



## PrabotulinumtoxinA

*Potential biosimilar for therapeutic indications*



Corporate Presentation

October 2024

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# Biosimilar Pathway - Faster to Market With Broader Indication Potential

Biosimilar Pathway	→ Pursuing the 351(k) regulatory pathway with <b>PrabotulinumtoxinA</b> 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)

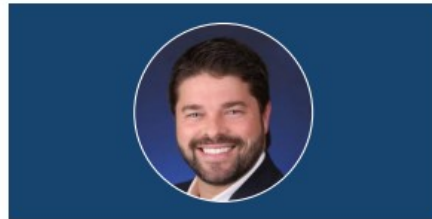


**Chad Oh, MD**

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
<b>Molecular Size</b>	900 kDa	900 kDa	150 kDa	~400 kDa	150 kDa
<b>Approved Therapeutic Indications</b>	<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>
<b>In Development</b>	<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>
<b>FDA Approved</b>					
<b>US Share</b>	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

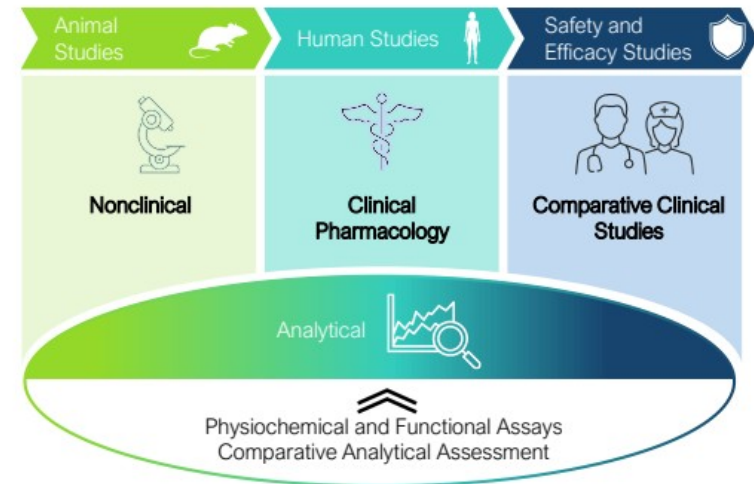
- ✓ Physiochemical and functional assays supportive of “similarity”
- Comparative analytical studies to confirm structural and functional similarity

## 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

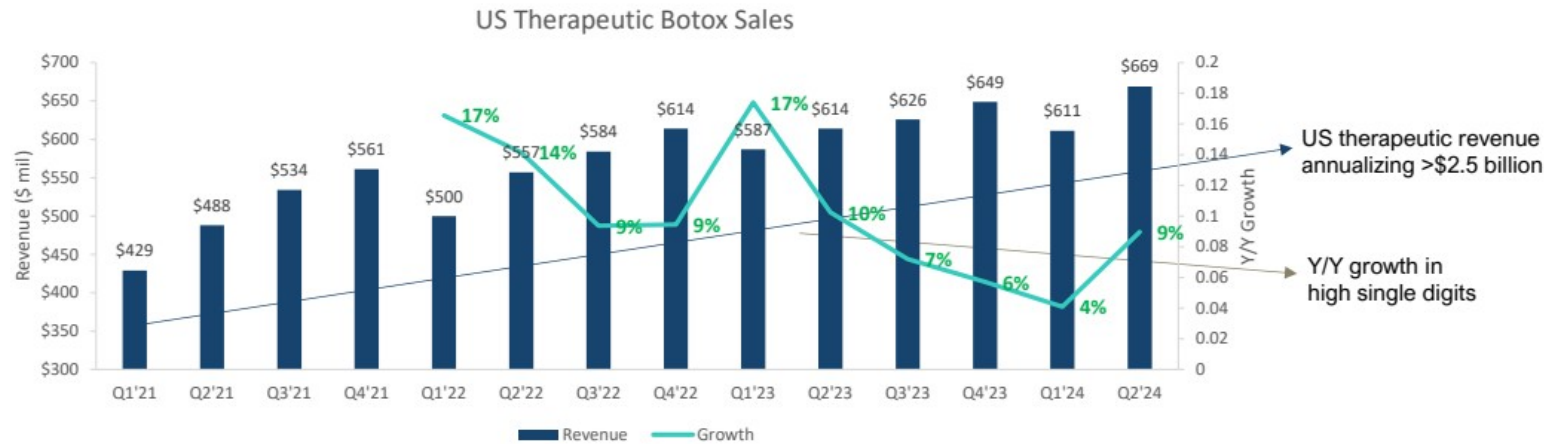


- A biosimilar can meet the requirements for approval based on data from a clinical study that demonstrates safety and effectiveness in an appropriate condition<sup>1</sup>
- FDA may approve a biosimilar for indications without direct clinical studies in those indications if the manufacturer provides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

