

THE FIRST NO-NEEDLE, NO-INJECTION SOLUTION for Type I Allergic Reactions



Q2 2023



Forward-looking statements

This presentation contains forward-looking statements which include, but are not limited to, statements regarding the design and potential benefits of neffy; the anticipated Prescription Drug User Fee Act (PDUFA) date for *neffy*; the timing of regulatory approval for and the commercial launch of *neffy*, if approved; ARS Pharma's commercialization strategy; the potential market opportunity for *neffy*; the projected growth thereof and *neffy*'s ability to capture and grow that market; ARS Pharma's expected competitive position; ARS Pharma's potential to become the standard in treatment and transform the treatment of allergic reactions; the likelihood of neffy attaining favorable coverage; the expected intellectual property protection for neffy; 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. ARS Pharma's expectations and beliefs regarding these matters may not materialize. Actual outcomes and results may differ materially from those contemplated by these forward-looking statements as a result of uncertainties, risks, and changes in circumstances, including but not limited to risks and uncertainties related to: the ability to obtain and maintain regulatory approval for neffy; results from clinical trials may not be indicative of results that may be observed in the future; the FDA advisory committee's decision should not be relied on as an indication that neffy will ultimately be approved; the FDA is not bound by decision of its advisory committee or any of its recommendations and there are a number of instances where the FDA has voted against the recommendations of advisory committees; potential safety and other complications from neffy; the labelling for neffy, if approved; the scope, progress and expansion of developing and commercializing neffy; the size and growth of the market therefor and the rate and degree of market acceptance thereof vis-à-vis intramuscular injectable products; the ARS Pharma's ability to protect its intellectual property position; the impact of health epidemics or pandemics on ARS Pharma's business and the actions ARS Pharma may take in response thereto; 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 the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the Securities and Exchange Commission ("SEC") on May 15, 2023. This and other documents ARS files with the SEC can also be accessed on ARS's web page at ir.ars-pharma.com by clicking on the link "Financials & Filings." The forward-looking statements included in this presentation are made only as of the date hereof. ARS Pharma does not assume any obligation and does not intend to update these forward-looking statements, except as required by law.

ARS



Potential to Transform the Treatment of Type I Allergic Reactions

- neffy®: first "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
- Mid-2023 PDUFA anticipated; FDA AdCom supports favorable benefit-risk assessment of neffy
- Potential multi-billion-dollar market driven by HCP and consumer preference and adoption
- NCE-like IP exclusivity potential until at least 2038
- \$264.5 million in cash and securities as of 3/31/2023

Proven leadership team with track record developing and commercializing intranasal and consumer-driven medicines



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









Sarina Tanimoto, M.D. Chief Medical Officer, Co-Founder Led FDA approvals for multiple nasal spray products 20+ years of experience









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









Harris Kaplan EVP, Commercial Strategy 40+ years of commercial strategy across more than 125 product launches



Nexium VIAGRA



Dan Relovsky SVP, Marketing 30+ years of marketing, sales and operational experience across specialty and consumer markets



Brian Dorsey Chief Operating Officer 25+ years of R&D experience as including multiple head of R&D roles including Pernix, Apricus and Somaxon



Kathy Scott Chief Financial Officer 30+ years of finance experience with multiple CFO roles including Neurana. Recros and Oncternal



Alex Fitzpatrick Chief Legal Officer 30+ years of legal experience with multiple GC roles including Evofem, Kyriba, Verenium, Blackbaud



Justin Chakma Chief Business Officer 10+ years of M&A. licensing, financing and strategy experience including Celgene, Receptos and Auspex



Robert Bell, Ph.D. Chief Scientific Officer. Co-Founder 30+ years of senior R&D leadership experience including Barr and Somerset

Top-tier board of directors



Pratik Shah, Ph.D.
Chairman of Board of Directors
Executive Chairman at Design,
Former Chairman of Synthorx
(acq. \$2.5B), Former CEO at
Auspex (acq. \$3.5B)



Richard Lowenthal, M.S.

