## ARS Update neffy<sup>®</sup> Approval

August 12, 2024



### **Forward-looking statements**

4

Statements in this presentation that are not purely historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this presentation include, without limitation, statements regarding: the design and potential benefits of neffy, including the likelihood allergy patients and caregivers will choose to carry and dose neffy compared to needle-bearing options; ARS Pharma's expected competitive position; the potential market, demand and expansion opportunities for neffy; alignment with the FDA on post-marketing studies; plans to file a supplemental regulatory application for a neffy 1 mg dose for children 15 kg to <30 kg in Q3 2024; the timeline for potential regulatory approval and commercialization of neffy in Europe; the timing for potential foreign regulatory filings in, for example, China, Japan, Australia and Canada; the timing of data from the Phase 2b randomized placebo-controlled urticaria trial and initiation of a single pivotal study in urticaria; ARS Pharma's marketing and commercialization strategies, including potential partnerships in foreign jurisdictions; the expected composition and reach of ARS Pharma's commercial force; the potential for the neffy Experience Program; the availability and functionality of neffyconnect; the anticipated pricing and co-pay buydown; the likelihood of neffy attaining favorable coverage; the expected timing for when neffy will be commercially available; ARS Pharma's projected operating runway; 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. 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," "demonstrate," "expect," "indicate," "plan," "potential," "target," "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 ability to maintain regulatory approval for neffy; results from clinical trials and non-clinical studies may not be indicative of results that may be observed in the future; potential safety and other complications from neffy; the labeling for neffy in any future indication or patient population; the scope, progress and expansion of developing and commercializing neffy; the potential for payors 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; 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 June 30, 2024, filed with the Securities and Exchange Commission ("SEC") on August 6, 2024. This and other documents ARS Pharma files with the SEC can also be accessed on ARS Pharma's website at ir.ars-pharma.com by clicking on the link "Financials & Filings" under the "Investors & Media" tab.

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



# *neffy*<sup>®</sup> (epinephrine nasal spray) NOW APPROVED!

**INDICATION** *neffy* is indicated for the emergency treatment of allergic reactions (Type I), including anaphylaxis, in adults and children who weigh ≥30kg



## Type I Allergy Patients Face Significant Limitations with Current Treatment Options that *neffy* may help to address

<b>PROBLEM:</b> ONLY 10% - 20% of patients with active Rx use as indicated <sup>7</sup>	NO TREATMENT READILY AVAILABLE	REFUSAL OF TREATMENT	DELAY IN TREATMENT	USER ERROR IN TREATMENT
	Only 50% carry one <sup>1</sup> (<20% carry two)	~25% - 60% do not administer <sup>, 1,3 5, 6</sup>	~40% - 60% of patients delay <sup>2</sup>	23% - 35% fail to dose correctly <sup>4</sup>
SOLUTION: neffy	SMALL	NO NEEDLE NO INJECTION	EASIER AND MORE CONSISTENT DOSING	RELIABLE
	<ul> <li>Fits in your pocket; easy to carry the recommended 2 devices</li> <li>~10% of cases require repeat doses of epinephrine<sup>1</sup></li> </ul>	<ul> <li>Rapid administration without a needle</li> <li>No risk of needle-related injuries; lacerations<sup>2</sup> or cardiotoxic blood vessel injections</li> <li>Less hesitation to dose</li> </ul>	<ul> <li>Simple place and press administration (no hold time)</li> <li>100% of adults and children are able to dose <i>neffy</i> successfully without any training</li> </ul>	<ul> <li>99.999% delivery of effective dose in reliability testing; not obstructed by any anaphylaxis symptoms; no inhalation required</li> <li>30-month shelf-life at room temperature, with <i>neffy</i> stored at up to 3 months at high temperatures (122°F)</li> </ul>



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## **U.S. prescribing information for neffy**

### **Indication Statement:**

*neffy* is indicated for the emergency treatment of Type I allergic reactions, including anaphylaxis, in adults and children who weigh ≥ 30kg

### **Dosing and Administration:**

- One spray of *neffy* administered in one nostril
- Administer second dose in same nostril starting 5 min after first dose in absence of clinical improvement or if symptoms worsen
- Advise patients when to seek emergency medical assistance for close monitoring of the anaphylactic episode and in the event further treatment is required
- Recommended patients are prescribed and have access to two *neffy* nasal sprays at all times
- Nasal use only

