despite PK differences

Immediate administration of epinephrine is critical

Patients and caregivers reluctant to use or carry current devices

- Needle-phobia
- Concerns with safety
- Cumbersome to carry

Unmet need for needle-free, easy to use, easy to carry, safe and effective epinephrine option

***neffy* can fit that need for our patients**

neffy Profile

Richard Lowenthal

CEO, ARS Pharma

ARS PHARMA

neffy is a High Bioavailability, Low 2 mg Dose Saline-Based Nasal Spray: Proven Triad of FDA-Approved Components

High bioavailability with low dose minimizes side effects that mimic anaphylaxis (GI symptoms) and risk of cardiotoxicity from overdosing

> 9 FDA Approvals in Allergy
(> 100 years of clinical experience)

Epinephrine

7 FDA Approvals of Sprayer
(> 55 million Rx, 99.999% reliable)[1]

3 FDA Approvals incl. Intravail
(> 1 million Rx)[1]

TOSYMRA® VALTOCO®

OPVEE®

Intravail®
dodecyl-maltoside: GRAS absorption enhancer

Sprayer

NARCAN® VALTOCO® NAYZILAM®

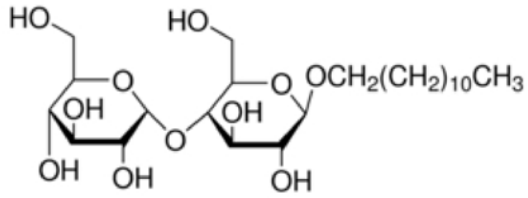
IMITREX® TOSYMRA® ZAVZPRET®

OPVEE®

References: 1. IQVIA Prescription data, and ARS company data on file

ARS PHARMA

Intravail® Allows Injection-Like PK at a Low Intranasal Dose Without Irritation or Pain, and Robust IP Protection to 2038+



n-Dodecyl beta-D-maltoside (Intravail®)

- Generally recognized as safe (GRAS) absorption enhancing agent
- Biologic surfactant that loosens tight junctions (paracellular) coupled with fluidization and penetration of cell membranes (transcellular)
- **No irritation, pain or damage to nasal mucosa**
- Extensive toxicology and safety program

NCE-like exclusivity enabled by Intravail

- **No systemic absorption via nose without Intravail** when epinephrine is put in water-based solution
- Intravail allows systemic intranasal absorption of epinephrine within the known therapeutic dose window for injection products
- **No inhalation required – absorption in nasal mucosa**
- **Issued composition of matter patents in the US and globally covering Intravail® + epinephrine[1, 2]**
- **Issued method of treatment patents blocks other low dose aqueous nasal sprays (<4 mg dose)[3-7]**
- **Exclusivity until at least 2038 without PTE**

References: 1. US10,576,156, **2.** US11,173,209, **3.** US10,682,414, **4.** US11,191,838, **5.** US11,744,895, **6.** US11,717,571, **7.** US11,918,655

Designed for Easier Carry and Portability

Case holds two neffy 2mg devices.

Basis of Approval for Community Use Products

- Approved community use products include IM and SC dosing (FDA briefing book)
- Almost all approved without PK data

Device	Approval Basis	Pharmacokinetics (any data including literature)	FDA Approved Route and Dose
EpiPen® (1987)	No PK Data	Significant differences (EpiPen vs. IM) only known for ~10 yrs Blood vessel injection risk (IV bolus) known last 5 yrs	IM & SC 0.15 & 0.3 mg
Twinject® (2003)	No PK Data	No PK data known to date	IM & SC 0.15 & 0.3 mg
Adrenaclick® (2003)	No PK Data	No PK data known to date	IM & SC 0.15 & 0.3 mg
Auvi-Q® (2012)	Single PK Study	More rapid PK vs. IM, but slower PK vs. EpiPen (T_{max} = 20 min vs 10 min)	IM & SC 0.1, 0.15 & 0.3 mg
Symjepi® (2017)	No PK Data	ARS studies show slower PK vs ***neffy*** or other autoinjectors	IM & SC 0.15 & 0.3 mg
Teva EpiPen® (2018)	No PK Data	None to date; shorter needle and different activation force	IM & SC 0.15 & 0.3 mg

All Products Demonstrate Efficacy Despite Different PK

- Despite PK differences no known difference in efficacy
- All products 90% resolution on single dose

Treatment[1]	Source	N	Mean Study C_{max} (pg/mL)	Median or Mean Study T_{max} (min)	Study T_{max} Range (min)
EpiPen 0.3 mg	Literature and ARS	507	288 – 869	5 to 40	1 – 240
IM 0.3 mg	Literature and ARS	381	209 – 489	30 to 60	3 – 360
Auvi-Q 0.3 mg	Literature	96	486 – 646	20 to 30	5 – 60
Symjepi 0.3 mg	ARS data	88	337 – 438	30	4 – 240
SC 0.3 mg	ARS	36	246	45	4 – 180
Total Range			**209 to 869**	**5 to 60**	**1 to 360**

References: 1. Srisiwat C, et al. *Asian Pac J Allergy Immunol.* 2022. **2.** Aquestive Therapeutics Press Release. Sept 2022. **3.** Edwards ES, et al. *Ann Allergy Asthma Immunol.* 2013. **4.** Dworaczyk D & Hunt A. Abstract Presentation AAAAI 2021 (Virtual Meeting). **5.** Aquestive Therapeutics Press Release. May 2023.

ARS PHARMA

Development Program Focused on Comparison to PK / PD Profile of Approved Epinephrine Products

PK to ensure efficacious and safe exposures within range of approved products - Bracketing Approach

- Minimum exposure ≥ IM/SC (efficacy)
- Maximum exposures < EpiPen (safety)

PD response to support effect at achieving receptor response

- Blood pressure (BP): α_1 & β_1 (β_2) receptors
- Heart rate (HR): β_1 receptors

Registrational Studies Demonstrate Comparability on Both PD Surrogates for Efficacy and PK with *neffy*

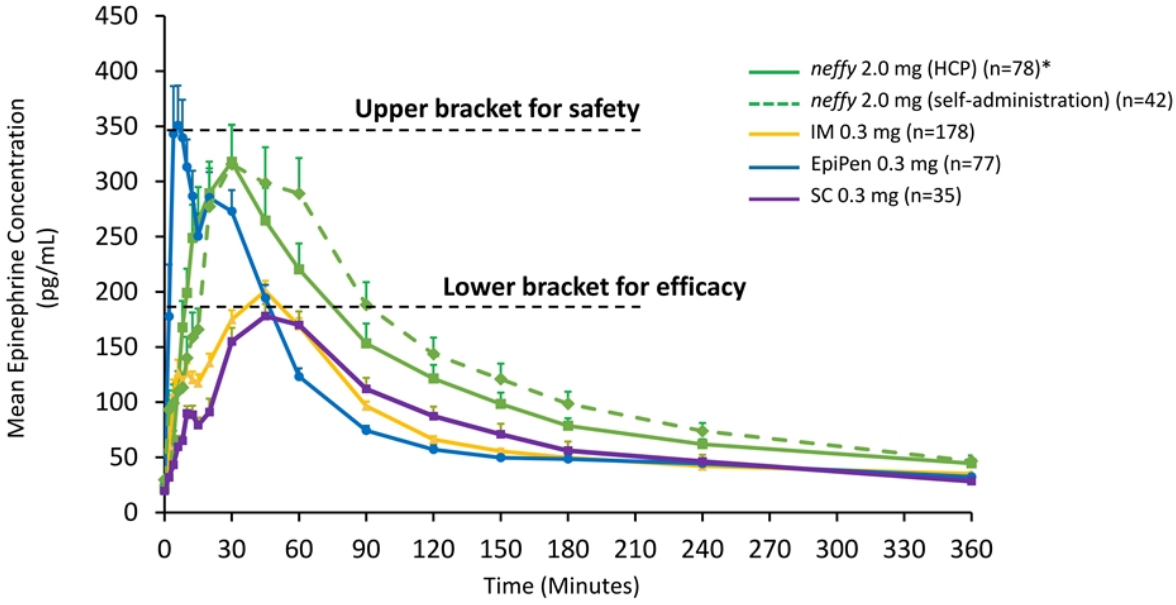
PD and PK Data

- 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*

Pharmacokinetic Results from *neffy* 2 mg Studies Satisfies Bracketing Approach designed with FDA