Chief Executive Officer, Co-Founder

Led FDA approvals for
multiple nasal spray products

25+ years of experience



Peter Kolchinsky, Ph.D.
Managing Partner and Founder
at RA Capital



Rajeev Dadoo, Ph.D. Managing Partner at SR One



Brent Saunders
Chairman at The Beauty Health Co.,
Former CEO of Allergan (acq. \$63B),
Actavis, Forest Labs, and Bausch +
Lomb (acq. \$8.7B)



Michael Kelly
Former President, US Operations at
Adapt (acq. \$735M), CEO at Covis
(acq. \$1.2B), founder at Azur



Jonathan Leff
Partner at Deerfield Management
Chairman of Deerfield Institute



Philip Schneider
Former CFO at IDEC, former Board
member at Arena (acq. \$6.7B), Auspex
(acq. \$3.5B), GenProbe (acq. \$3.7B)



Laura Shawver, Ph.D.
CEO at Capstan, former CEO at
Silverback, Synthorx (acq. \$2.5B)



Peter Thompson, M.D.Private Equity Partner at Orbimed



Saqib Islam, J.D.CEO of Springworks, former CBO at Moderna and EVP at Alexion

Type I allergic reactions: a life-threatening hypersensitivity reaction

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



~25 to 40 million people in US with systemic Type I allergic reaction to allergens (e.g., 2+ organ systems involved)



10+ million people
with other Type I allergy
indications
(e.g. urticaria flares, asthma
exacerbations)



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



More than half a million¹ ER visits each year due to systemic Type I allergic reactions, costing an average of \$1600+ per visit²



Epinephrine is effective, but significant device limitations exist



Epinephrine recognized as the **only first-line therapy** by allergy society treatment guidelines¹, but...

Apprehension to dose due to needle

Lack of portability

Reluctance to use in public

Safety concerns: lacerations, caregiver self-injection, blood vessel hits

Lack of reliability

Not user friendly

Epinephrine Auto-Injector Devices by Amneal and Impax: CDER Alert - FDA Alerts Patients and Health Care Professionals About Device Malfunction

FDA alerts patients and health care professionals of EpiPen auto-injector errors related to device malfunctions and user administration



7 fatalities and 35 hospitalizations reported due to failures



FDA U.S. FOOD & DRUG

Early intervention with epinephrine is critical in a Type I allergic reaction

REACTION PROGRESSION

SERIOUS PATIENT DISCOMFORT

HIGHER RISK OF HOSPITALIZATION AND DISEASE PROGRESSION^{2,3,4}



ANTIGEN EXPOSURE



FIRST 15 MINUTES

TYPE I SEVERE
ALLERGIC REACTION

- Hypotension, dizziness, faintness
- Rhinitis, watery red eyes
- Rashes, itching (urticaria)
- Rapid swelling (angioedema) including lips, tongue, throat
- Bronchospasm, difficulty breathing, wheezing
- Abdominal and chest pain, vomiting



15 TO 30 MINUTES

LIKELIHOOD OF LIFE-THREATENING REACTION

Time to respiratory arrest or shock¹

• **FOOD**: 30–35 minutes

• INSECT STINGS: 10–15 minutes

• DRUGS: <10 minutes



30 MINUTES
ANAPHYLAXIS

- Sudden drop in blood pressure leads to anaphylactic shock and cardiovascular failure
- Airways narrow blocking breathing, leading to loss of consciousness
- Possible death

Up to 18 minutes average wait to dose epinephrine⁵ among the ~50% who have injection available and are willing to inject themselves



Limitations of injection lead to hesitation and decreased or ineffective usage *neffy* may address these limitations to transform the treatment paradigm

PROBLEM

Only 10% 20% of Rx
filled or used
as indicated⁶

neffy®

SOLUTIONS



NO TREATMENT AVAILABLE

~50% of patients carry¹

(<20% carry two)



REFUSAL OF TREATMENT

~25% - 50%^{1, 3, 5} do not administer



DELAY IN TREATMENT

~40 - 60%² of patients delay



FAILURE OF TREATMENT

23 - 35%⁴ fail to dose correctly



SMALL

- Fits in your pocket; can carry more than 1
- ~10% of cases require multiple doses of epinephrine¹



NO NEEDLE NO INJECTION

- Rapid administration without a needle
- No risk of needle-related injuries; lacerations² or cardiotoxic blood vessel injections
- Less hesitation to dose



EASIER AND MORE CONSISTENT DOSING

- 0% critical dosing errors in registration self-administration study
- Low 2 mg dose of epinephrine achieves comparable PK without overexposure risk



