



## PrabotulinumtoxinA

*Potential biosimilar for therapeutic indications*



Corporate Presentation

October 2024

# Forward-Looking Statements

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# Biosimilar Pathway - Faster to Market With Broader Indication Potential

Biosimilar Pathway

→ Pursuing the 351(k) regulatory pathway with **PrabotulinumtoxinA** as biosimilar to Botox  
Potential to receive approval for all Botox therapeutic indications (12 currently)

Limited Competition/Large Market

→ Only one other known biosimilar in active development  
Botox revenue ~\$2.5B for US therapeutic indications – growing high single digits

Established Regulatory Pathway

→ Aligned with the FDA on the regulatory pathway during Q3 2024 meeting  
Comparative analytical assessment (CAA) studies anticipated to commence in Q4 2024

FDA Approved Manufacturing

→ PrabotulinumtoxinA approved in 2019 under aesthetic-only BLA (separately held by Evolus)  
Manufacturing site approved by FDA, EMA and Health Canada for aesthetic product

Substantial Existing Evidence

→ Previous analytical characterization provides evidence supporting functional and structural “similarity”  
Successfully completed Phase 2 study (September 2022) in cervical dystonia

Next Steps & Limited IP Risk

→ Plan to conduct BPD\* Type 2 meeting with FDA in 2025 to review the results from the CAA studies and confirm the remainder of the proposed study package

No neurotoxin composition-of-matter patents minimizes litigation risk

# Experienced Management Team

Leadership team with relevant industry experience and track record of success



Marc Forth

Chief Executive Officer



- 25+ years of Biopharma experience
- Former US Business Lead for BOTOX® Therapeutic
- 16 years at Allergan dedicated to the entire BOTOX® franchise
- 7 years at TAP Pharmaceuticals responsible for Lupron Depot (Urology, Oncology and Gynecology)



Chad Oh, MD

Chief Medical Officer



- 30+ years of combined experience in academia and the pharmaceutical industry
- Responsible for multiple IND, NDA, and BLA submissions
- Chief, Division of Allergy and Immunology at Harbor-UCLA Medical Center
- Associate Professor, Department of Pediatrics at UCLA School of Medicine
- Published multiple scientific papers, books, book chapters, and abstracts, including 38 peer-reviewed original scientific papers



Alex Wilson

EVP, Chief Legal Officer & Secretary



- 12+ years of legal experience in corporate governance, mergers & acquisitions and capital markets
- Associate General Counsel of Glaukos Corporation, responsible for business development activities, capital markets, corporate governance and SEC reporting
- Counsel at O'Melveny & Myers












Jennifer Sy

VP, Corporate Controller



- 18+ years of finance and accounting experience in biotech, healthcare, technology and software industries
- Senior management roles, responsible for establishing stream-lined accounting and financial reporting functions for publicly-traded and privately-held companies
- Extensive experience in SPAC mergers, SEC reporting and ERP implementations

# PrabotulinumtoxinA - Same 900 kDa Molecular Weight as Botox

	 onabotulinumtoxinA AbbVie Inc.	 AEON BIOPHARMA	 incobotulinumtoxinA Merz Pharma	 (abobotulinumtoxinA) Ipsen Group	 daxibotulinumtoxinA-lanm injection Revance
Molecular Size	900 kDa	900 kDa	150 kDa	~400 kDa	150 kDa
Approved Therapeutic Indications	<ol style="list-style-type: none"> <li>Chronic migraine</li> <li>Overactive bladder</li> <li>Detrusor overactivity</li> <li>Pediatric detrusor overactivity</li> <li>Adult upper limb spasticity</li> <li>Adult lower limb spasticity</li> <li>Pediatric upper limb spasticity</li> <li>Pediatric lower limb spasticity</li> <li>Cervical dystonia</li> <li>Axillary hyperhidrosis</li> <li>Blepharospasm</li> <li>Strabismus</li> </ol>	None	<ol style="list-style-type: none"> <li>Blepharospasm</li> <li>Cervical dystonia</li> <li>Adult upper limb spasticity</li> <li>Chronic sialorrhea</li> </ol>	<ol style="list-style-type: none"> <li>Cervical dystonia</li> <li>Spasticity</li> </ol>	<ol style="list-style-type: none"> <li>Cervical dystonia</li> </ol>
In Development	<ol style="list-style-type: none"> <li>Episodic Migraine</li> <li>Essential Tremor</li> <li>IC/BPS</li> </ol>	Biosimilar	Undisclosed	<ol style="list-style-type: none"> <li>Neurogenic detrusor overactivity</li> <li>Migraine (episodic &amp; chronic)</li> </ol>	<ol style="list-style-type: none"> <li>Adult upper limb spasticity</li> </ol>
FDA Approved					
US Share	95%		2%	2%	

# Biosimilar Requirements for FDA Approval

FDA evaluates each proposed biosimilar and advises on the extent of testing to establish biosimilarity

## 1. Establish manufacturing

- PrabotulinumtoxinA approved in 2019 as Jeuveau and manufactured by Daewoong<sup>1</sup>

## 2. Analytical characterization

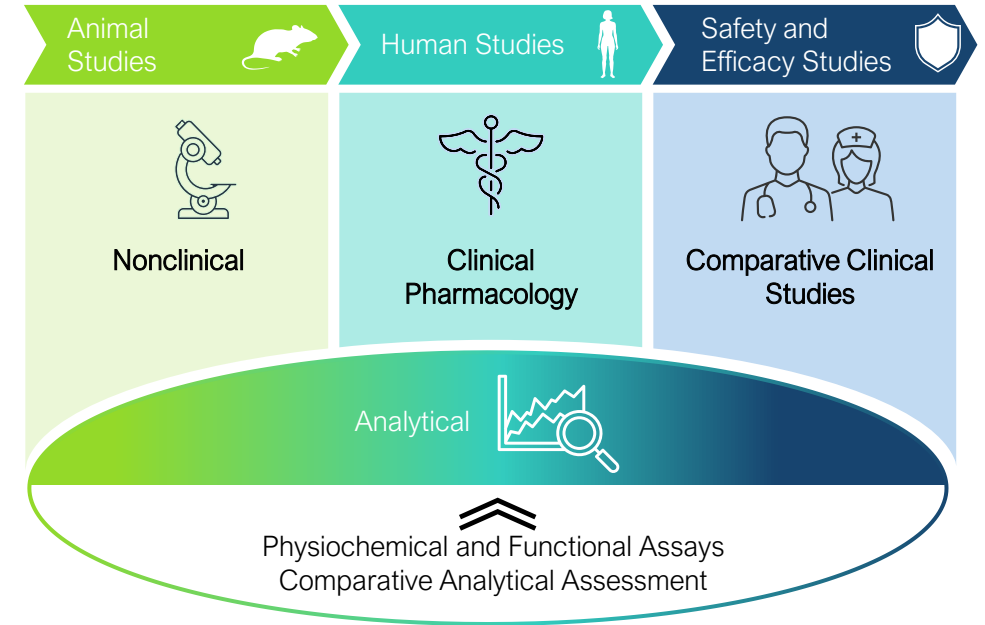
- Physiochemical and functional assays supportive of “similarity”
- Comparative analytical studies to confirm structural and functional similarity