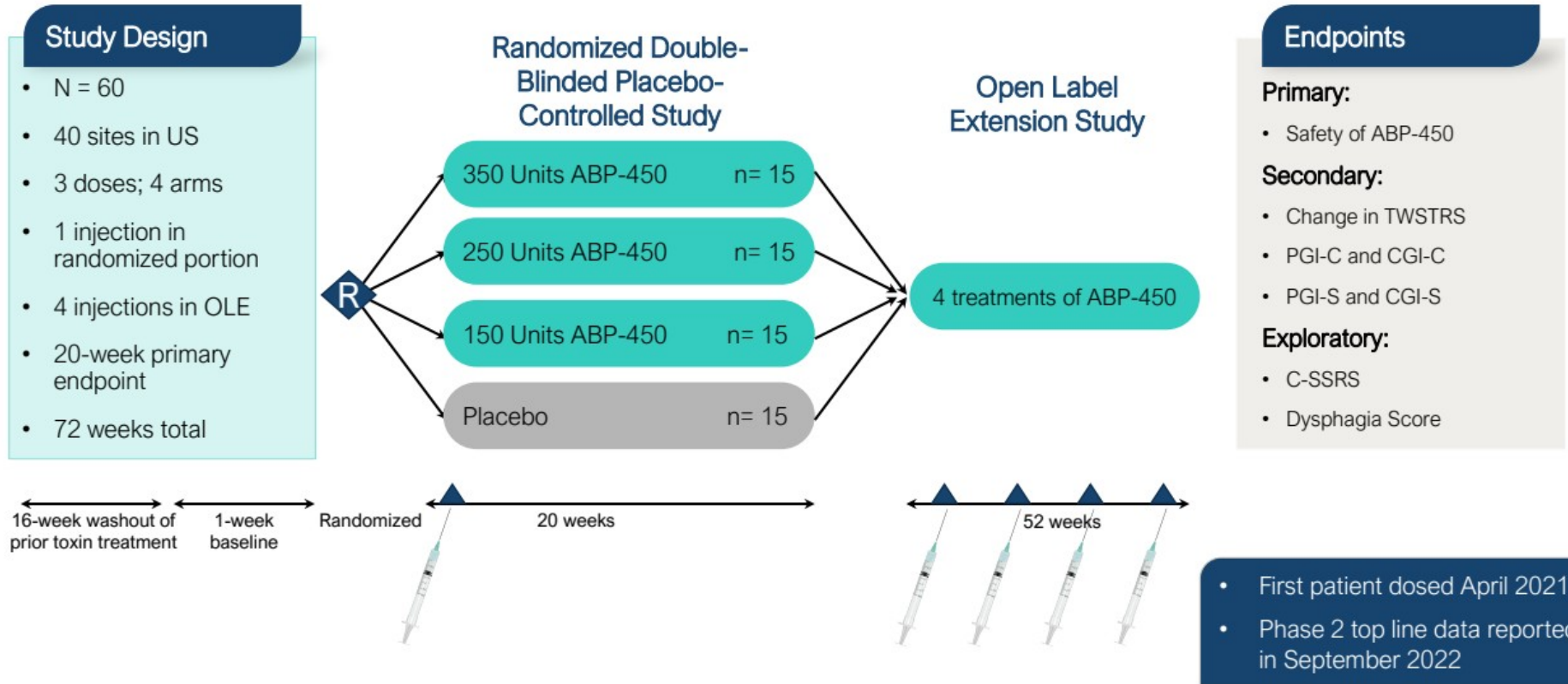
- CD has been the foundational disorder used to establish efficacy in the therapeutic setting during clinical development of botulinum toxins
- Regulatory endpoints well-established

## 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



# Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS)