RELIABLE

- 99.999% delivery of effective dose in reliability testing; no inhalation required
- Stability data up to 24 months, including at high temperature for up to 3 months







neffy Designed for Needle-free, Easier Carriage













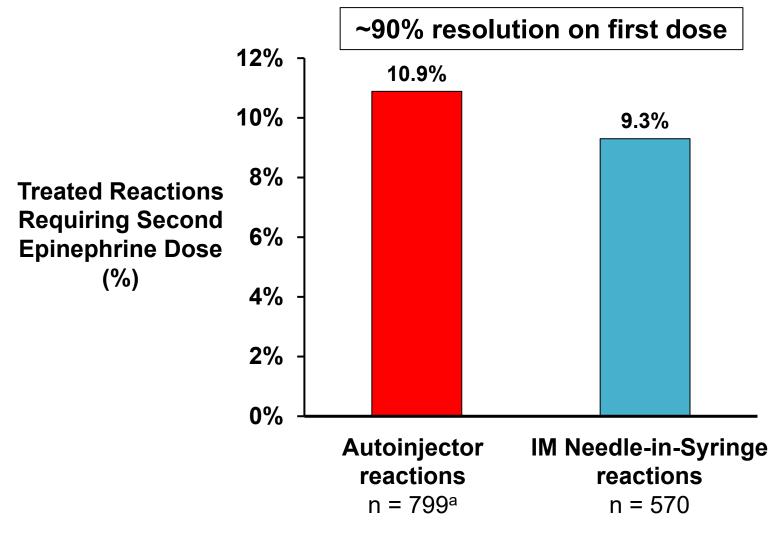
Approved injection products have a range of PK profiles, but are all deemed efficacious (no known difference across products)

Treatment	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 – 40	1 – 240
IM 0.3 mg	Literature and ARS	381	209 – 489	30 to 60	3 – 360
Auvi-Q 0.3 mg	Literature	67	486	20	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

- 0.3 mg IM (needle & syringe) is considered to be the gold standard, and autoinjectors were approved based on literature support from 0.3 mg IM for efficacy and safety^{1, 2}
- Autoinjectors are a variable mix of IV, SC or IM dosing depending on technique
- All approved products have indistinguishable clinical effect and time to observed clinical benefit
- All products approved without any PK or PD data required



Differences in PK (<u>including tmax</u> - time to max concentration) do not translate to any meaningful difference in efficacy among injection products



- Analysis of 12 studies with 100% autoinjector (≥ 80% EpiPen) or 100% IM-needle-and-syringe use in community or emergency room or hospital setting, respectively¹
- Differences in PK profile across products do not impact efficacy based on need for repeat dosing to resolve symptoms
- Cases in emergency room or hospital settings are typically more severe or advanced (where IM is administered) than those in a community setting, but still no difference in efficacy is observed with IM vs. autoinjectors



a. 79.6% of the autoinjector treated reactions are specifically identified occurring with EpiPen

Systolic blood pressure and heart rate are surrogates for efficacy, and most important to clinicians given the high variability of PK

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

PD responses show that *neffy* activates the receptors that reverse anaphylaxis symptoms

neffy clinical program under NDA review; FDA Advisory Committee voted that data supports favorable benefit-risk for allergic reactions (type I)

FDA confirmed three primary registration studies required for neffy approval

EPI-15: Single dose and twice dosing in healthy volunteers (n=42)

EPI-16: Nasal challenge in allergic rhinitis patients (n=36)

EPI-17: Self-administration in Type I allergy patients (n=42)

IM needle & syringe is the gold standard and reference-listed drug

Primary outcomes for all trials: PD (SBP, HR) and PK (bioavailability)

EPI-10 pediatric trial interim data included in NDA submission, FDA requested

neffy meets the endpoints discussed with FDA in completed clinical studies*

Criteria is comparability to epinephrine injection products: PD (SBP, HR \geq approved products) and PK bracketed (exposures \geq IM/SC for efficacy, < EpiPen for safety)

Target PDUFA action date anticipated in mid-2023

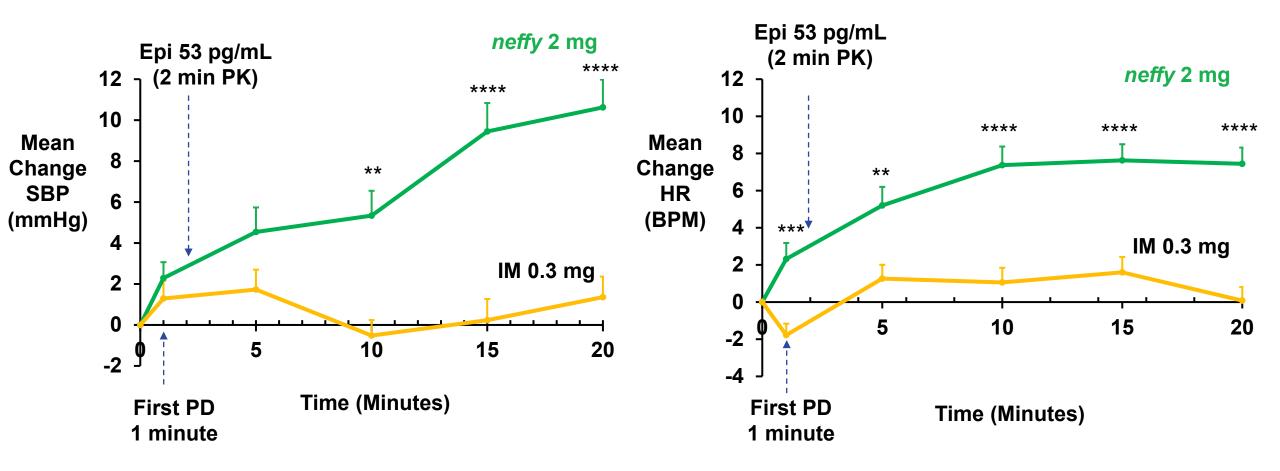
FDA Advisory Committee / PADAC (May 11) voted 16:6 and 17:5 in favor of adults and children <18 years of age and ≥30 kg that available data support a favorable benefit-risk assessment