#### **Available Dose Strengths:**

• 2 mg nasal spray device

### **Contraindications:**

• None

### **Boxed Warning:**

• None

### Warnings and Precautions:

- Potential altered absorption with underlying structural or anatomical nasal conditions
- Angina pectoris, ventricular arrhythmias, coexisting conditions

### **Adverse Reactions (incidence** ≥2%):

 Nasal discomfort (9.7%), headache (6%), rhinorrhea (3%), nausea (3%), dizziness (3%), throat irritation (2%), vomiting (2%) with single doses



## **Alignment with FDA on post-marketing studies**



File completed EPI-10 study for pediatric patients 15 to 30 kg in body weight (1 mg dose)



Registry to collect clinical data from allergy challenge clinics (PMC)



Nominal cost and no material impact on operating runway anticipated



### **Rigorous registration program conducted in adults and children**

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- Goal was to develop a low-dose, small, easy to use, and well-tolerated epinephrine nasal spray
- > 1,200 administrations of neffy in > 700 subjects
  - 5 pilot and exploratory studies
  - 5 supportive studies with 1 mg dose (for 15 to 30 kg population)
  - 5 primary registration studies conducted in adults and children
- Demonstrated PK/PD parameters within the range of approved products to reference efficacy and safety
  - Bracketed pharmacokinetic (PK) exposures
  - Comparable pharmacodynamic (PD) response

Five Primary Studies	Patient Population		
EPI 15: HCP administration (single and twice dosing)	Adult: healthy volunteers		
EPI 16: nasal-allergen challenge (single dosing)	Adult: allergic rhinitis patients		
EPI 17: self-administration	Adult: type I allergy patients		
EPI 18: nasal-allergen challenge (repeat dosing)	Adult: allergic rhinitis patients		
EPI 10: pediatric	Pediatric: type I allergy patients: ≥ 30kg body weight (NDA) Pediatric: type I allergy patients: 15 to < 30kg (sNDA planned)		



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

### **III.** PD and PK Data

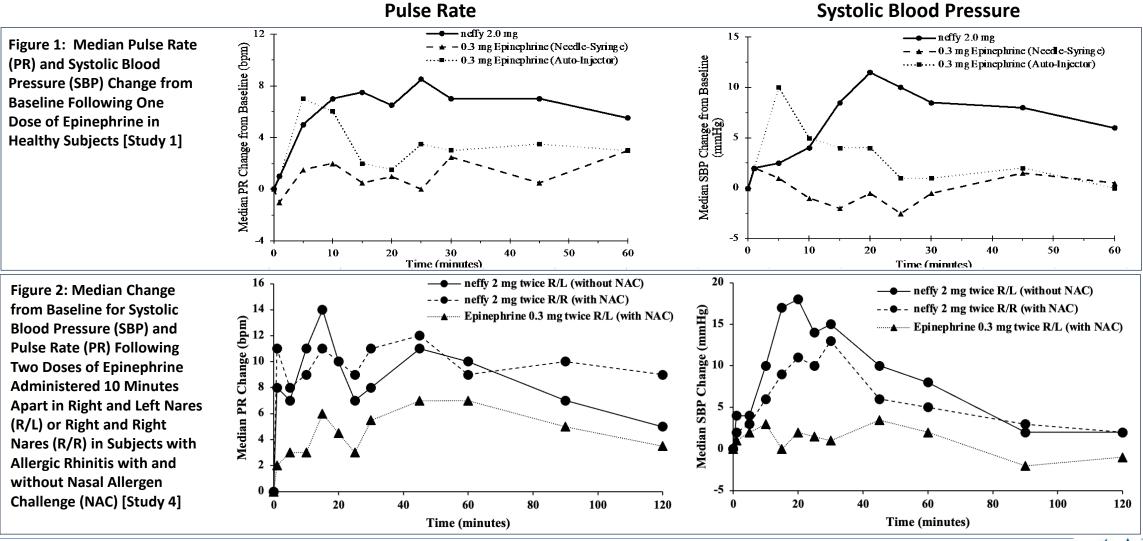
- 2 mg neffy met all clinical endpoints
- PD surrogates for efficacy comparable to approved products (SBP/HR ≥ approved injection products)
- Rapid and significant response on PD surrogates for efficacy observed even 1 minute after dosing
- PK bracketed by approved products (exposures ≥ IM/SC for efficacy,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