TWSTRS is well-established primary endpoint for toxin approvals

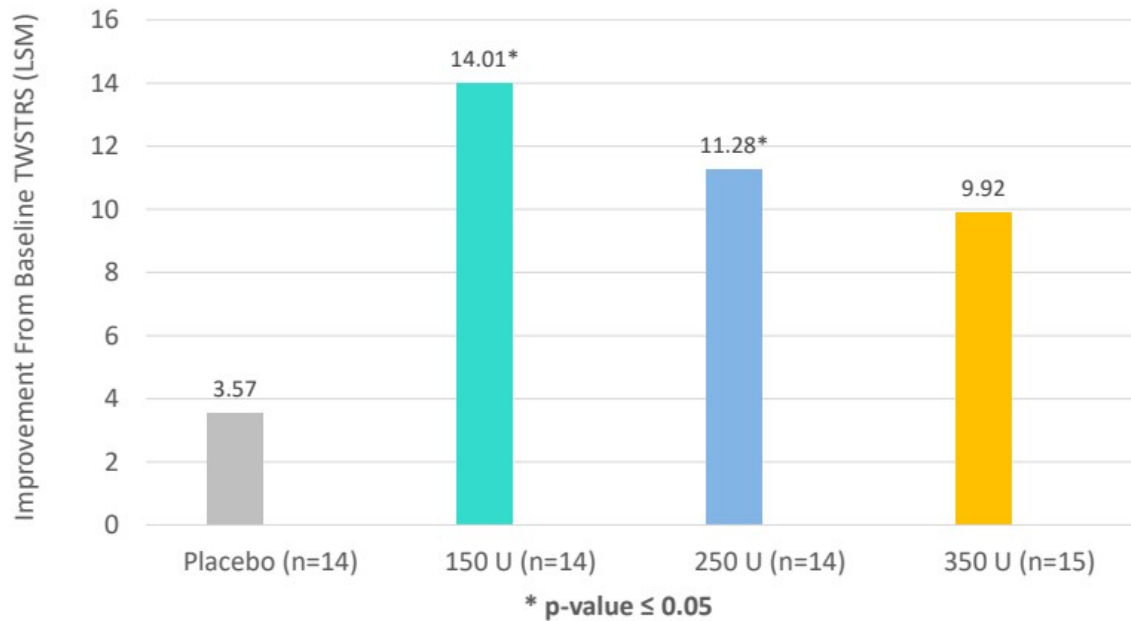
- FDA accepted primary endpoint most often used in neurotoxin studies in cervical dystonia as basis for approval.
- Maximum score of 85 (most severe)
  - Decreasing TWSTRS score indicates improvement
  - 3 subscales: severity, disability, and pain
- Validated outcome parameter
- Change from baseline 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>							 <small>WE MOVE                      WWW.MOVE-EDUCATION-AND-ASSESSMENT.COM                      MOVEMENT DISORDERS</small>
Patient _____	Chart No. _____			Date _____			
	MONTH	DAY	YEAR				
<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, as minor may use distracting or opposing maneuvers. When degree of deviation is between scores, choose the higher of the two.</small>						<b>SCORE</b>
1. Rotation	0	1	2	3	4		
2. Laterocollis	0	1	2	3			
3. Anterocollis or Retrocollis							
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	2	3	4	5	
		(x 2)	(x 2)	(x 2)	(x 2)	(x 2)	
<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>INJECTION RECORD ON REVERSE SIDE</b>							
<b>TOTAL TWSTRS SCORE</b>							
PHYSICIAN'S SIGNATURE _____							



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

200 U dose will be utilized in Phase 3



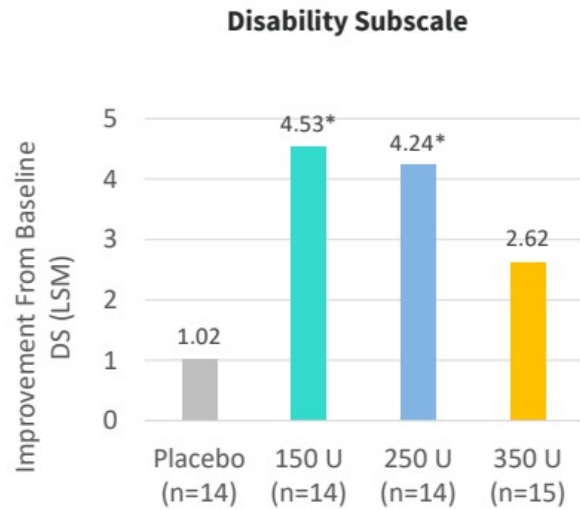
- 150 U and 250 U demonstrated statistically significant improvement over placebo.