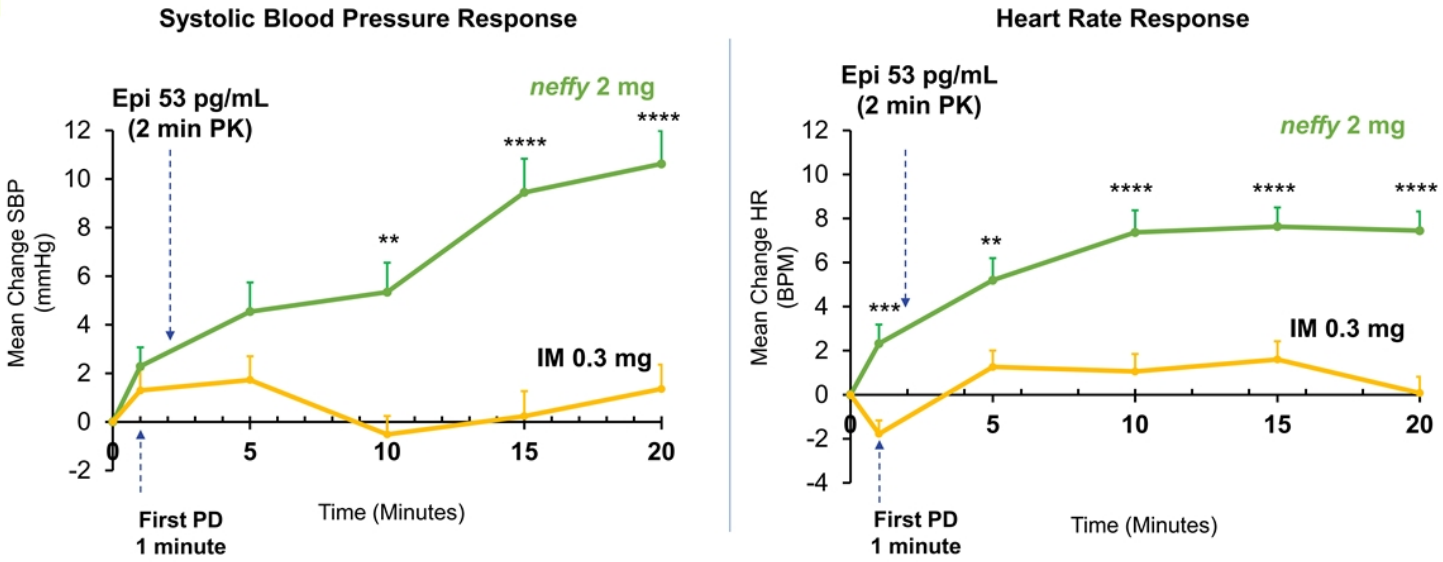


*Includes Studies EPI-15 and EPI-16

neffy PK is Bracketed by EpiPen Studies (Cmax or tmax)

Treatment	Study Reference	N	Mean Study C_{max} (pg/mL)	Median Study T_{max} (min)
EpiPen (0.3 mg)	AQST-109 EPIPHAST II Results (2022)	22	869	22
	ARS EPI-JP01 Data (2020)	30	676	10
	AQST-109 Pilot Results (2023)	27	628	10
	ARS EPI-15 (2022)	35	612	8
	Tal et al. EAACI (2022)	12	550	9
	ARS EPI-11b Data (2021)	9	537	6
	Edwards et al. NDA #201739 (2012)	67	520	10.2
	Chen et al. AAAAI (2019)	11	511	5
	ARS EPI-12 Data (2021)	36	493	8
	ARS EPI-13 Data (2022)	39	490	6
neffy (2.0 mg)	ARS EPI-16 data (2022)	36	491	20
	ARS integrated analysis (2022) – EPI-15/16	**78**	**485**	**20.5**
	ARS EPI-15 data (2022)	42	481	30
	ARS EPI-17 data (2022)	42	421	30
EpiPen (0.3 mg)	Worm et al. Clin Transl Allergy (2020)	12	390 to 530	9 to 30
	Turner et al. Clin Exp Allergy (2021)	37	386	40
	Amphastar US2021/030502 (2021)	56	364 - 458	7-15
	ARS EPI-07 Data (2019)	35	375	24
	Dworaczyk et al. AAAAI (2020)	55	308 to 440	10-16
	Oppenheimer et al. AAAAI (2022)	10	341	22
	ARS EPI-01 Data (2018)	12	333	20
	Aquestive R&D Day (2021)	9	300	10
	Dworaczyk et al. AAAAI (2021)	25	288	10
	Dworaczyk et al. ACAAI (2023)	26	279	20
	Dworaczyk et al. ACAAI (2023)	25	228	21

Robust Response on PD Surrogate Markers for Efficacy



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

Integrated analysis of ARS clinical studies (EPI-15 and EPI-16)

Positive FDA AdCom vote supports benefit-risk of *neffy*

FDA Advisory Committee (May 2023) voted that benefit-risk of *neffy* supported FDA approval

- 17:5 and 16:6 voted in favor for approval in pediatric and adult populations, respectively
- Advisory members who voted against approval desired comparative clinical efficacy data for anaphylaxis, which cannot be ethically conducted in this population

FDA Advisory Committee viewed single dose NAC study data as "encouraging" and "favorable" due to greater concentration levels during the period when clinical response is observed with epinephrine

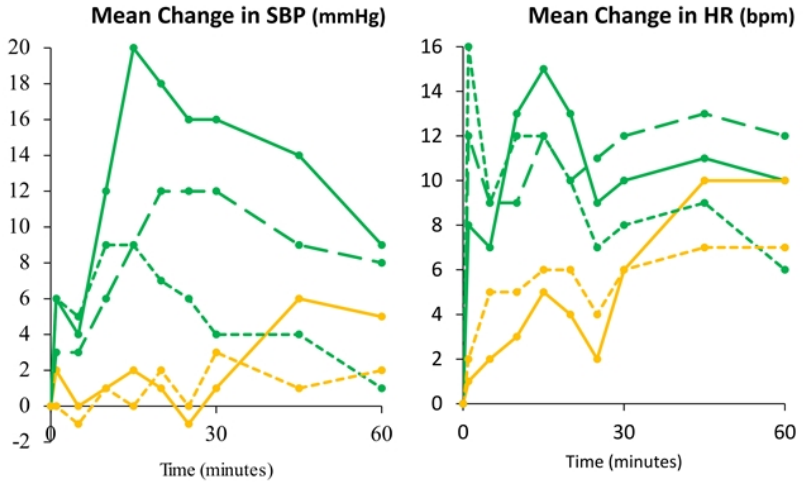
- Nasal congestion following nasal-allergen challenge (spraying purified antigen directly into the nose) accelerates absorption of *neffy* in the first 20 minutes vs. normal state
- Treatment guidelines recommend giving a second dose if no response is observed within 5 to 15 minutes of administration
- FDA reported that the rate of nasal mucosal symptoms in anaphylaxis patients ranges from 2 to 11% *(weighted average frequency in the literature is ~4% based on aggregated analysis of 13 publications)*