Notable PD response observed with *neffy* even at 1 minute after dosing, and comparable to or significantly higher than 0.3 mg IM injection

Systolic Blood Pressure Response

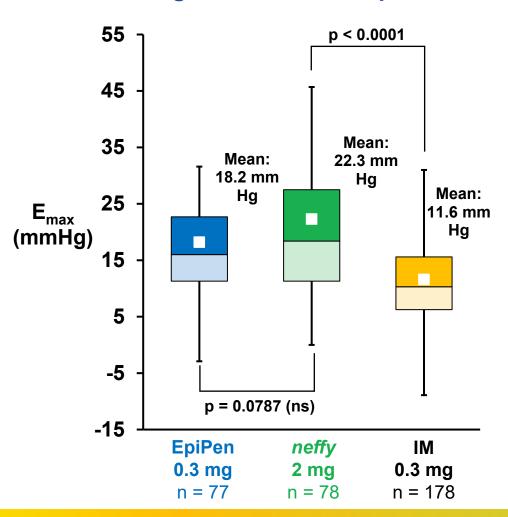
Heart Rate Response



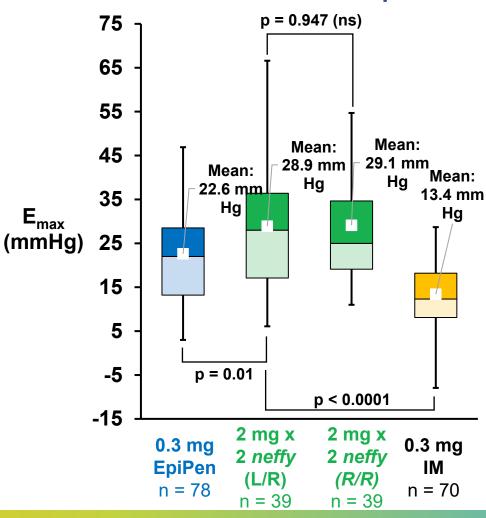
Significance level: ** p <0.01, *** p <0.001 **** p <0.0001

PD response is comparable to EpiPen on single dose, with significantly higher response on second dose