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)

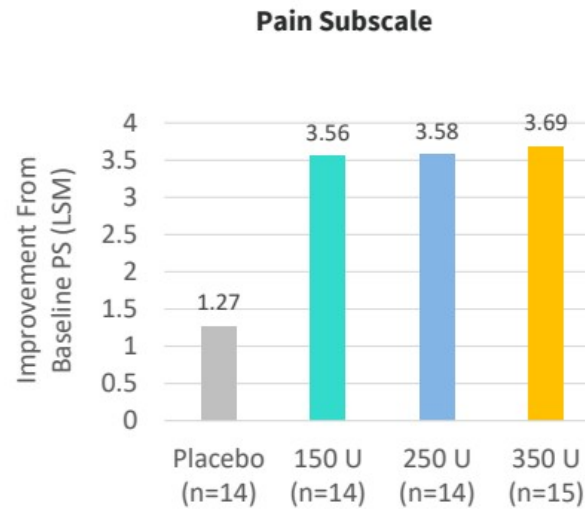
# Secondary Efficacy Endpoint at Week 4 (TWSTRS – Subscales)

PrabotulinumtoxinA demonstrated consistency across the 3 subscales



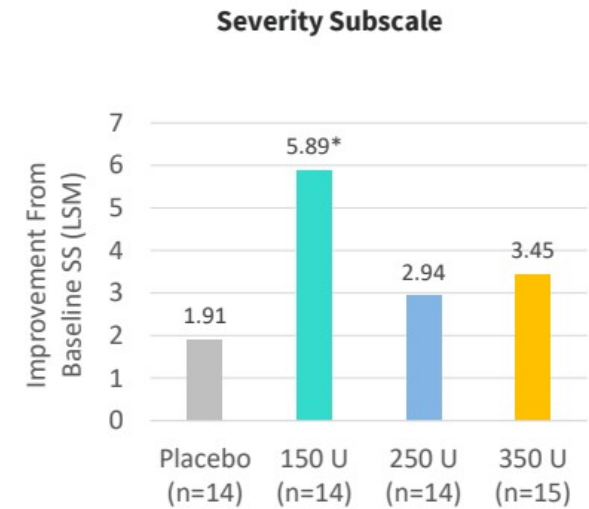
**Statistics Test Result:**

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



**Statistics Test Result:**

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

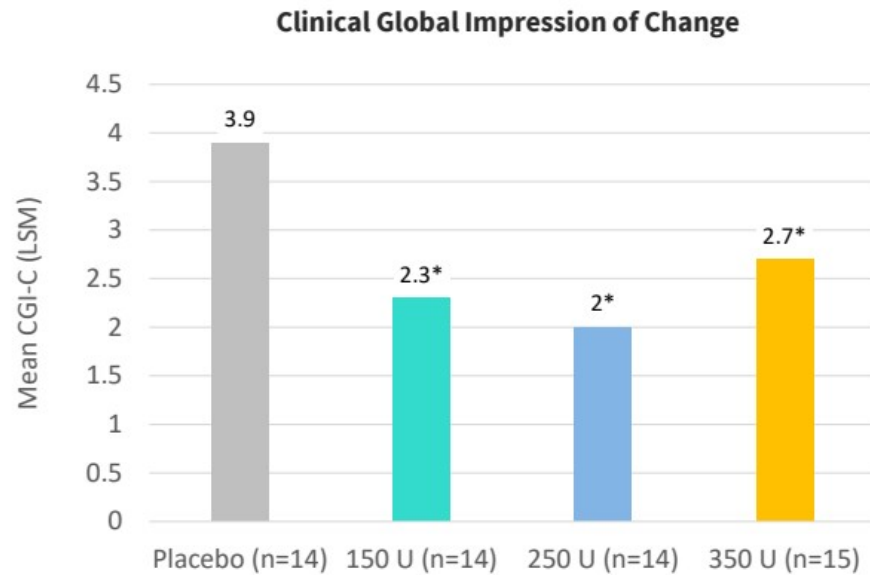


**Statistics Test Result:**

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