No member of the Advisory Committee requested a repeat dose rhinitis study as a prerequisite for FDA approval

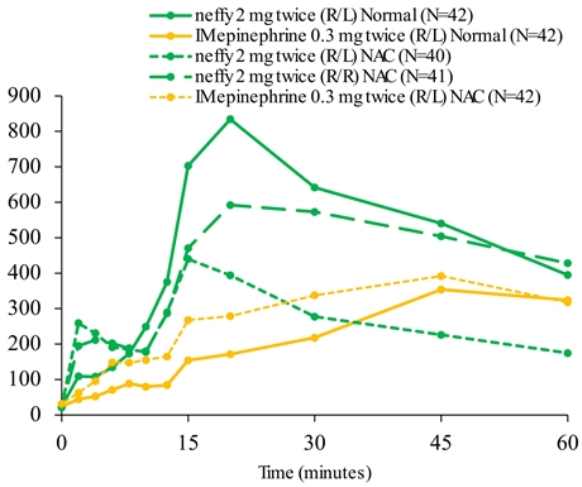
ARS PHARMA

Completion of Repeat Dose *neffy* NAC study per FDA's CRL Request Shows PK/PD Greater or Similar to IM Injection

PD Response (Mean Change in SBP, HR)



PK Profile (Mean Plasma Concentrations, pg/mL)



Response to FDA's CRL anticipated by early Q2 2024 followed by up to 6-month FDA review

Note: FDA explicitly requested IM epinephrine as the comparator in this study because IM is the basis for efficacy for epinephrine products, and there are no known differences between the various approved injection devices despite different PK

Risk-benefit assessment of *neffy*

Thomas B. Casale, M.D.
Professor of Medicine & Pediatrics
Chief, Allergy & Immunology
University of South Florida

Ideal Properties of an Epinephrine Delivery Product

Does it work?

- Consistent and reproducible PK/PD profiles (no to minimal outliers) and drug administration that is not affected by anaphylaxis symptoms or pre-existing conditions or co-morbidities
- Robust and rapid PD effects that are especially important for severe anaphylaxis

Is it safe?

- No risk of injury and minimal side effects
- Minimize risk of overdosing with epinephrine
- Avoid side effects that are also anaphylaxis symptoms

Will patients use it?

- Minimal side effects
- Palatable
- Small
- Easy to use

Severe or Fatal Anaphylaxis Due to Laryngeal / Airway Edema in Children; Presence of Hypotension in Adults

Both

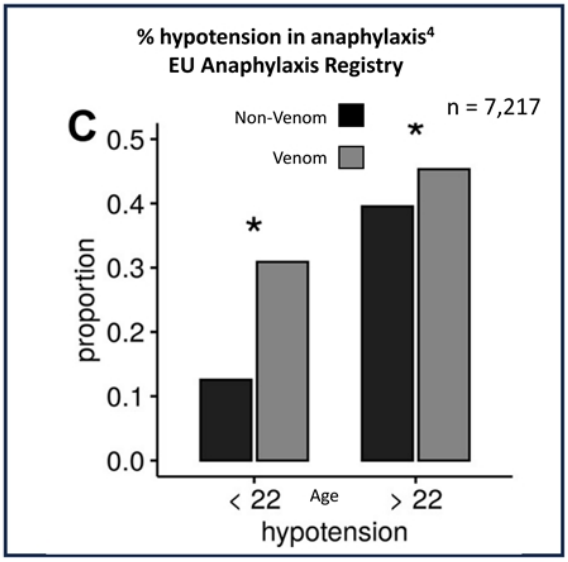
- Most frequent symptom is laryngeal edema: 41% to 46% prevalence of upper air way edema (lips to larynx) in fatal anaphylaxis[1, 2]

Children

- Deaths are rather secondary to the laryngeal edema, observed in 40%-50% of cases.[3]
- Cardiovascular involvement is rare in infants, most often observed in adolescents, probably related to age-dependent physiological changes."[3]

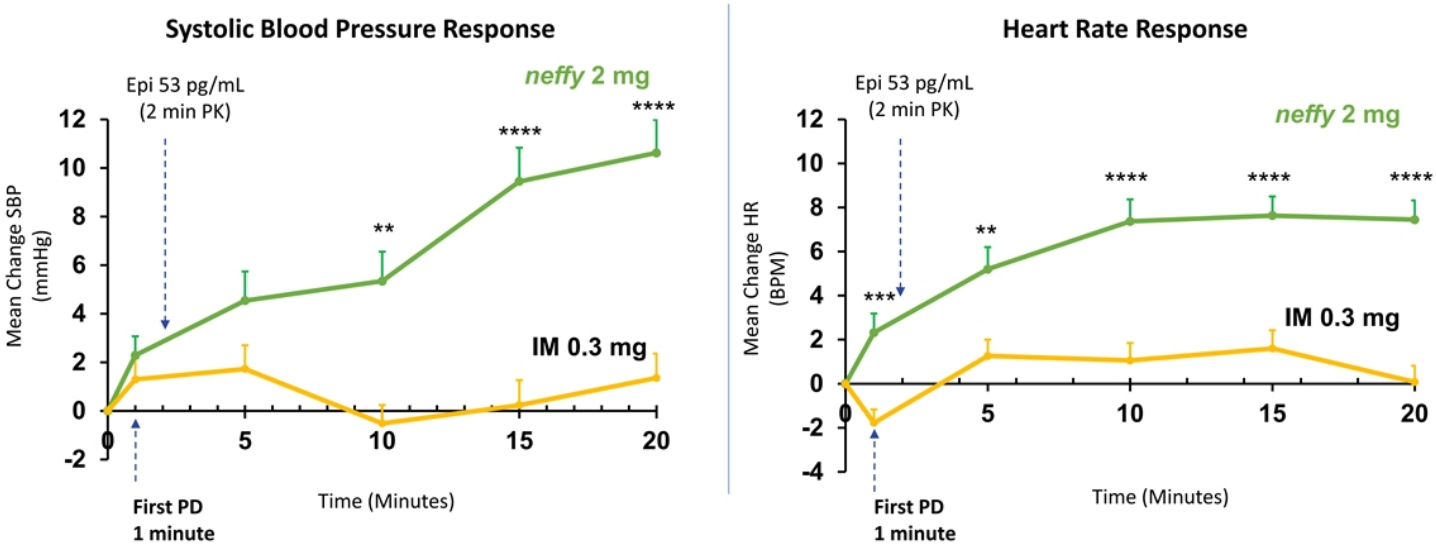
Adults

- Significantly higher rates of hypotension and cardiovascular involvement in older adults[4]



References: 1. Xu YS, et al. *Allergy Asthma Clin Immunol.* 2014. **2.** Pumphrey RS, et al. *J Clin Pathol.* 2000. **3.** Tanno LK, et al. *Pediatr Allergy Immunol.* 2020. **4.** Francuzik W et al. *J Allergy Clin Immunol.* 2021.