## 3. Animal studies

- Toxicology and pharmacology information

## 4. Clinical studies

- Phase 2 in cervical dystonia
- Potential comparative Phase 3 program with clinical efficacy endpoint



**FDA meeting  
in Q3 2024:**

1. Aligned on conducting comparative analytical studies
2. Plan to meet in 2025 to review results and confirm remainder of the proposed study package

# Seeking Approval of PrabotulinumtoxinA as a Biosimilar to Botox

Potential approval for all 12 therapeutic indications - >\$2.5 B in US sales

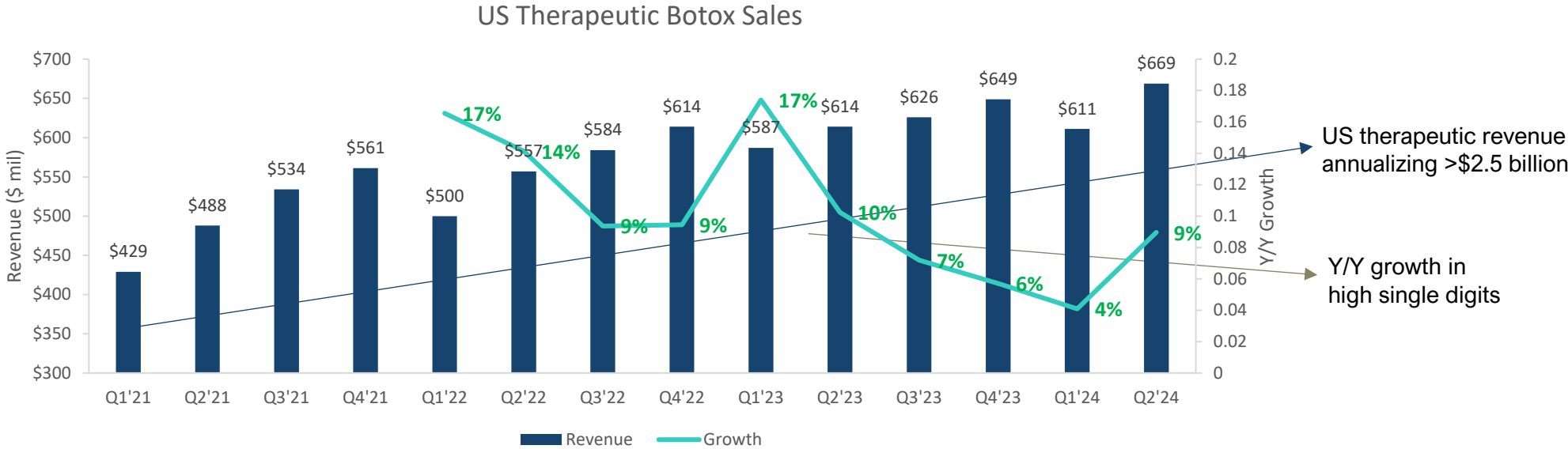
The logo for the U.S. Food and Drug Administration (FDA), consisting of the letters "FDA" in white on a blue square background.

- A biosimilar can meet the requirements for approval based on data from a clinical study that demonstrates safety and effectiveness in an appropriate condition<sup>1</sup>
- FDA may approve a biosimilar for indications without direct clinical studies in those indications if the manufacturer provides adequate scientific justification<sup>1</sup>

- ✓ Chronic migraine
- ✓ Overactive bladder
- ✓ Detrusor overactivity
- ✓ Pediatric detrusor overactivity
- ✓ Adult upper limb spasticity
- ✓ Adult lower limb spasticity
- ✓ Pediatric upper limb spasticity
- ✓ Pediatric lower limb spasticity
- ✓ Cervical dystonia
- ✓ Axillary hyperhidrosis
- ✓ Blepharospasm
- ✓ Strabismus

# Botox US Therapeutic Sales 2021-present – 95% Share of US Market

\$2.5B in US therapeutic sales in 2023 continues to show consistent growth



Anticipated Volume Growth Drivers

- **Current indications:** Organic growth in current indications driven primarily by continued investment in disease awareness and growing patient populations
- **New indications:** Development in therapeutic specialties that do not currently have a toxin treatment option
- **Improved reimbursement:** Favorable dynamics to facilitate coverage at current and projected pricing levels





# Cervical Dystonia

Phase 2 completed

Potential comparative Phase 3 to support BLA submission



# Cervical Dystonia - Gold Standard Indication to Establish Toxin Efficacy

Phase 2 successfully completed in 2022

## The Disorder

- ~50,000 US patients
- Cervical dystonia is a chronic condition with no cure
- Painful and debilitating twisting movements of neck and shoulders
- Botulinum toxin injection is the standard of care
- Established outcome measures and regulatory pathway

## Foundational Indication

- CD has been the foundational disorder used to establish efficacy in the therapeutic setting during clinical development of botulinum toxins
- Regulatory endpoints well-established