Single Dose SBP Response

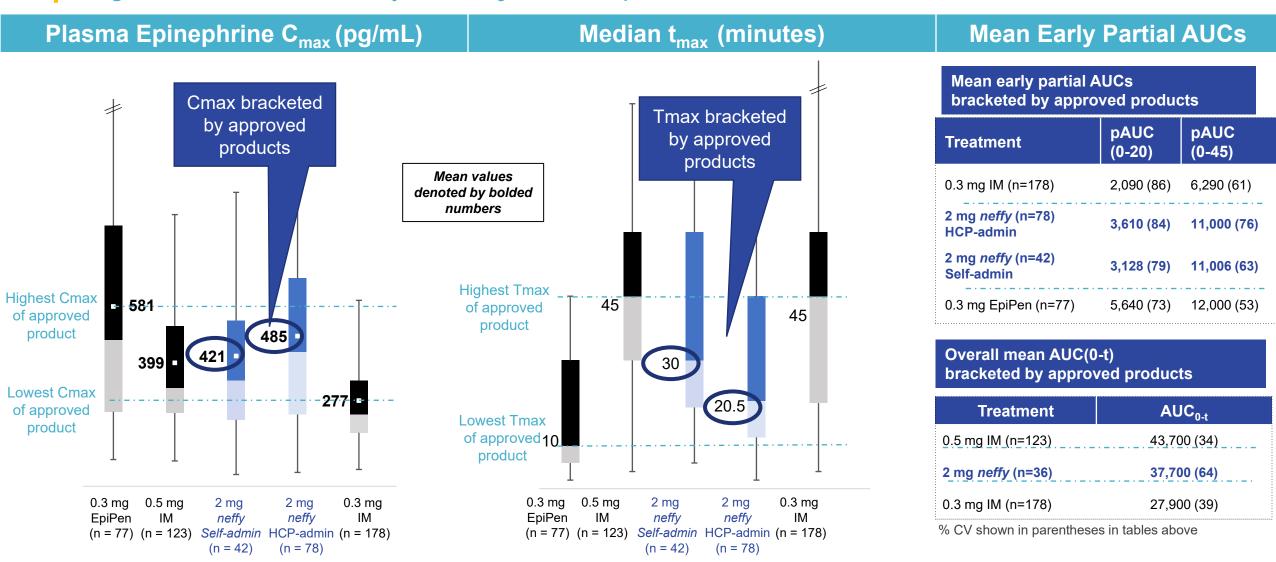


Twice Dose SBP Response



neffy meets PK endpoints agreed with FDA in 3 primary studies*

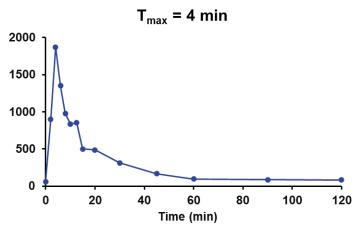
Integrated PK data summary for *neffy* and comparators



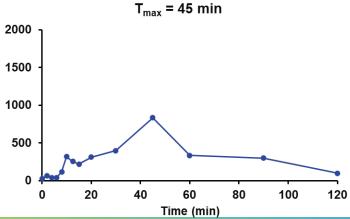
neffy PK is Bracketed by EpiPen Studies (high variability)

Treatment	Study Reference	N	Mean Study C _{max} (pg/mL)	Median Study T _{max} (min)
	AQST-109 EPIPHAST II Results (2022)	22	869	22
	ARS EPI-JP01 Data (2020)	30	676	10
	ARS EPI-15 (2022)	35	612	8
	Tal et al. EAACI (2022)	12	550	9
EpiPen (0.3 mg)	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
noffic (2.0 mg)	ARS EPI-16 data (2022)	36	491	20
	ARS integrated analysis (2022) EPI-15/16	78	485	20.5
neffy (2.0 mg)	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 ⁴
	Dworaczyk et al. AAAAI (2021)	25	288	10

IV Like PK profile with EpiPen



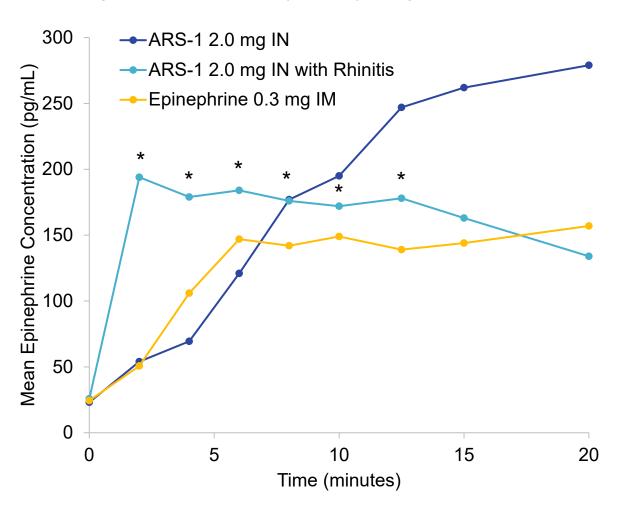
IM Like PK profile with EpiPen





Dosing neffy immediately following nasal allergen challenge (worst-case conditions) shows no clinically meaningful impact on PK or PD

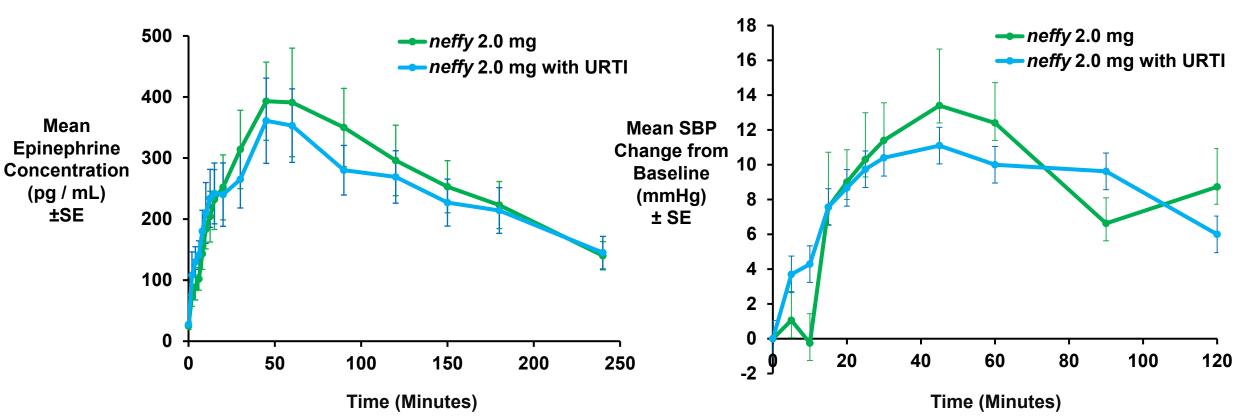
*significant difference (p<0.05) neffy with rhinitis vs. IM