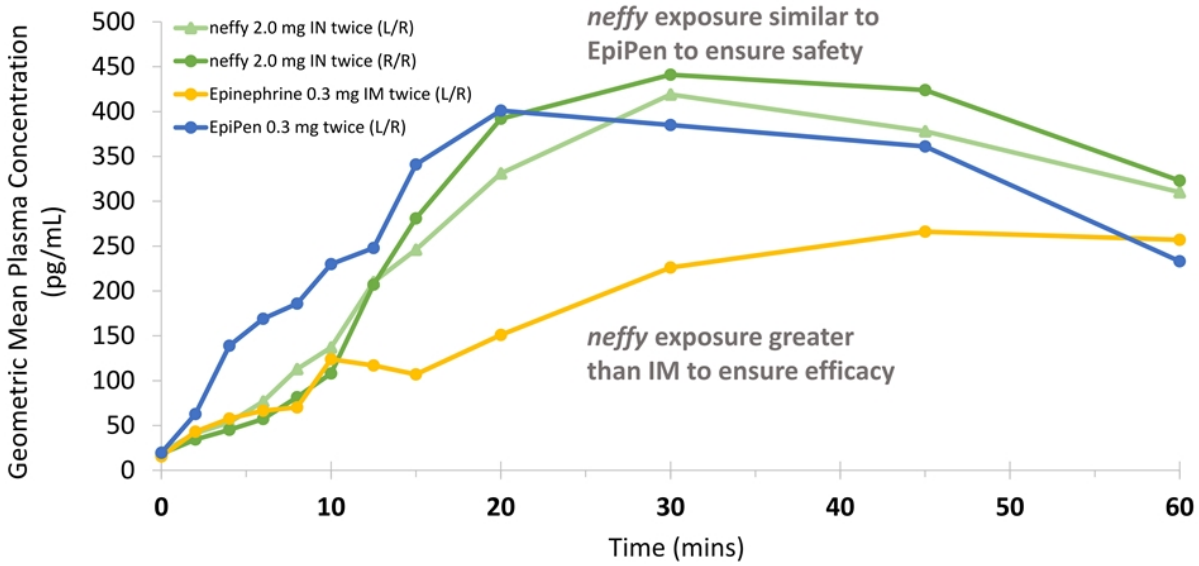
neffy Shows Rapid and Robust PD Response that Demonstrates Engagement of Receptors that Reverse Anaphylaxis Symptoms



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

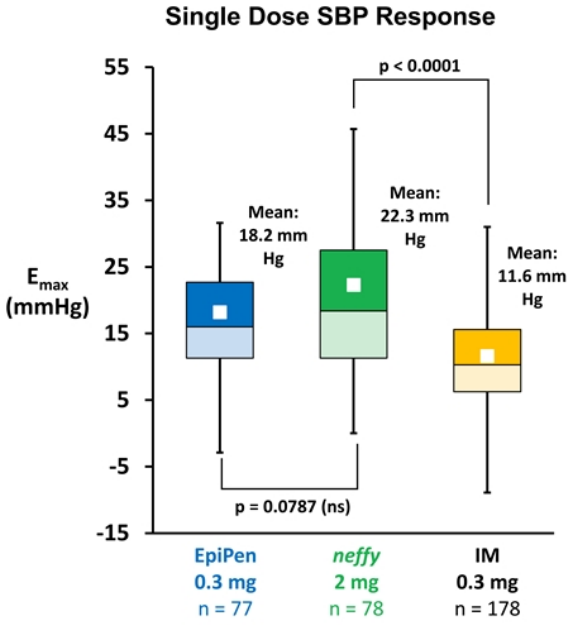
Exposures of Repeat Doses of *neffy* in Healthy Subjects are also in the Range of FDA Approved Epinephrine Injection Products

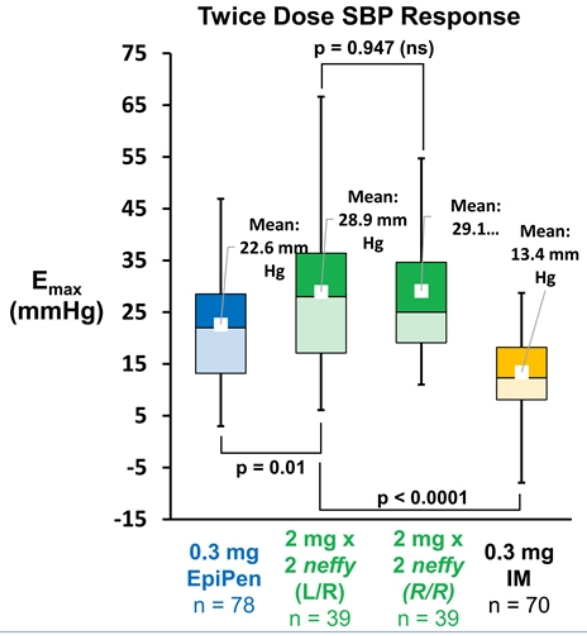
Repeat dosing 10 min apart in healthy subjects



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

PD Response as Shown to be at Least as Good as EpiPen, Supporting Engagement of Receptors that Reverse Anaphylaxis Symptoms





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

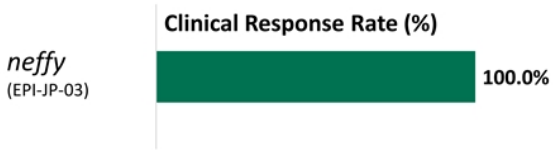
Efficacy Study of *neffy* in Oral Food Challenge Induced Anaphylaxis (EPI-JP-03)[1]

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



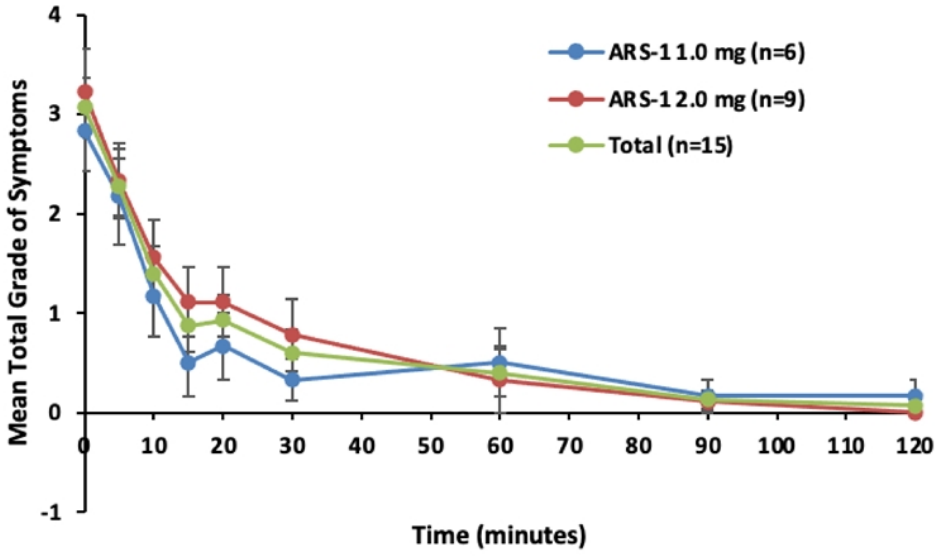
100% **of patients responded to a single dose of *neffy* in the first 15 minutes, and did not require a second dose of epinephrine per treatment guidelines**

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).