## Phase 3-Ready

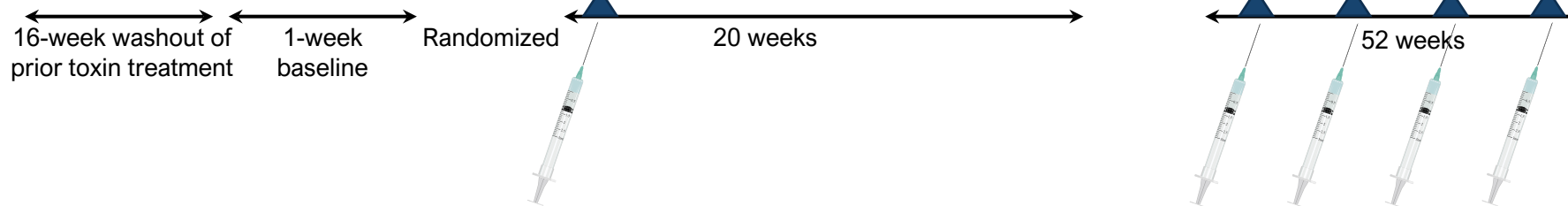
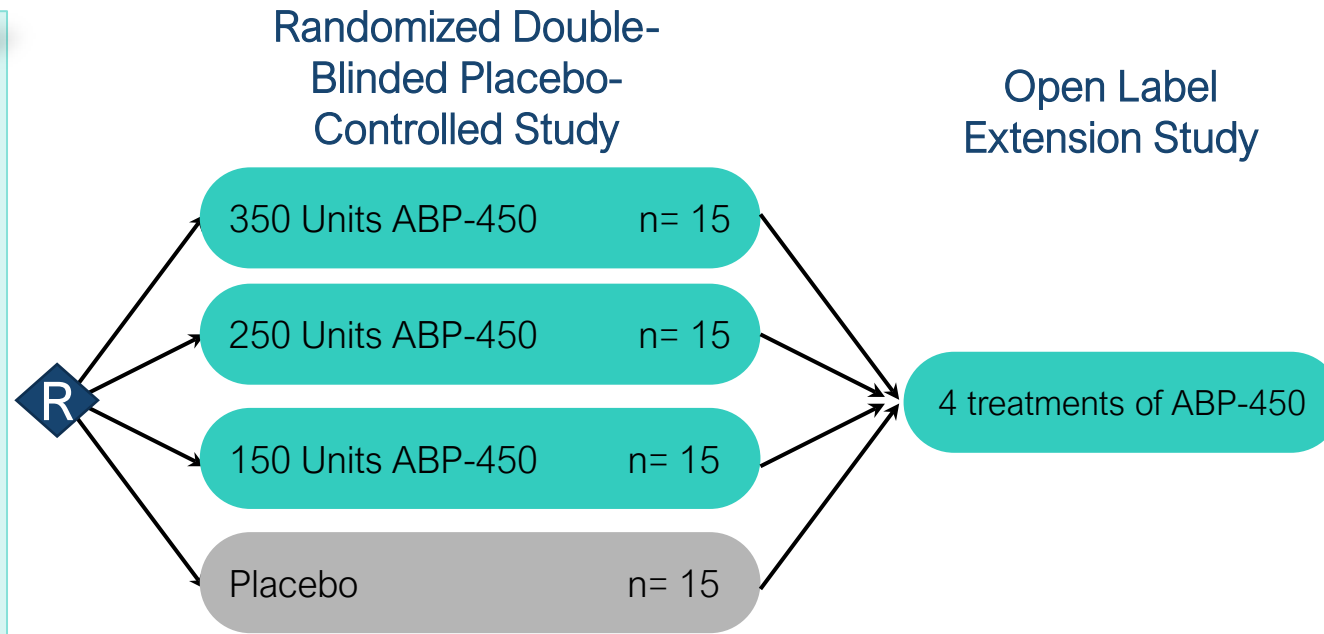
- Phase 2 program was successfully completed in 2022
- Anticipate Phase 3 program would include a head-to-head comparison to Botox® to demonstrate therapeutic equivalence if there are residual uncertainties after completion of analytical assessments

# Cervical Dystonia Phase 2 Dose Ranging Study Design

Data reported September 2022 - 17 months after first patient dosed

## Study Design

- N = 60
- 40 sites in US
- 3 doses; 4 arms
- 1 injection in randomized portion
- 4 injections in OLE
- 20-week primary endpoint
- 72 weeks total



## Endpoints

### Primary:

- Safety of ABP-450

### Secondary:

- Change in TWSTRS
- PGI-C and CGI-C
- PGI-S and CGI-S

### Exploratory:


- C-SSRS
- Dysphagia Score

- First patient dosed April 2021
- Phase 2 top line data reported in September 2022

# Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS)

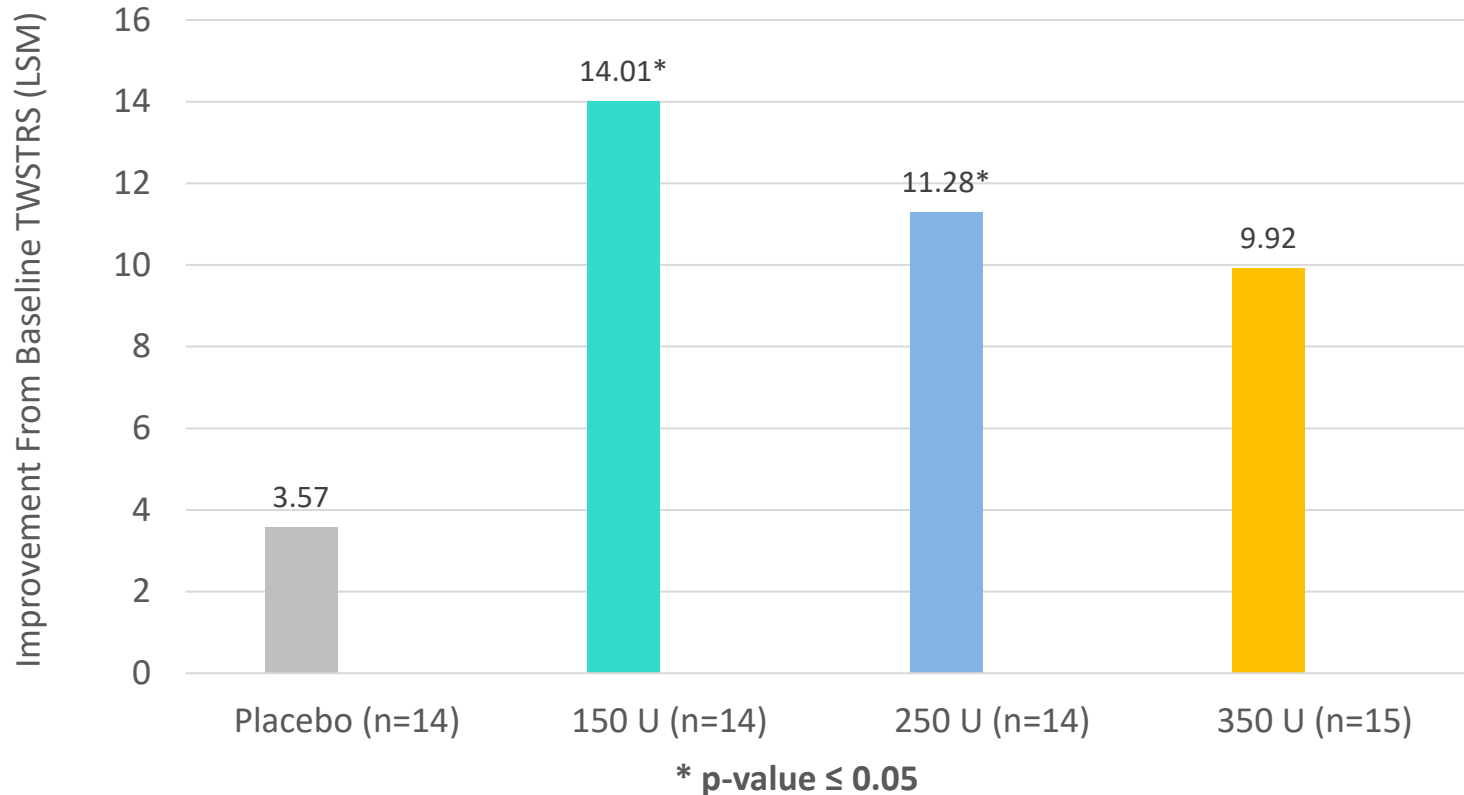
TWSTRS is well-established primary endpoint for toxin approvals