- Adverse events generally mild in nature with no meaningful nasal irritation or pain up to 4 mg dose
- Most common adverse events (>5%) with single does of *neffy* 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*



## U.S. prescribing information for *neffy*: robust response on PD surrogate markers for efficacy





## US launch is first step to making *neffy* available to more patients worldwide

sNDA for 1 mg dose (15 to 30kg children) expected to be filed with FDA in Q3 2024



**Positive marketing authorization application (CHMP opinion)** by EMA in June 2024 **Product availability and Europe partnership announcement** expected later in 2024

China NDA filing expected in 2024 (partnered with Pediatrix)
Australia MAA filing expected in 2024 (partnered with CSL Seqirus)



Japan NDA filing expected in 2024 (partnered with Alfresa)

Planning in progress for filing in other major ex-US regions including Canada



### **Expansion opportunities**

- Data from Phase 2b randomized placebo-controlled trial in CSU patients on antihistamine therapy still experiencing acute exacerbations expected in 2025
  - Potential single pivotal study in urticaria to initiate after Phase 2b study



## Commercialization Strategy



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



Epidemiology prevalence data estimates ~40M patients with type 1 allergic reactions<sup>2-9</sup>



~20M diagnosed and under physician care over the last 3 years<sup>10</sup>



#### Consistent Market Growth (Units)

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



#### **Promotional Responsiveness**

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



**6.5M prescribed epinephrine**<sup>10</sup> Primarily managed by allergists & pediatricians

 \*3.2M fill ~5M 2-pack units of injectables annually, but ~80-90% do not use as indicated<sup>11</sup>
 (1) do not carry (~50%), (2) do not inject (25-60%),
 (3) wait (40-60%) or (4) dose incorrectly (23-35%)

Due to limitations of autoinjectors including needle, size and portability

## **<u><u></u></u>**

~13.5M Type I diagnosed but not prescribed Rx (past 3 years)<sup>10</sup>

Primarily managed by non-allergists and non-pediatricians Diagnosing HCP not well-educated about treating anaphylaxis

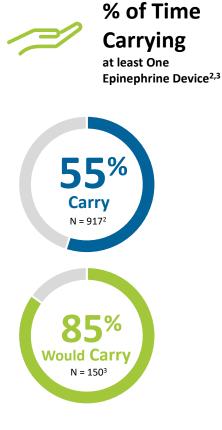


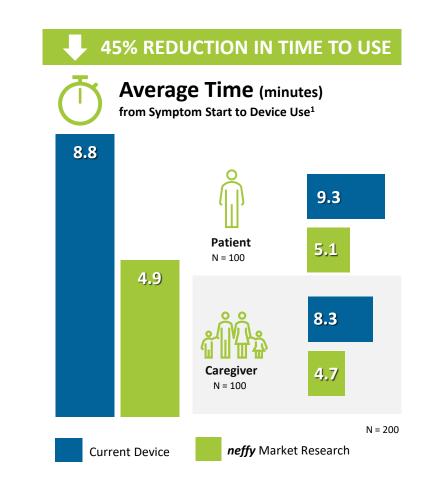
12 **References: 1.** Based on IQVIA prescription data (~5.2 million two-packs sold in 2023). **2.** Gupta RS, et al. *Pediatrics.* 2011. **3.** Gupta RS, et al. Pediatrics 2018. **4.** McGowan EC, et al. *J Clin Allergy Immunol.* 2013. **5.** Jackson KD, et al. *NCHS Data Brief.* 2013. **6.** Black LI, et al. CDC National Center for Health Statistics Data Brief. 2019. **7.** Gupta RS, et al. *JAMA Netw Open.* 2019. **8.** Verrill L, et al. *Allergy Asthma Pro.* 2015. **9.** Bilo BM, et al. *Current Opin Allergy Clin Immunol.* 2018. **10.** IQVIA Claims Data, 2023. **11.** Based on calculations from Warren CM, et al. *Ann Allergy Asthma Immunol.* 2018., Rooney E, et al. Poster Presentation at *ACAAI 2022* (Louisville, KY). Brooks C, et al. *Ann Allergy Asthma Immunol.* 2017., El Turki A, et al. *Emerg Med J.* 2017., Asthma and Allergy Foundation of American Patient Survey Report 2019, and Mehta GD, et al. *Expert Rev Clin Immunol.* 2023.