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



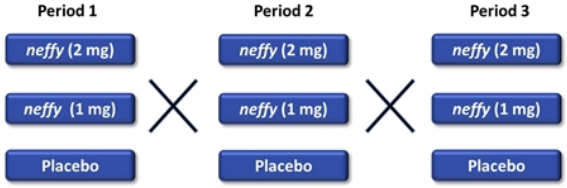
References: 1. Ebisawa M, et al. Presentation at AAAAI 2024 (Washington DC).

neffy Shows Robust and Rapid Clinical Responses in Treatment-Resistant Urticaria (Most Common Symptom of Anaphylaxis)

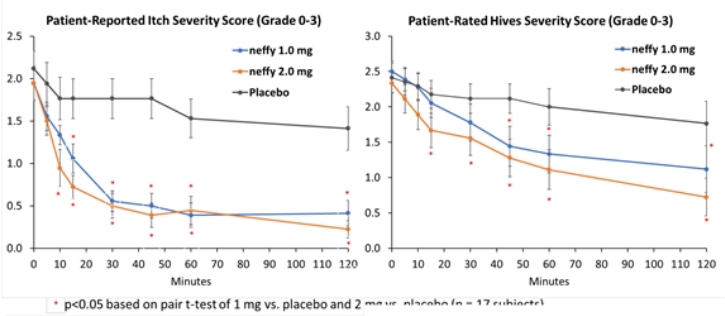
Randomized, Placebo-Controlled Efficacy Data in Treatment Refractory Chronic Urticaria (EPI-U01)[1]

Study Design

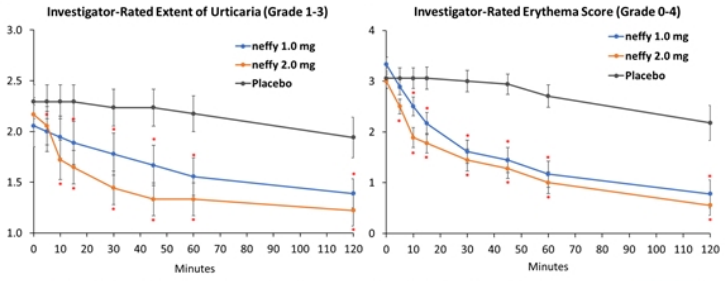
randomized, placebo-controlled crossover trial study



- 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)



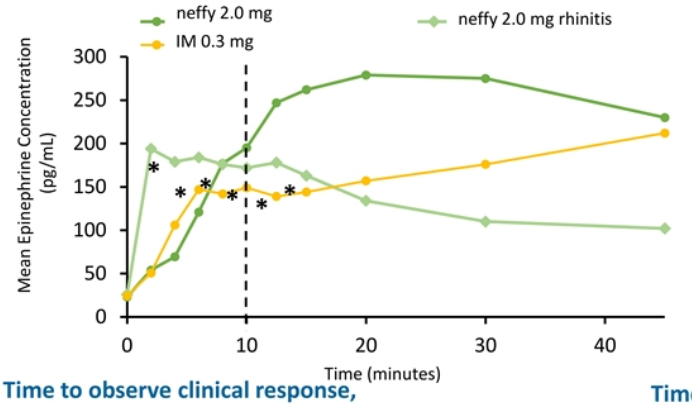
* p<0.05 based on pair t-test of 1 mg vs. placebo and 2 mg vs. placebo (n = 17 subjects)

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

Experimental NAC-Induced Rhinitis Does Not Negatively Impact *neffy*'s PK Profile (Allergic Rhinitis Subjects)

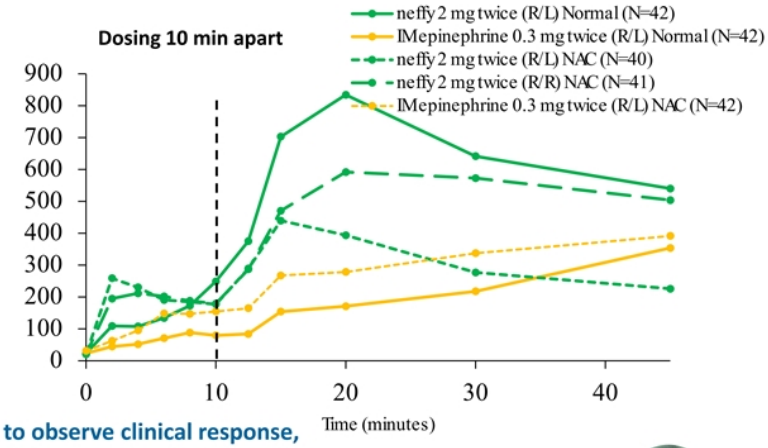
FDA Advisory Committee viewed *neffy* NAC data as "encouraging" and "favorable"

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 dose under NAC-induced rhinitis supports similarity to injection for more severe cases of anaphylaxis

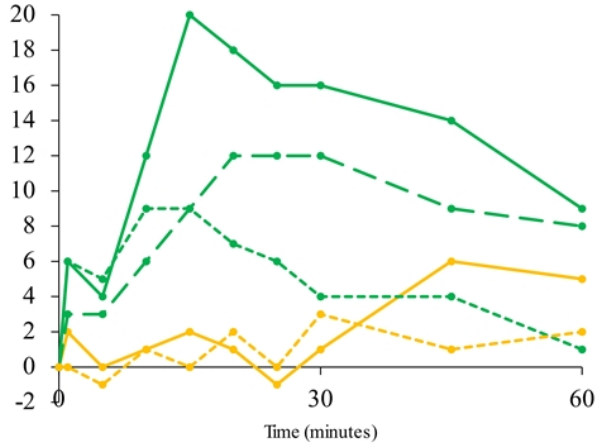


Time to observe clinical response, and re-dose per guidelines

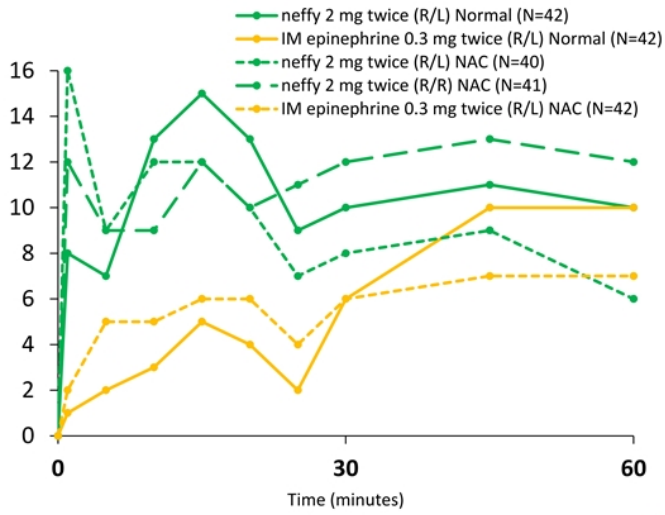
* Statistically significant differences between *neffy* with rhinitis compared to IM injection ($p < 0.05$)

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

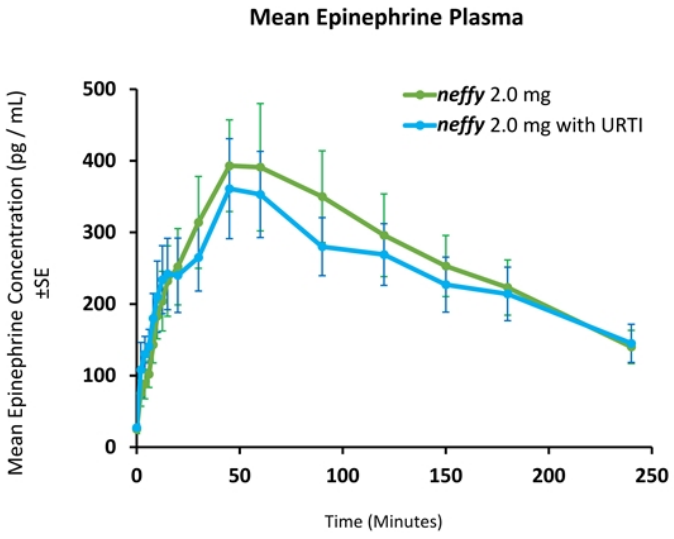
Mean Change in Systolic Blood Pressure (mmHg)