- ~2 to 11% of patients experience nasal symptoms during an allergic reaction¹
- Congestion accelerates absorption, and rhinorrhea accelerates drainage
- neffy during moderate to severe congestion and rhinorrhea following nasal allergen challenge in allergic rhinitis patients has significantly higher exposures than IM during early time points when treatment response is observed
- If no response is observed within 15 minutes, a second dose of epinephrine is given
- Regardless, PD response after one dose of *neffy* (with rhinitis) is comparable to injection (no rhinitis)
 through 60 min despite the systemic inflammation
 reported to be triggered by allergic rhinitis²

Dosing *neffy* during congestion/rhinitis due to an upper respiratory tract infection (e.g. cold or flu) has no clinically meaningful impact on PK or PD



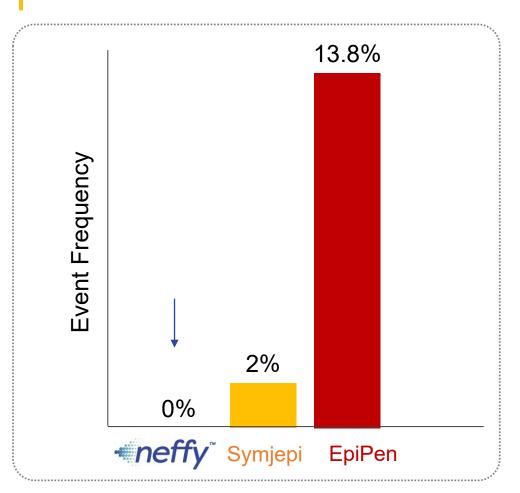


N = 21 URTI / 16 Normal (returned)

neffy well-tolerated across 600+ individuals dosed in clinical program

- Well-tolerated at all single-doses (0.5 mg to 2 mg) and repeat doses up to 4 mg within 10 minutes
- Mostly grade 1 events and comparable to injection products
- Low Pain Scores: recorded by VAS (100mm scale) with mean scores between 5 and 8 out of a score of 100 across studies
- No irritation based on formal scoring in all studies
- No serious treatment-related adverse events
- No risk of needle-related injuries or blood vessel injections

Risk of blood vessel injection during selfadministration that could lead to adverse events



neffy 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)** blocks any intranasal epinephrine product using a different technology using a low dose (<2.5 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



Commercial Opportunity and Strategy

Significant existing US market opportunity for *neffy* penetration

CURRENT ~\$1 BILLION¹ ANNUAL EPINEPHRINE MARKET IS THE IMMEDIATE OPPORTUNITY

~16M

diagnosed and HCPmanaged patients with severe type I allergic reactions (claims data)

~3.3M

Patients have injectable today (~10 million devices)³

~2.5M

Former patients discontinued or did not fill Rx in last 3 years

Up to 40M total type I allergy patients (epidemiology)

MULTIPLE LEVERS OF CURRENT MARKET GROWTH

Consistent market growth

+5% y/y in the last ~15 years

Promotional responsiveness

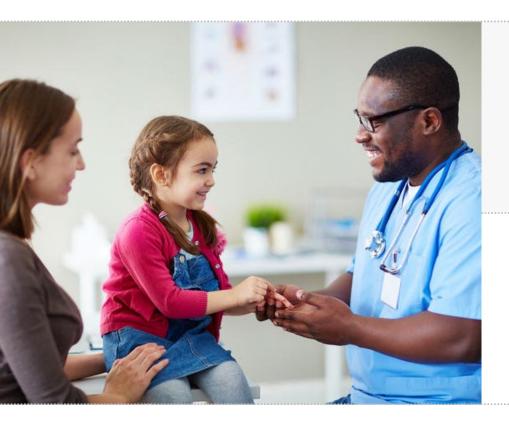
+31% historic lift from Mylan
No meaningful promotion today