- FDA accepted primary endpoint most often used in neurotoxin studies in cervical dystonia as basis for approval.
- Maximum score of 85 (most severe)
  - Decreasing TWSTRS score indicates improvement
  - 3 subscales: severity, disability, and pain
- Validated outcome parameter
- Change from baseline in TWSTRS score was utilized in Aeon Phase 2 study and will be primary endpoint for Phase 3.

TWSTRS Examination Record <small>[TO BE COMPLETED BY THE EXAMINER]</small>									
Patient _____					Chart No. _____				
Date _____			MONTH   DAY   YEAR		Time _____			AM PM	
									
<b>I. Torticollis Severity Scale (MAXIMUM = 35)</b>									
<b>A. Maximal Excursion</b> <small>Rate maximum amplitude of excursion asking patient not to oppose the abnormal movement; examiner may use distracting or aggravating maneuvers. When degree of deviation is between scores, choose the higher of the two.</small>									
		0	1	2	3	4			<b>SCORE</b>
1. Rotation		0	1	2	3	4			
2. Laterocollis		0	1	2	3				
3. Anterocollis or Retrocollis		0	1	2	3				
a. Anterocollis		0	1	2	3				
b. Retrocollis		0	1	2	3				
4. Lateral shift		0	1						
5. Sagittal shift		0	1						
<b>B. Duration Factor</b> <small>(Weighted x 2)</small>		0	1 <small>(x 2)</small>	2 <small>(x 2)</small>	3 <small>(x 2)</small>	4 <small>(x 2)</small>	5 <small>(x 2)</small>		
<b>C. Effect of Sensory Tricks</b>		0	1	2					
<b>D. Shoulder Elevation/Anterior Displacement</b>		0	1	2	3				
<b>E. Range of Motion</b>		0	1	2	3	4			
<b>F. Time</b>		0	1	2	3	4			
<b>SUBTOTAL SEVERITY</b>									
<b>II. Disability Scale (MAXIMUM = 30)</b>									
<b>A. Work</b>		0	1	2	3	4	5		
<b>B. Activities of Daily Living</b>		0	1	2	3	4	5		
<b>C. Driving</b>		0	1	2	3	4	5		
<b>D. Reading</b>		0	1	2	3	4	5		
<b>E. Television</b>		0	1	2	3	4	5		
<b>F. Activities Outside the Home</b>		0	1	2	3	4	5		
<b>SUBTOTAL DISABILITY</b>									
<b>III. Pain Scale (MAXIMUM = 20)</b>									
<b>A. Severity of Pain</b> <small>(worst + best + (2*usual))/4</small>		Best _____		Worst _____		Usual _____			
<b>B. Duration of Pain</b>		0	1	2	3	4	5		
<b>C. Disability Due to Pain</b>		0	1	2	3	4	5		
<b>SUBTOTAL PAIN</b>									
<b>TOTAL TWSTRS SCORE</b>									
INJECTION RECORD ON REVERSE SIDE									
PHYSICIAN'S SIGNATURE _____									

# Primary Efficacy Endpoint: Change from Baseline TWSTRS at Week 4

200 U dose will be utilized in Phase 3



- 150 U and 250 U demonstrated statistically significant improvement over placebo.

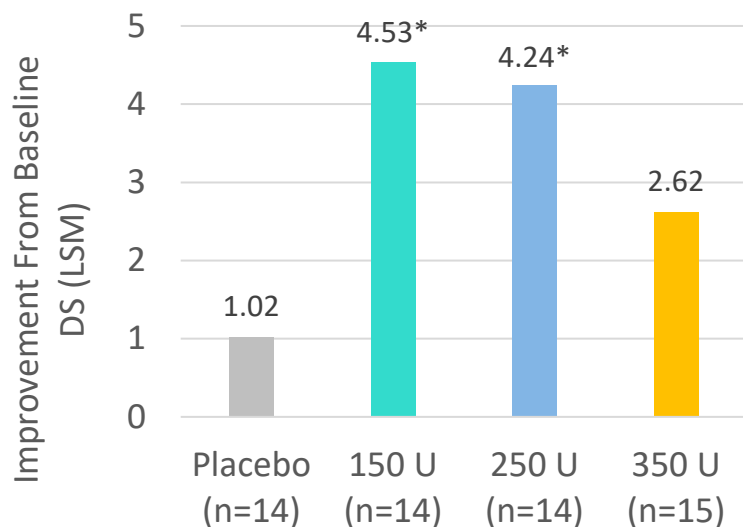
p=0.0070 (150 U vs. Placebo)  
p=0.0406 (250 U vs. Placebo)  
p=0.0864 (350 U vs. Placebo)

- Treatment effect between active doses was not statistically significant.  
p=0.4624 (150 U vs. 250 U)  
p=0.2598 (150 U vs. 350 U)  
p=0.7071 (250 U vs. 350 U)

# Secondary Efficacy Endpoint at Week 4 (TWSTRS – Subscales)

PrabotulinumtoxinA demonstrated consistency across the 3 subscales

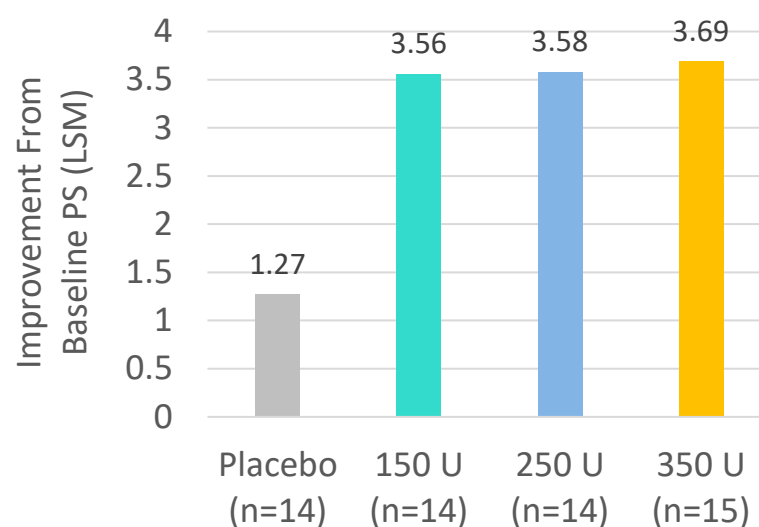
### Disability Subscale



#### Statistics Test Result:

p=0.0258 (150 U vs. Placebo)  
p=0.0420 (250 U vs. Placebo)  
p=0.2942 (350 U vs. Placebo)