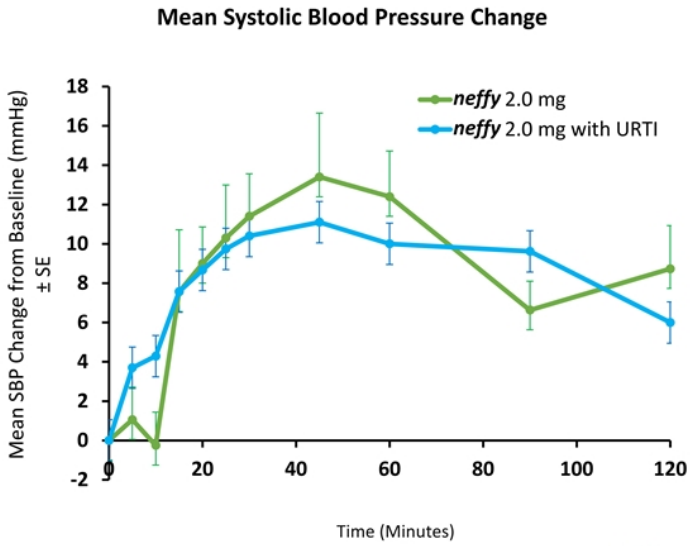


Mean Change in Heart Rate (bpm)



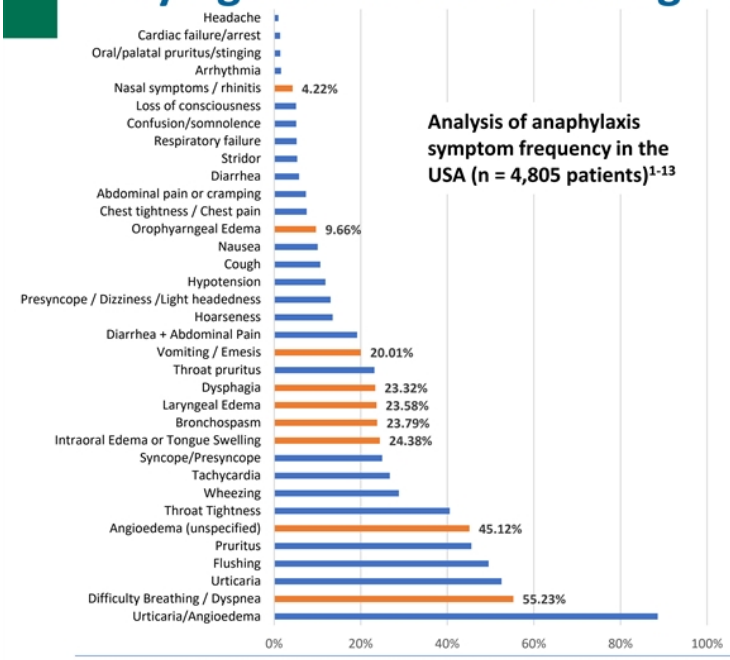
Upper Respiratory Tract Infection (URTI)-Induced Rhinitis has no Clinically Meaningful Impact on the PK/PD Profile of *neffy*





N = 21 URTI / 16 Normal (returned)

PK/PD Profile and Ability to Dose May Be Influenced By Varying Conditions Including Anaphylaxis Itself



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 / 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.

Excellent Tolerability and Palatability

Adverse events generally mild in nature with no meaningful nasal irritation or pain up to 4 mg dose

No serious adverse events in any clinical study

No risk of needle-related injuries or blood vessel injections with *neffy*

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 stinging or burning)
- No irritation based on formal assessment (no erythema or ulcers)

Excellent palatability – no taste or smell with *neffy*

- "Inherent bitterness of epinephrine may hinder acceptability for patients, especially children"[1]

References: 1. Rachid O, et al. *AAPS PharmaSciTech.* 2010.

Adverse Event Profile Compares Favorably to Autoinjectors

Incidence of adverse events in *neffy,* EpiPen and Auvi-Q studies (greater than 5% frequency)

Adverse Event	2 mg neffy[1]	0.3 mg EpiPen[2]	0.3 mg Auvi-Q[2]
Injection-site erythema	0%	32.6%	31.3%
Injection-site pain	0%	24.4%	13.4%
Tremors	0%	14.1%	13.4%
Mild nasal discomfort	9.7%	0%	0%
Mild headache	6.0%	<5%	<5%
Anxiety	<1%	7.4%	10.4%
Injection-site bleeding	0%	9.6%	4.5%
Injection-site induration	0%	6.7%	4.5%

References: 1. FDA Advisory Committee, **2.** Edwards ES, et al. *Ann Allergy Asthma Immunol.* 2013.

Low Dose is an Important Benefit of *neffy* that Minimizes Risk of Overdosing, and Difficulty Monitoring Clinical Response

Epinephrine has a therapeutic window and potential for overdose

if too much is systemically absorbed too fast (e.g. IV bolus)[1, 2] – multiple cardiac events and fatalities reported in literature[3, 4]

2 mg *neffy* has essentially minimal risk of overexposure

even with higher bioavailability in the event of increased permeability during an allergic reaction or population variability (nasal abnormalities, impact of using other drugs or substances on nasal mucosa, etc.)

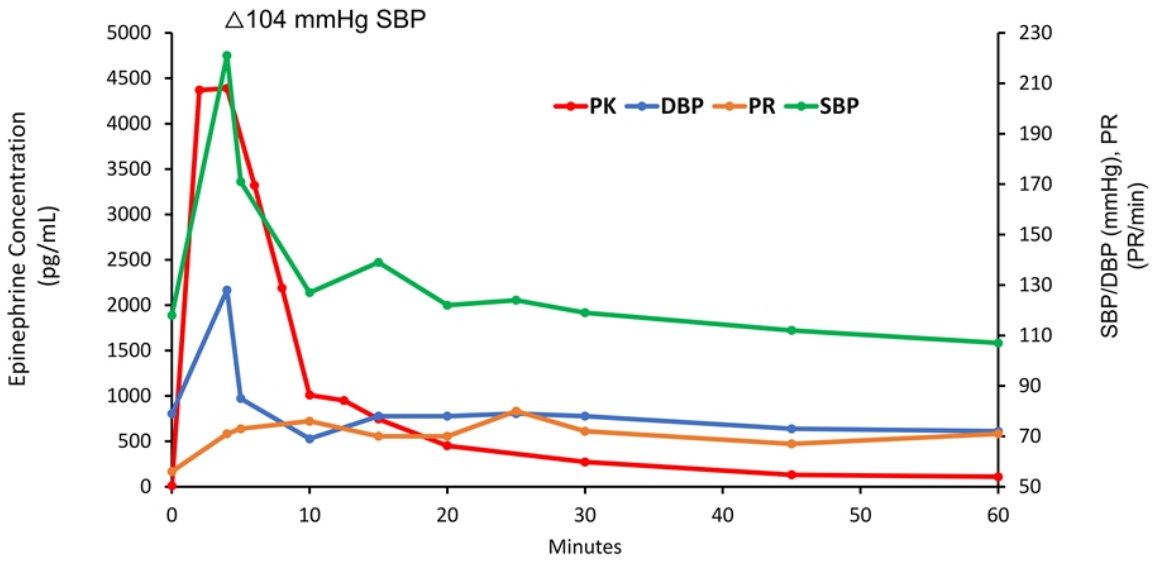
High dose of epinephrine can also lead to swallowing of non-absorbed epinephrine and GI side effects (vomiting/abdominal pain)[5, 6]