More devices per patient

Potential for twice as many *neffy* devices annually vs. injectables



Physicians supportive of adopting *neffy* into practice





8.5 out of 10 rating viewed as a major advance in therapy

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

100%

Would prescribe *neffy* if their patients asked for it

No difference in uptake of **neffy** by physician specialty

neffy addresses the unmet need and is better aligned with what healthcare providers, patients and parents want





~80% OF PATIENTS EXP OF PATIENTS EXPECTED TO

75%

OF NON-FILLING PATIENTS STATED THEY WOULD ASK THEIR PHYSICIAN ABOUT neffy RX



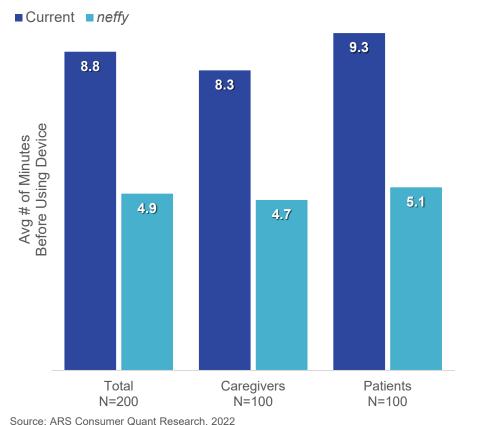
65% to 72% OF THE TIME,

PEOPLE WHO USE AN OTC WOULD USE neffy FIRST

69% **OF PEOPLE** WOULD USE *neffy* SOONER THAN CURRENT **AUTOINJECTOR**

Caregivers are enthusiastic about *neffy* and its benefits





77

This is fantastic.

Much easier than jabbing the thigh.

Father

77

We are talking about someone's life and lifestyle here. **Great improvement.**

- Mother

"

I want this. Is it available yet? Let me know when it is, I will literally call the doctor from my car.

Mother

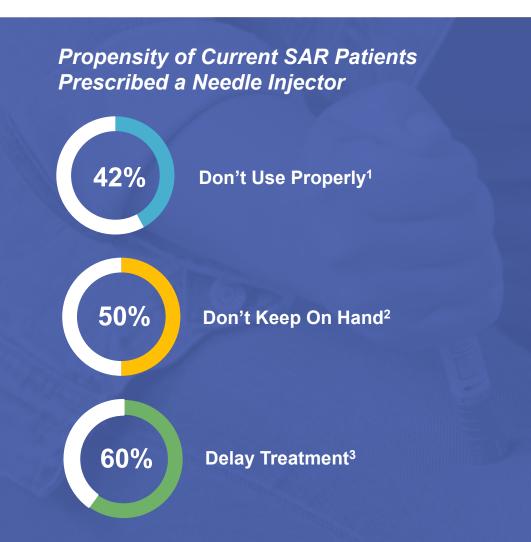
777

I don't have a co-pay, but I'd get this for my daughters even if I have to pay \$50.

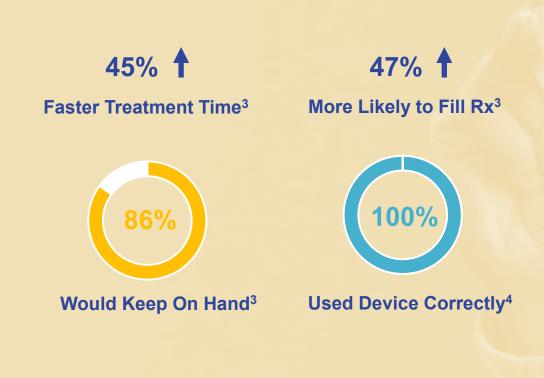
Mother

Guidelines recommend immediate treatment with epinephrine. Earlier administration is associated with improved clinical outcomes and decreased likelihood of hospitalizations.

By Addressing Needle Injector Deficiencies neffy can Become the Standard in Treatment







(1) ARS Consumer Quant Research, 2022, (2) Warren et al. Ann Allergy Asthma Immunol (2018), (3) Data on file from ARS market research, (4) ARS human factors studies



Payer research supports positive reimbursement environment

Key findings from discussions with ~50 decision-makers within the major payers and PBMs:

- Category is generally not restricted, unlike biologics and orphan disease drugs with high WACs
- Payers view neffy as a valuable and differentiated treatment option
- High likelihood of attaining favorable coverage (Tier 2 or 3) for ~80% of lives



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

Payer

"Nasal delivery will overcome some negative perceived factors of an injection."

Payer

"If this is priced properly, this could be a 'state-of-theart therapy' for patients."