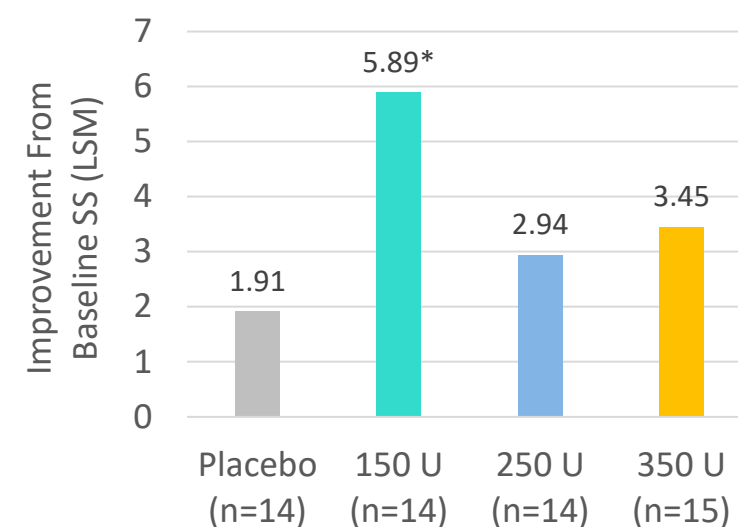
### Pain Subscale



#### Statistics Test Result:

p=0.1351 (150 U vs. Placebo)  
p=0.1332 (250 U vs. Placebo)  
p=0.1081 (350 U vs. Placebo)

### Severity Subscale



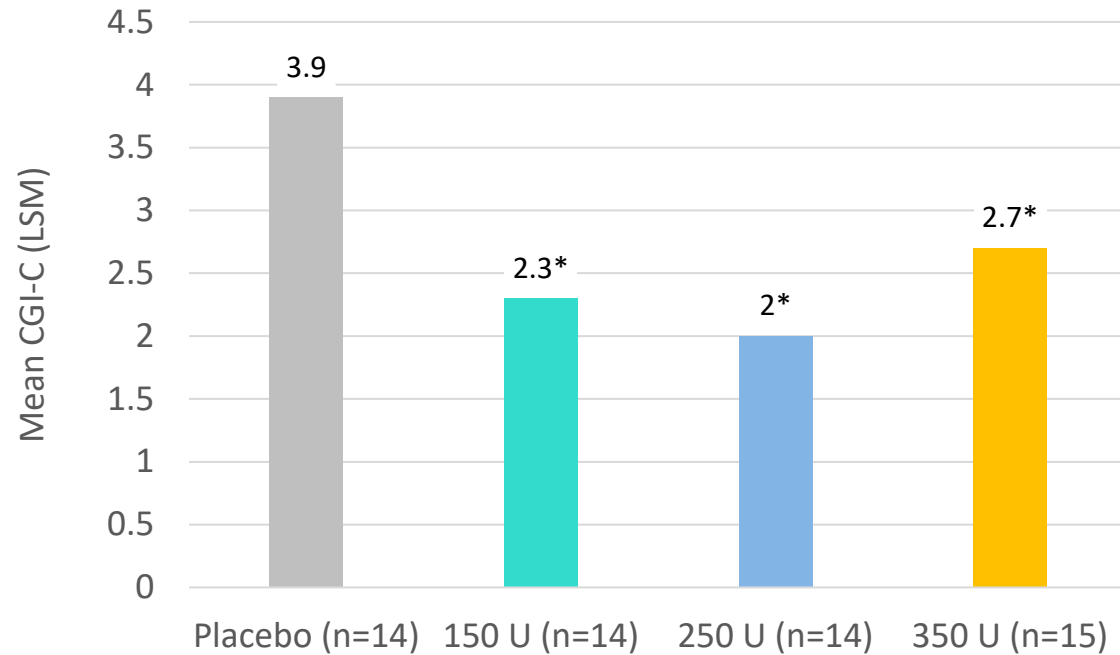
#### Statistics Test Result:

p=0.0027 (150 U vs. Placebo)  
p=0.4290 (250 U vs. Placebo)  
p=0.2173 (350 U vs. Placebo)

# Secondary Efficacy Endpoint at Week 4: Clinical & Patient Global Impression of Change (CGI-C & PGI-C)

PrabotulinumtoxinA demonstrated statistically significant improvement on both PRO instruments

### Clinical Global Impression of Change

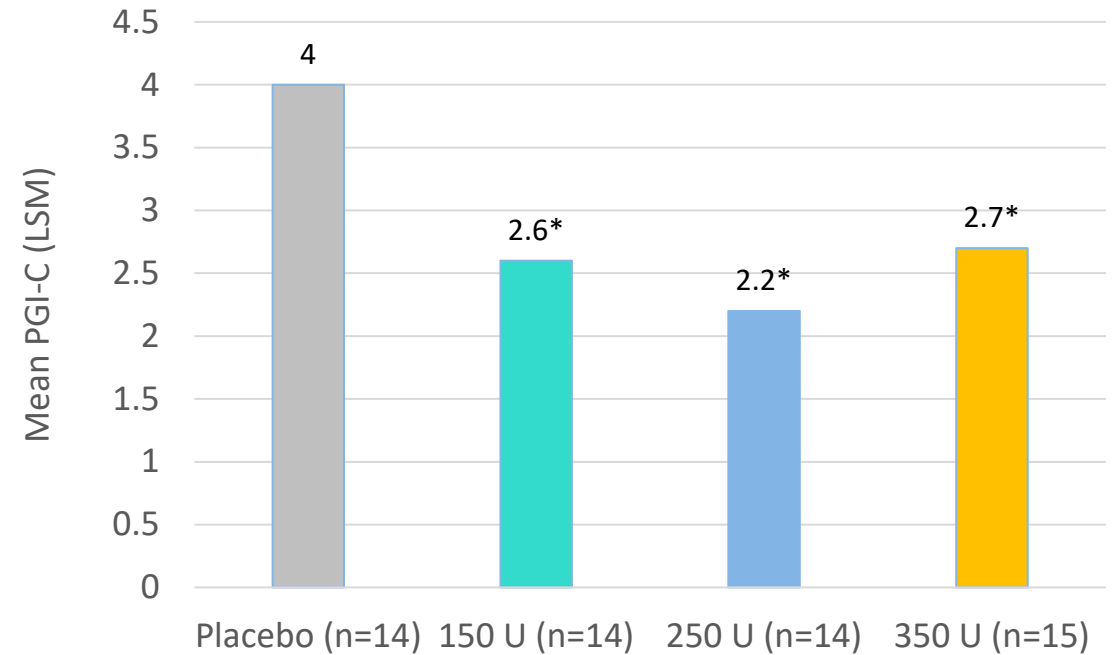


\* p-value <0.05

#### Statistics Test Result:

p=0.0010 (150 U vs. Placebo)  
p=0.0001 (250 U vs. Placebo)  
p=0.0095 (350 U vs. Placebo)