Vomiting/abdominal pain is a common symptom of food-induced anaphylaxis (especially biphasic) that can confound monitoring of clinical response leading to unnecessary treatment and re-dosing[7, 8, 9]

neffy has minimal to no GI side effects

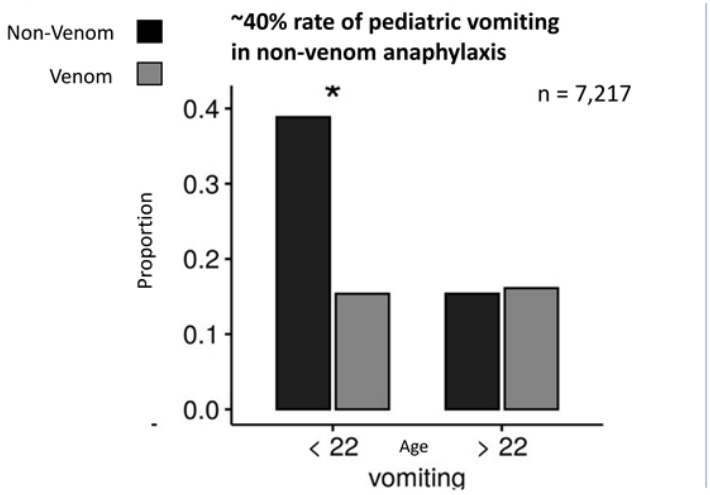
References: 1. Casale TB, et al. *Ann Allergy Asthma Immunol.* 2024. **2.** Ebisawa M, et al. *J Allergy Clin Immunol Glob.* 2023. **3.** Pumphrey RS, et al. *Clin Exp Allergy.* 2020. **4.** Ring J, et al. *Dtsch Arztebl Int.* 2018. **5.** Schlegel C, et al. *J Dtsch Dermatol Ges.* 2009. **6.** Dworaczyk D & Hunt A. Presentation at AAAAI 2023 (San Antonio, Texas), **7.** Francuzik W et al. *J Allergy Clin Immunol.* 2021. **8.** Pflipsen MC & Colon KMV. *Am Fam Physician.* 2020. **9.** Gupta, RS, et al. *J Allergy Clin Immunol Pract.* 2021.

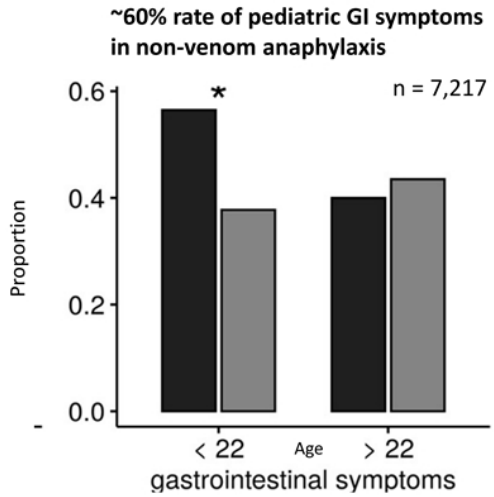
Too Much Epinephrine, too Fast, can be Dangerous, without More Benefit: Suspected IV Bolus Case-Study with EpiPen[1]



References: 1. Ebisawa, et al. *JACI: Global*, 2023.

Children more likely to experience vomiting and GI symptoms than adult anaphylaxis patients with non-venom allergies





Important side effect to avoid for monitoring of clinical outcomes
(and also a co-morbidity that could alter absorption of dosing via mouth)

References: 1. Francuzik W et al. *J Allergy Clin Immunol.* 2021.

Human Factors Studies and Real-World Data Have Proven that *neffy* is Easy for Patients to Carry and Simple to Administer

Proven ease of use in human factors studies and real-world emergency use settings

100% of adults (including passersby without allergies) able to use ***neffy*** successfully without training

100% of children (about half of the current autoinjector prescriptions) able to use ***neffy*** successfully without training

Same device available over the counter in NARCAN OTC (no training required)

Patients Should be Carrying and Dosing Sooner with *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

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

Commercial Opportunity

Eric Karas
Chief Commercial Officer

ARS PHARMA

PHYSICIAN

Significant Opportunity to Address Unmet Needs in Current US Severe Allergic Reaction Market (~$1B Net[1])

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%)

~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

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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).

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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.

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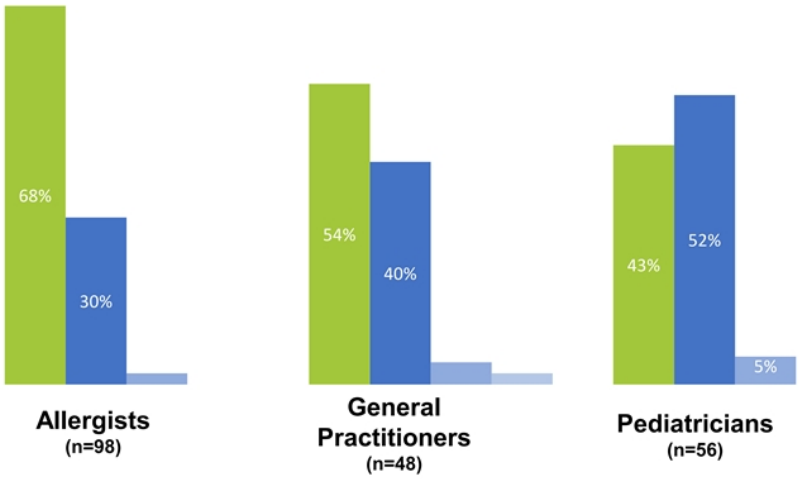
Two-Thirds of Allergists and Half of GPs Ready to Prescribe *neffy* as Soon as Possible; Majority of Pediatricians Expected to Prescribe within One Year

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.

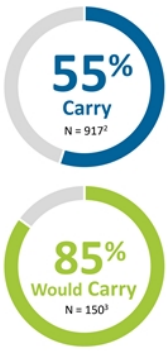
PATIENT

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

Benefits of needle-free alternative to address major unmet needs

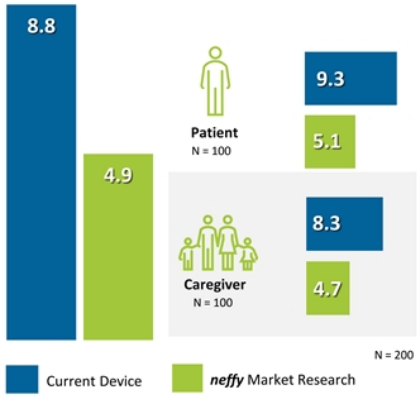
- More allergy patients and caregivers are likely to carry ***neffy*** compared to current needle-bearing options
- Patients are likely to dose ***neffy*** more rapidly with a needle-free device

% 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.

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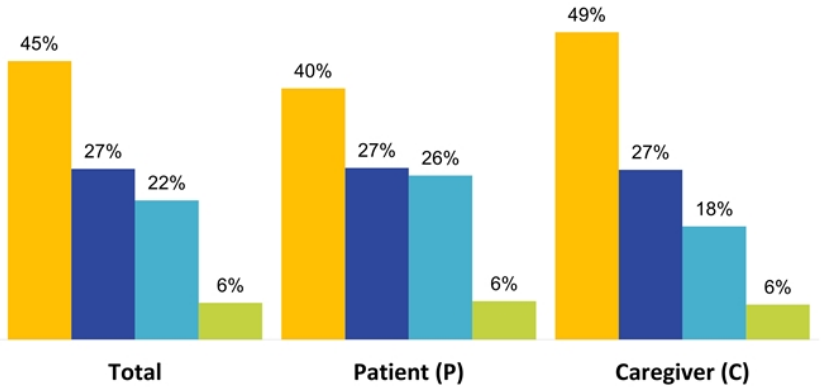
PATIENT

~ 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.