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



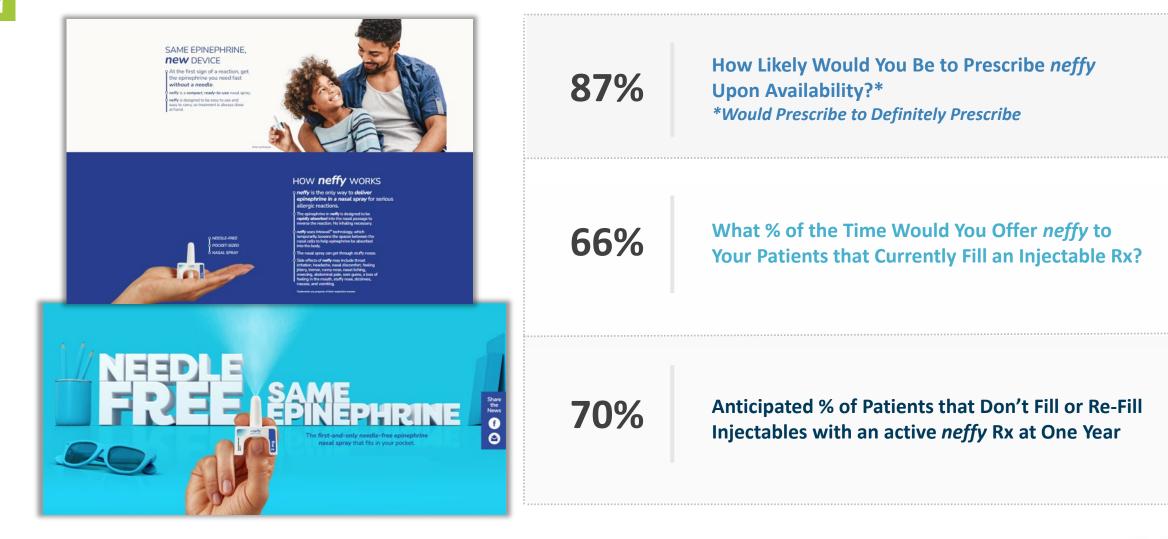
- More allergy patients and caregivers are likely to carry *neffy* compared to current needle-bearing options<sup>3</sup>
- Patients are likely to dose *neffy* more rapidly with a needle-free device<sup>1</sup>







### HCPs Indicate Substantial Opportunity to Convert and Grow Market May 2024 Awareness, Trial and Usage Study, Sample = 202 HCPs





### neffy Strategic Objectives for Commercialization



**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* 





## Drive adoption within specialty and high decile prescribers

### **Healthcare Provider Launch Objectives**

- Commercial force of 110 Sales and Virtual Representatives and Area Sales Managers
- 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
- Education, awareness, and resources to drive adoption (*neffy* Experience)







## *neffy* shows robust and rapid clinical resolution of oral food challenge anaphylaxis symptoms (preview of *neffy* Experience in US)

### Efficacy Study of *neffy* in Oral Food Challenge Induced Anaphylaxis (EPI-JP-03, n = 15 pediatric subjects)<sup>1</sup>

Clinical Response Rate (%)

*neffy* (EPI-JP-03)



**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* 

### *neffy* Experience Program (rescue therapy at allergy challenge clinics)

- Enable real-world experience with *neffy*
- Target allergist offices that conduct inoffice food challenge testing
- <u>HCPs</u> will have the ability to gain firsthand knowledge of *neffy's* effectiveness
- <u>Patients</u> undergoing allergy challenge will also be exposed to *neffy*







## **Committed to ensuring** *neffy* access for all patients



Virtual pharmacy (BLINKRx) available to Healthcare Providers via EMR systems which centralizes all services for *neffy* fulfillment

- Patient education and training resources
- Inclusive insurance support and co-pay buydown (down to \$25)
- Benefit investigation, prior authorization, and appeals support
- Home delivery or retail pick up
- Triage to Patient Assistance Program (PAP)







## *neffy* profile supports strong value-proposition, and offers potential savings to patients and payers

### INNOVATION

ARS is proud to bring an innovative treatment option to the marketplace that provides freedom and peace of mind by enabling patients to dose at first sign of allergic symptoms

#### **SUPPORT**

ARS is committed to the SAR community of patients, caregivers, advocates, and physicians – **co-pay buy-down to \$25 for commercial patients**, and **patient assistant program** 