### Patient Global Impression of Change



\* p-value <0.05

#### Statistics Test Result:

p=0.0017 (150 U vs. Placebo)  
P<0.0001 (250 U vs. Placebo)  
p=0.0028 (350 U vs. Placebo)

# Safety Summary

AE Summary	Placebo (N=14) n, %	ABP-450 150 Units (N=14) n, %	ABP-450 250 Units (N=16) n, %	ABP-450 350 Units (N=15) n, %	TOTAL ABP-450 (N=45) n, %
ANY TREATMENT-EMERGENT ADVERSE EVENT (TEAE)	9 (64.3%)	8 (57.1%)	12 (75%)	11 (73.3%)	31 (68.9%)
ANY SERIOUS TEAE	0	0	0	0	0
ANY TREATMENT-RELATED TEAEs* (TRTEAE)	2 (14.3%)	3 (21.4%)	8 (50%)	5 (33.3%)	16 (35.6%)
Dysphagia#	0	0	2 (12.5%)	3 (20%)	5 (11.1%)
Muscular Weakness	0	2 (14.3%)	0	1 (6.7%)	3 (6.7%)
Headache	0	0	1 (6.3%)	1 (6.7%)	2 (4.4%)
Joint swelling	0	0	1 (6.3%)	0	1 (2.2%)
Neck pain	1 (7.1%)	0	1 (6.3%)	0	1 (2.2%)
Torticollis	0	0	1 (6.3%)	0	1 (2.2%)
Nausea	0	0	1 (6.3%)	0	1 (2.2%)
Dizziness	0	0	1 (6.3%)	0	1 (2.2%)
Head discomfort	0	1 (7.1%)	0	0	1 (2.2%)
Presyncope	0	0	0	1 (6.7%)	1 (2.2%)
Feeling abnormal	0	0	1 (6.3%)	0	1 (2.2%)
Injection site pain	1 (7.1%)	1 (7.1%)	0	0	1 (2.2%)
Injection site pruritus	0	0	1 (6.3%)	0	1 (2.2%)
Malaise	0	0	1 (6.3%)	0	1 (2.2%)
Diplopia	0	0	1 (6.3%)	0	1 (2.2%)
Rash macular	0	0	0	1 (6.7%)	1 (2.2%)

\* All TRTEAEs were either mild or moderate in severity and transient in nature.

# All dysphagia cases were mild.



# Phase 2 Data Conclusions

- **Phase 2 trial met primary and other key endpoints, supporting the safety and efficacy of PrabotulinumtoxinA in reducing signs and symptoms associated with CD.**
- **PrabotulinumtoxinA demonstrated adverse event rates similar to other botulinum toxins.**
  - Zero discontinuations due to Treatment-Emergent Adverse Events (TEAEs)
  - Low rate of treatment-related TEAEs (TRAEs)
  - Zero dysphagia cases in the 150 U arm and low rate of dysphagia (11%) and muscle weakness (6.7%) overall
  - All TRAEs were mild to moderate in severity and transient in nature
- **PrabotulinumtoxinA demonstrated efficacy similar to other botulinum toxins.**
  - TWSTRS at Week 4 improved 14.01 points in 150 U; 11.28 points in 250 U; 9.92 points in 350 U; 3.57 points in placebo
    - Statistical significance in lower dose arms (150 U and 250 U) vs. placebo and numerical improvement in high dose arm (350 U) vs. placebo
  - Patient Global Impression of Change (PGI-C) demonstrated statistically significant improvement in all three ABP-450 dose groups over placebo
  - Clinical Global Impression of Change (CGI-C) demonstrated statistically significant improvement in all three ABP-450 dose groups over placebo

# Biosimilar Market Landscape

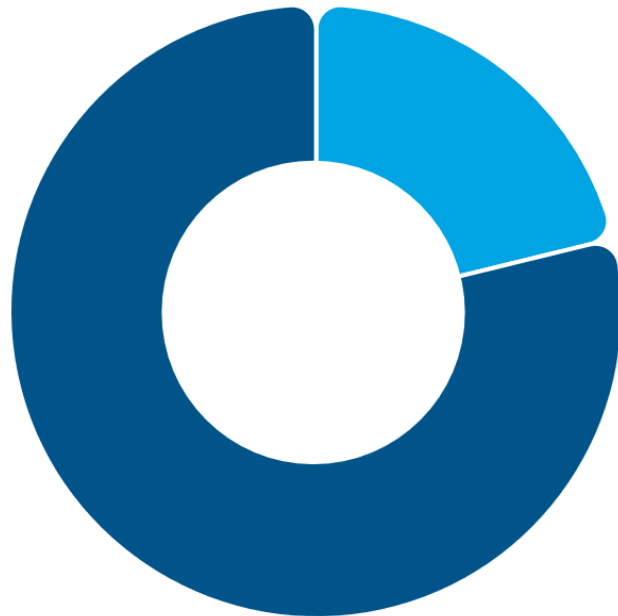
Favorable regulatory environment  
Higher penetration with more recent launches  
Still limited competition and predictable pricing dynamics