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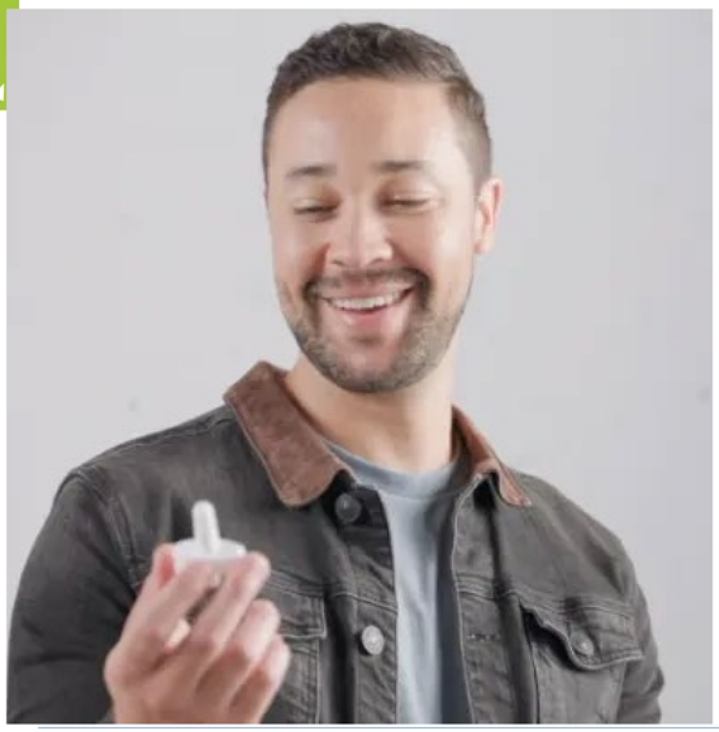

neffy Strategic Objectives

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
  - **Reaching >80%** of Prescriptions from Allergists and Pediatricians

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

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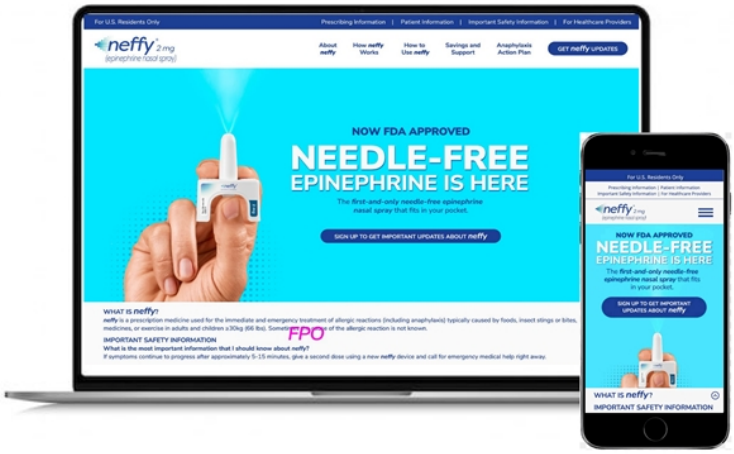
ACTIVATE

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

Consumer Launch Objectives

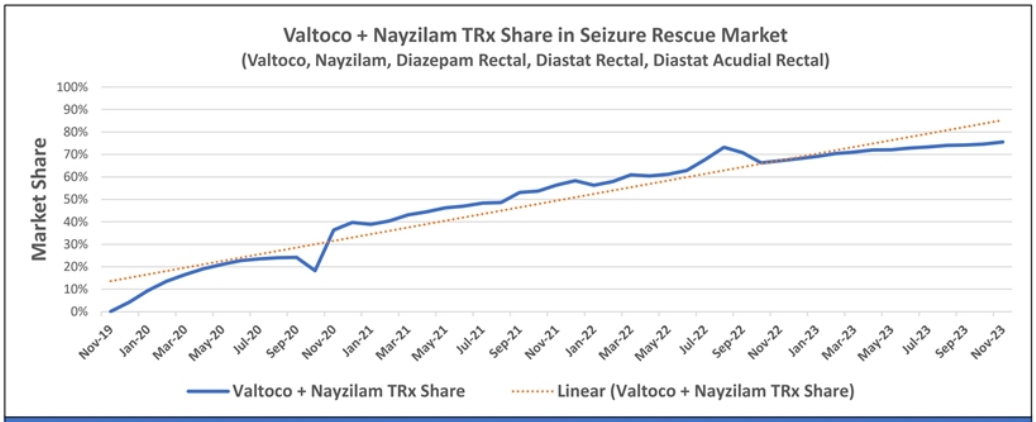
- Drive awareness & motivate patients and caregivers to request ***neffy*** by name
- Enable patients and caregivers to feel fully prepared to act during a potential crisis moment
- Activate patients and caregivers to share their ***neffy*** story to encourage peer uptake



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

VALTOCO®

NAYZILAM®



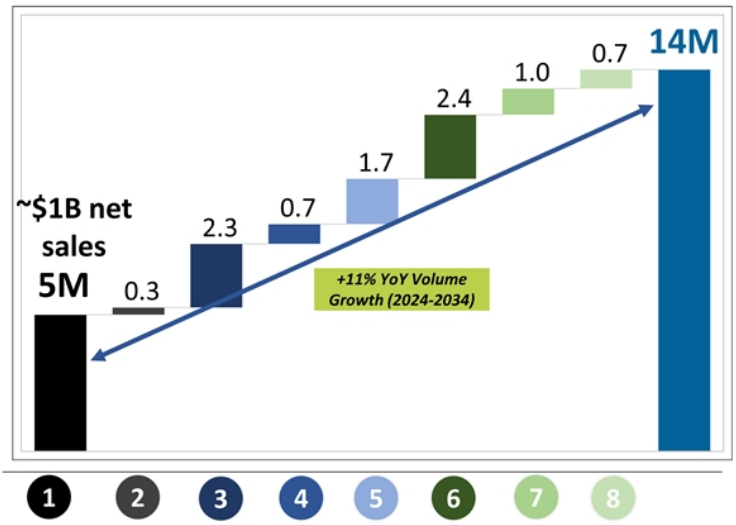
75% market share at 50 months post-launch

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. ~$1+ billion net sales US epinephrine market in 2023 (~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
Note that current estimated $1B+ net sales are based on generic epinephrine autoinjector products (90%+ of volume), not the intended pricing of neffy as a branded innovator product.

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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

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Financial Update
*Post-Marketing Requirements/Post-Marketing Commitments
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Financial highlights

Cash and short-term investments: **$228M**

Debt: **$0M**

Common Shares: **96.4M**

As of 12/31/2023

Estimated at least three years of operating runway including the anticipated launch and commercialization of *neffy*

Significant Ex-US opportunity for *neffy*

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

Source: 2023 IQVIA MIDAS (USD MNF)

Significant Catalysts for *neffy* in 2024

- **US NDA response to CRL** by early Q2 2024
- **PDUFA action date** anticipated in H2 2024

- **EMA decision (CHMP Opinion)** expected by mid-2024

- **China NDA filing** expected by YE 2024
- **Japan NDA filing** expected by YE 2024
- **Planning in progress for filing in other major ex-US regions** including Canada

- **Expansion opportunities**
  - Positive data from Phase 2 chronic urticaria study reported in Feb 2024
  - **Initiation of Phase 2b outpatient urticaria study**


Q&A
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