### **ACCESS & AFFORDABILITY**

ARS believes that affordability should never prevent access: *neffy*connect was developed to deliver on that commitment **Cash price for two doses of** *neffy* is \$199

### **RAPID & BROAD UNRESTRICTED FORMULARY COVERAGE**

anticipated given high degree of interest in *neffy*, positive receptivity in early conversations, strong value proposition vs. competition, and programs to support formulary exceptions

	neffy	Branded IM Injection	Generic IM Injection
Patient Co-Pay – most insured	\$25	\$35 <sup>1</sup>	Avg <b>\$40</b>
Cash Price - uninsured	\$199	<b>\$150-\$289</b> <sup>1</sup>	\$111-\$272
Product expiration (up to)	30 months	~18 months	~18 months
Average Patient Cost Per Month (Co-Pay or Cash Price/Shelf Life)	\$0.83 / \$6.63	\$1.94 / \$12.19	\$2.22 / \$10.63 (average)





## Create awareness & motivate to seek neffy

### **Consumer Launch Objectives**

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





## neffy: The only needle-free way to administer epinephrine



ARS

## **Closing Thoughts**

\*Post-Marketing Requirements/Post-Marketing Commitments



### ARS in 2024 and beyond

### *neffy*<sup>®</sup> in type I allergies

### **Global opportunity and pipeline**

### Solid company fundamentals

- Q3 2024: 2 mg availability with commercial field force deployed in parallel
- Q3 2024: Anticipated sNDA for 1 mg dose to be filed with FDA
- Mid-2025: Targeted at least 80% unrestricted access in US

- Q3 2024: Anticipated approval in Europe
- 2024: Filings by partners in Australia, China and Japan; filings in Canada and others
- 2025: Phase 2b trial results expected for treating acute urticaria exacerbations in CSU patients on antihistamine therapy

- Strong balance sheet of \$218.7M<sup>1</sup>
- Expected operating runway of at least3 years to support US commercialization
- Robust composition of matter and method of treatment IP protection through at least 2038



We appreciate your unwavering support and commitment to *neffy*!

Patients

Parents and Caregivers

Advocates

**ARS Employees** 

# THANK YOU!

Advisors and Directors

**ARS Stakeholders and Investors** 

Healthcare Professional and Study Investigators



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## Appendix



## *neffy* Designed for Ease of Use and Easy Carry and to Minimize Risk of Side Effects

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

- 5 8'



**Proprietary Intravail technology allows** consistent intranasal absorption

> High bioavailability at low 2 mg dose minimizes risk of side effects

No meaningful pain or irritation

Issued composition of matter and method of treatment patent exclusivity until at least 2038





Case holds **two** neffy 2mg devices

neffv

## Differentiated FDA label for *neffy* compared to injection may reduce hesitancy to dose and lead to broader adoption

Label differentiation	Injection <sup>1</sup>	neffy <sup>2</sup>	
<ol> <li>Emergency medical assistance after dosing not automatic, consistent with new AAAAI treatment guidelines</li> </ol>	"In conjunction with the administration of epinephrine, the <u>patient should seek</u> immediate medical or hospital care."	" <u>Advise patients when to seek</u> emergency medical assistance for close monitoring of the anaphylactic episode, and in the event further treatment is required."	
	<ul> <li>Accidental IV injection may result in cerebral hemorrhage</li> </ul>		
2. Removes all injection-related warnings and precautions, which may	<ul> <li>Accidental injection into digits, hands or feet may result in loss of blood flow to the affected area, and immediate visit to emergency room</li> </ul>	No injection-related warnings or precautions	
reduce anxiety and hesitation to dose	<ul> <li>Needle-related injury due to lacerations, bent needle and embedded needles</li> </ul>		
	<ul> <li>Serious injection site infections including necrotizing fasciitis and myonecrosis</li> </ul>		
3. Wider temperature stability, which may facilitate carriage and continuous readiness	Excursions permitted from 59°F to 86°F	Excursions permitted from 5°F to 122°F	



## *neffy* can address the unmet need and is aligned with what patients and parents want<sup>1</sup>





88% OF PATIE VERY LII PHYSICI

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

89%

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



72% OF THE TIME, PEOPLE WHO USE AN OTC WOULD USE *neffy* FIRST<sup>2</sup> 81% OF PEOPLE

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