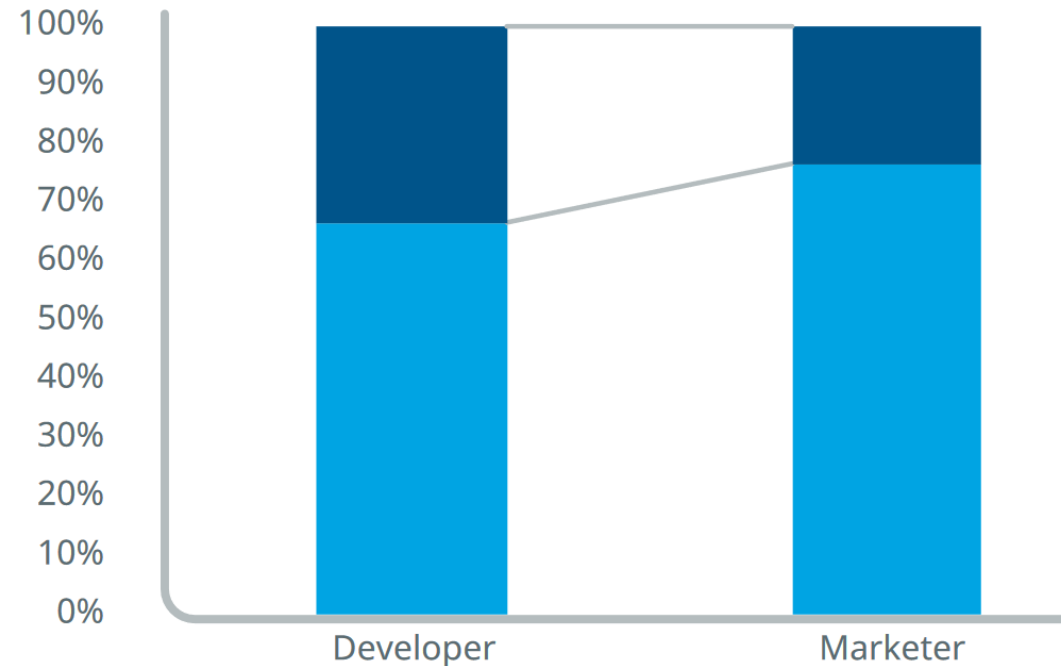
# New Biosimilar Development is Driven by Smaller Companies

~80% of new biosimilars being developed at small companies, but most marketed by larger pharma