- PBM

"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



Commercial strategy and imperatives

From needle to neffy:

- Convert the existing market
- Bring back patients that are lapsed
- Bring in patients who should be carrying epinephrine now, but do not carry

- 1 Ensure broad and rapid *neffy* coverage as well as affordable access for patients
- 2 Change HCP habits and switch prescribing from needle to *neffy*
- 3 Drive *neffy* awareness and new patient growth (into and back into) the market

Strategic Imperatives and CSFs: From Needle to *neffy*

Ensure broad and rapid *neffy* coverage as well as affordable access for patients

Change HCP habits and switch prescribing from needle to *neffy*

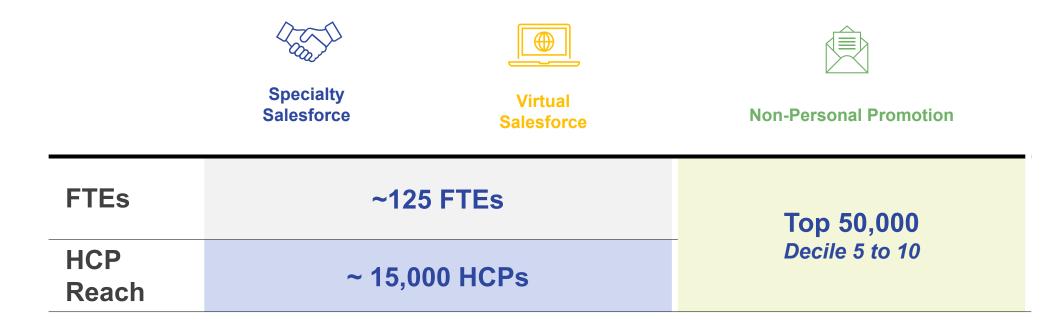
Drive *neffy* awareness and new patient growth (into and back into) the market

- Payers recognize the value proposition of *neffy*
- Patients can access *neffy*
- Prescriptions are filled seamlessly

- HCP awareness at launch
- Confidence in *neffy* and intranasal delivery
- Allergists and KOL endorsement

- Consumer awareness of *neffy*
- Patient understanding of effectiveness and safety
- Patients will ask for *neffy* proactively

Integrated HCP Promotion to Drive Awareness and Reach with Current Epinephrine Prescribers Representing >40% of Prescriptions*



HCP promotion will be supported by <u>DTC promotion</u> to drive expansion within the addressable SAR market

^{*} Reaching >80% of Prescriptions from Allergists, ENTs, and Pediatricians

neffy is positioned potentially to transform the treatment of serious allergic

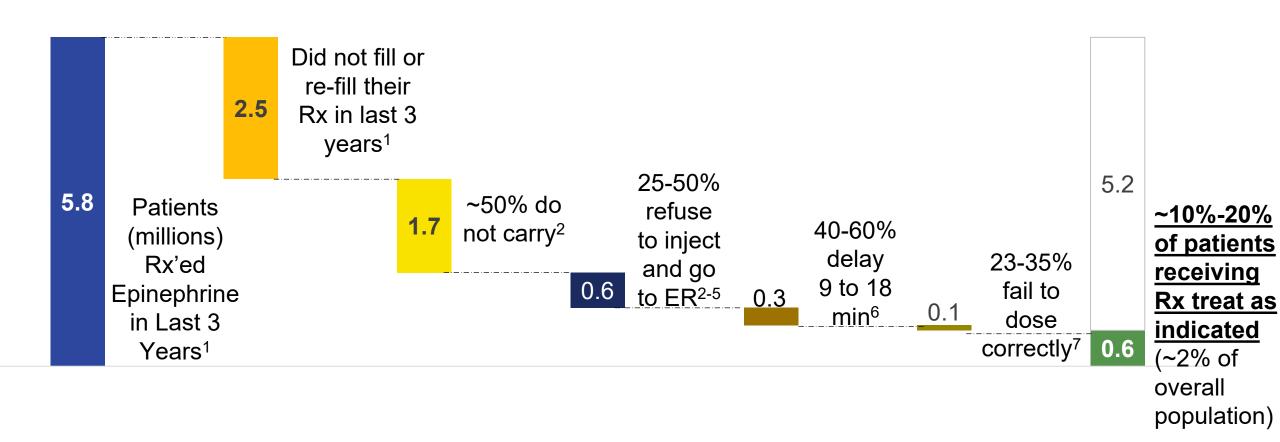






Many patients/caregivers do not administer treatment or delay use during reaction

Approx. 40,000,000 people with serious Type I Allergic Reactions ~5,800,000 people received Rx from a Physician in Last 3 Years



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 <i>neffy</i> 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