Biosimilars in development  
n = 118



Marketed biosimilars by company type and size  
n = 30

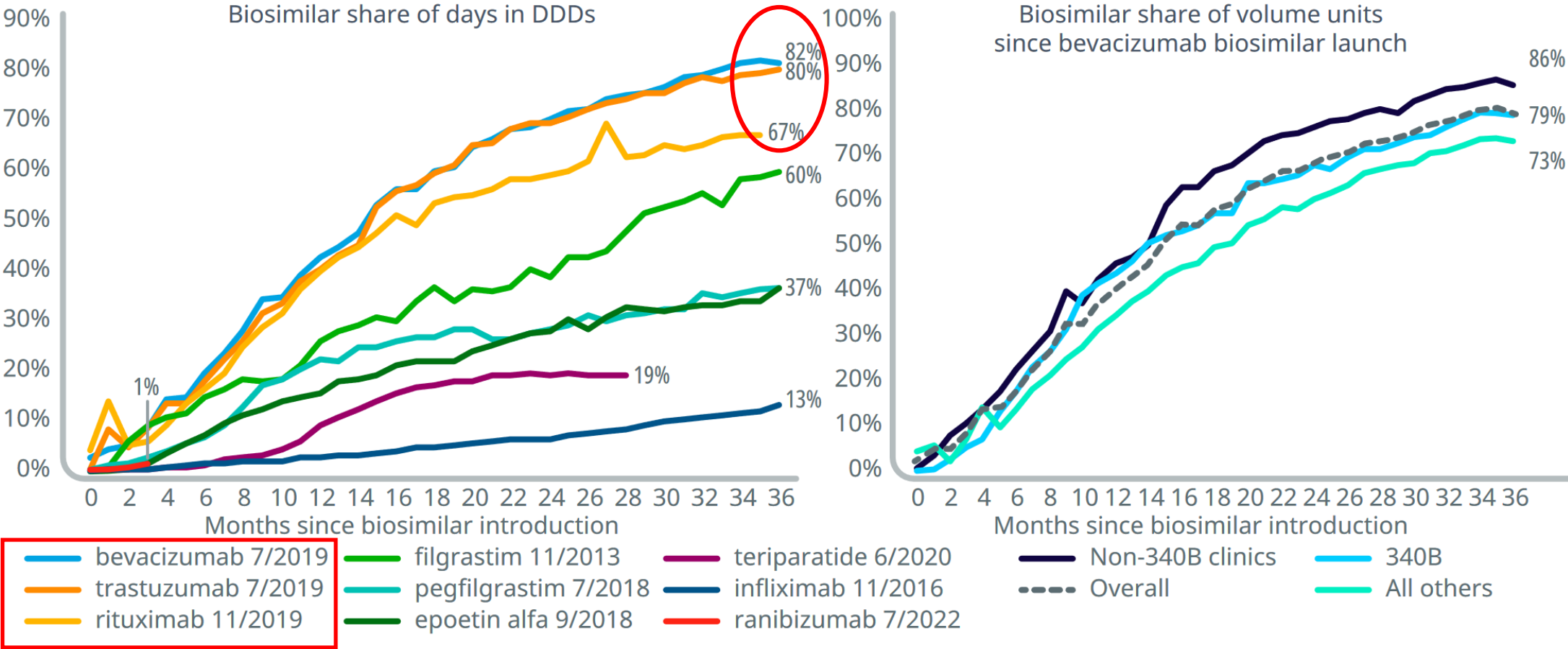


Large pharma

Other

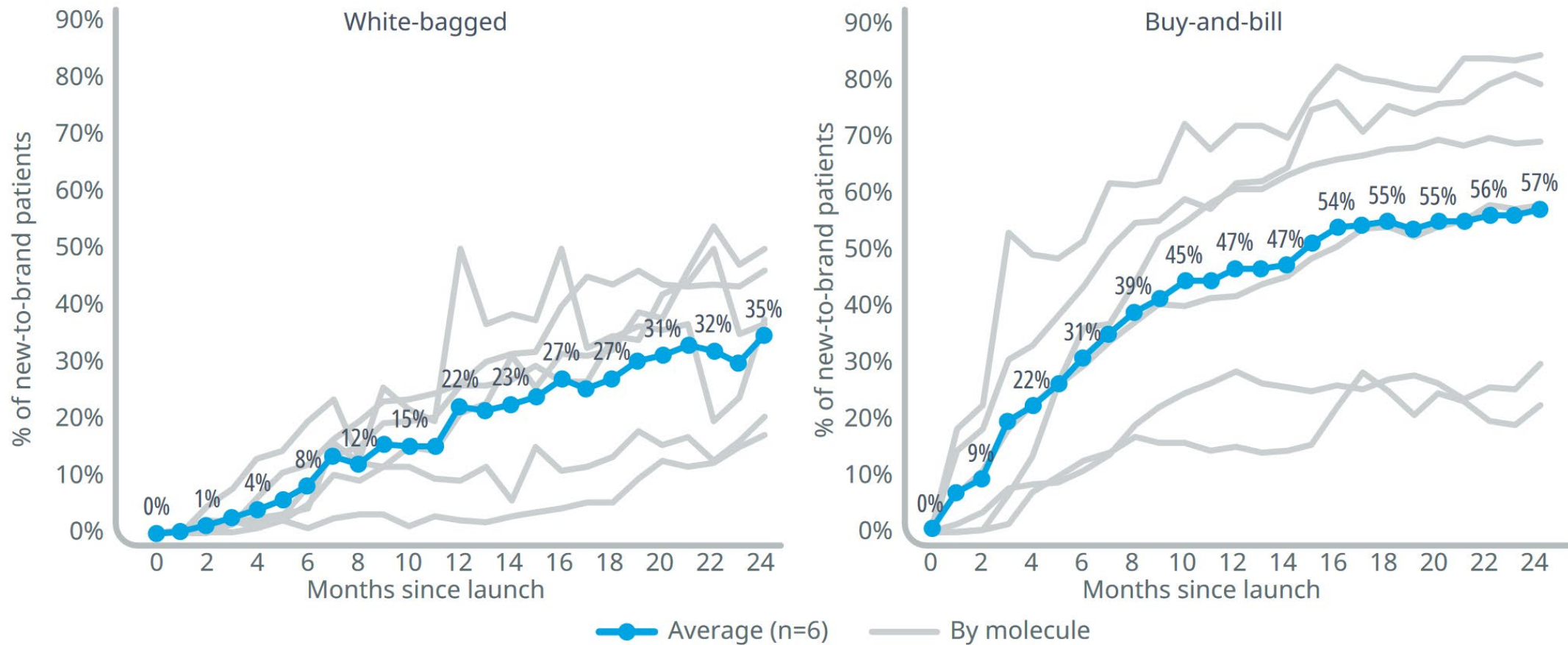
# More Recent Biosimilar Launches are Achieving Higher Shares

3 launches in 2019 achieved ~70% penetration within 3 years



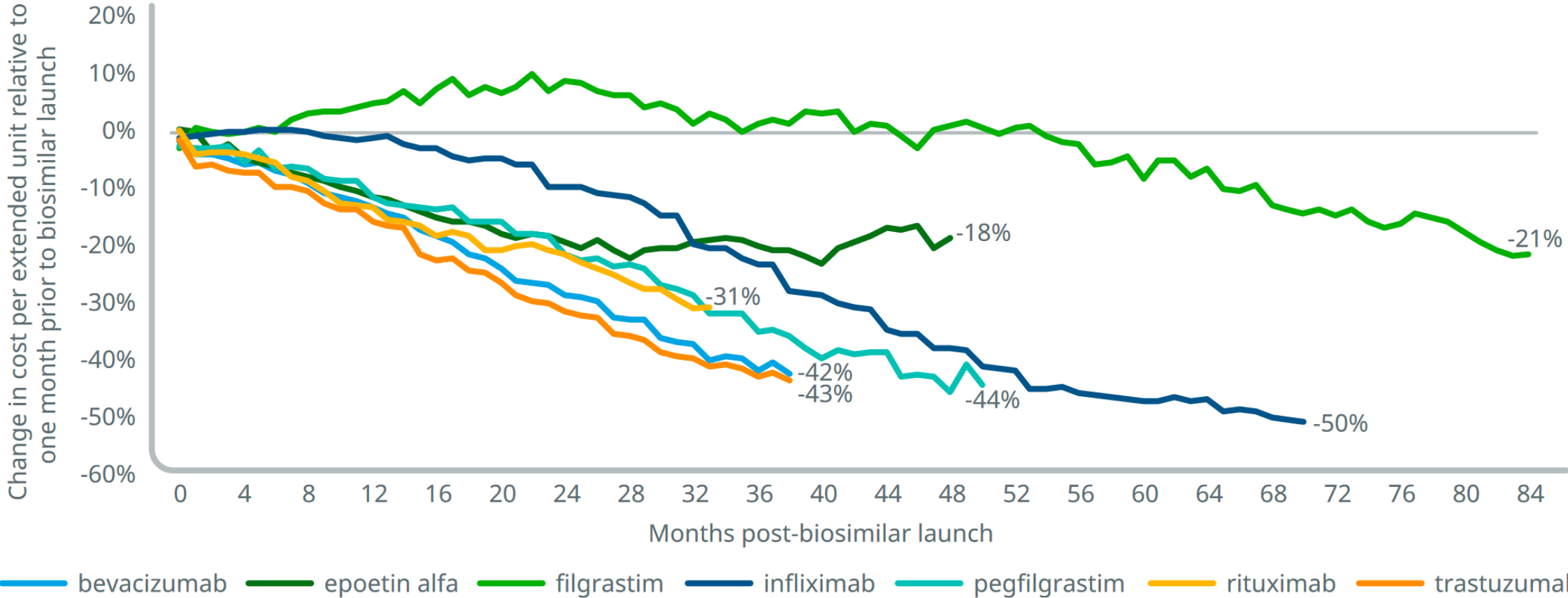
# Stronger Uptake of Biosimilars in Buy-and-Bill Markets

Physicians have incentive to select one product over another



# Biosimilar Pricing Dynamics

Price discounts in the 18-50% range within 3 years of launch



# AEON Model Could Allow Reimbursement Based Solely on Therapeutic Pricing

No competitive botulinum product has a separate BLA exclusively for therapeutic indications

AEON BLA only for therapeutic indications



## Value to Payor

Potential to offer financial incentives

- Potential therapeutic-only BLA could allow AEON's ASP\* to be unencumbered by pricing pressures from aesthetic indications that hamper the competition's reimbursement structure
- Physicians could receive consistent and favorable reimbursement from payors
- Flexibility to provide targeted economic incentives to payors and/or providers that competition cannot

## Value to Physician

Consistent, predictable reimbursement

Removing influence of price competition seen in the aesthetics market

# Summary and Key Milestones

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## Key points

- ✓ PrabotulinumtoxinA is the most advanced 900 kDa toxin (same molecular weight as BOTOX) in development
- ✓ Substantial analytical characterization has been previously completed
- ✓ PrabotulinumtoxinA manufacturing for aesthetic indications is already FDA approved\* and well-established
- ✓ Positive Phase 2 results demonstrate PrabotulinumtoxinA safety and efficacy in cervical dystonia
- ✓ Approval as biosimilar provides potential access to all 12 therapeutic BOTOX indications

## Upcoming events

- Q4 2024 – Initiate comparative analytical studies
- 2025 – Expect to conduct a Biosimilar Biological Product Development (BPD) Type 2 meeting with FDA to review the results from the analytical studies and confirm remainder of proposed study package



Thank You

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