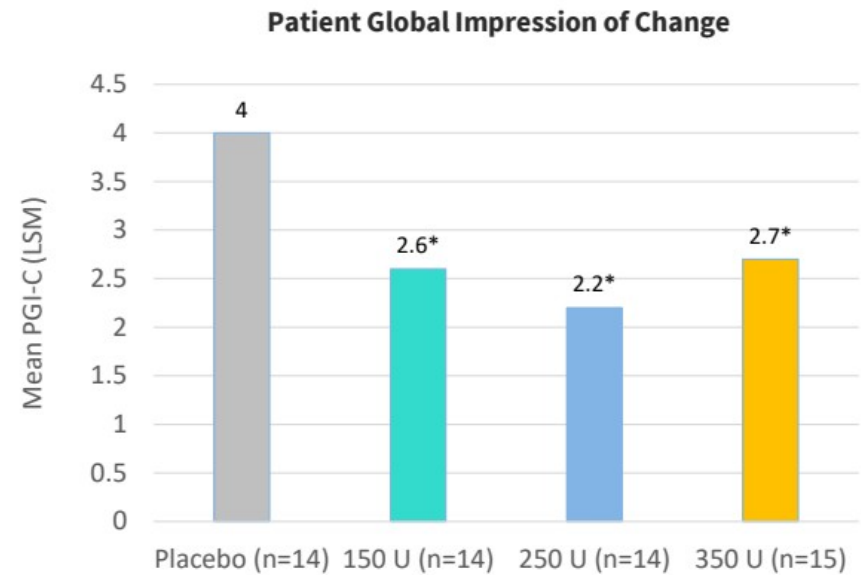
# Secondary Efficacy Endpoint at Week 4: Clinical & Patient Global Impression of Change (CGI-C & PGI-C)

PrabotulinumtoxinA demonstrated statistically significant improvement on both PRO instruments



\* 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)



\* 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

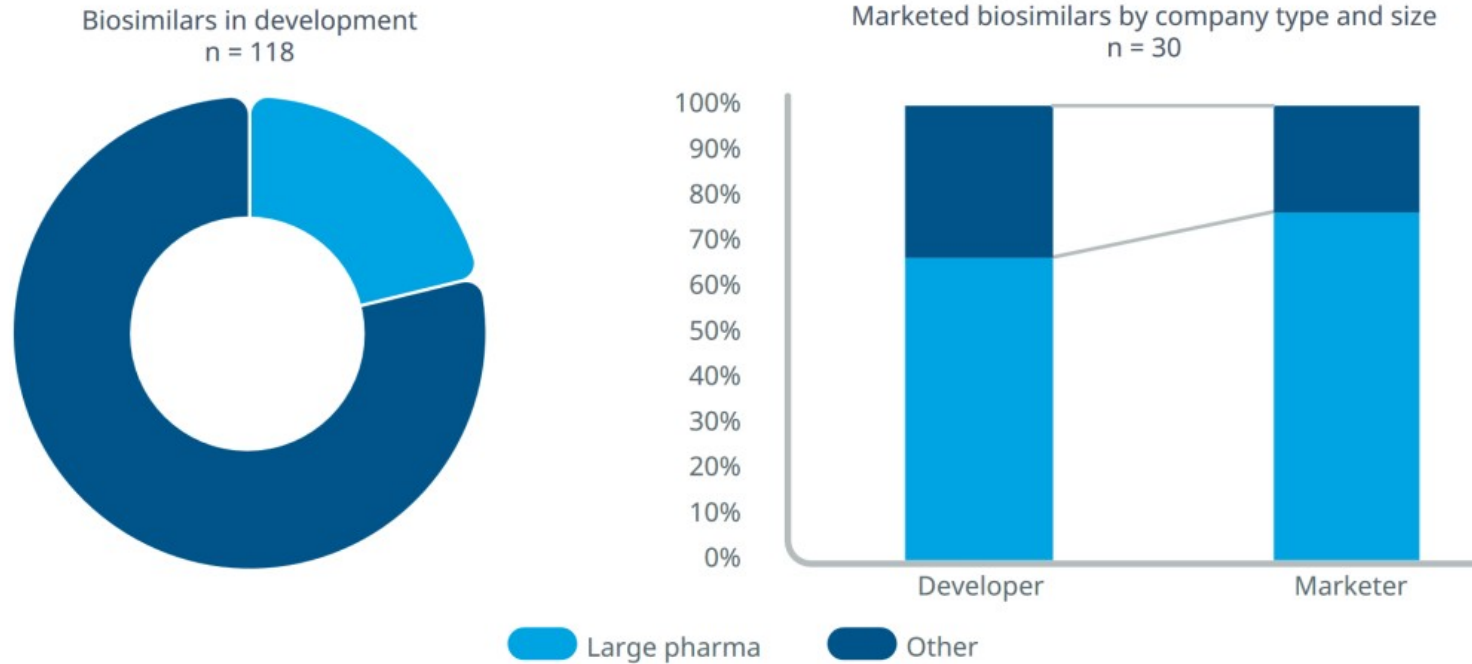
## Biosimilar Market Landscape

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



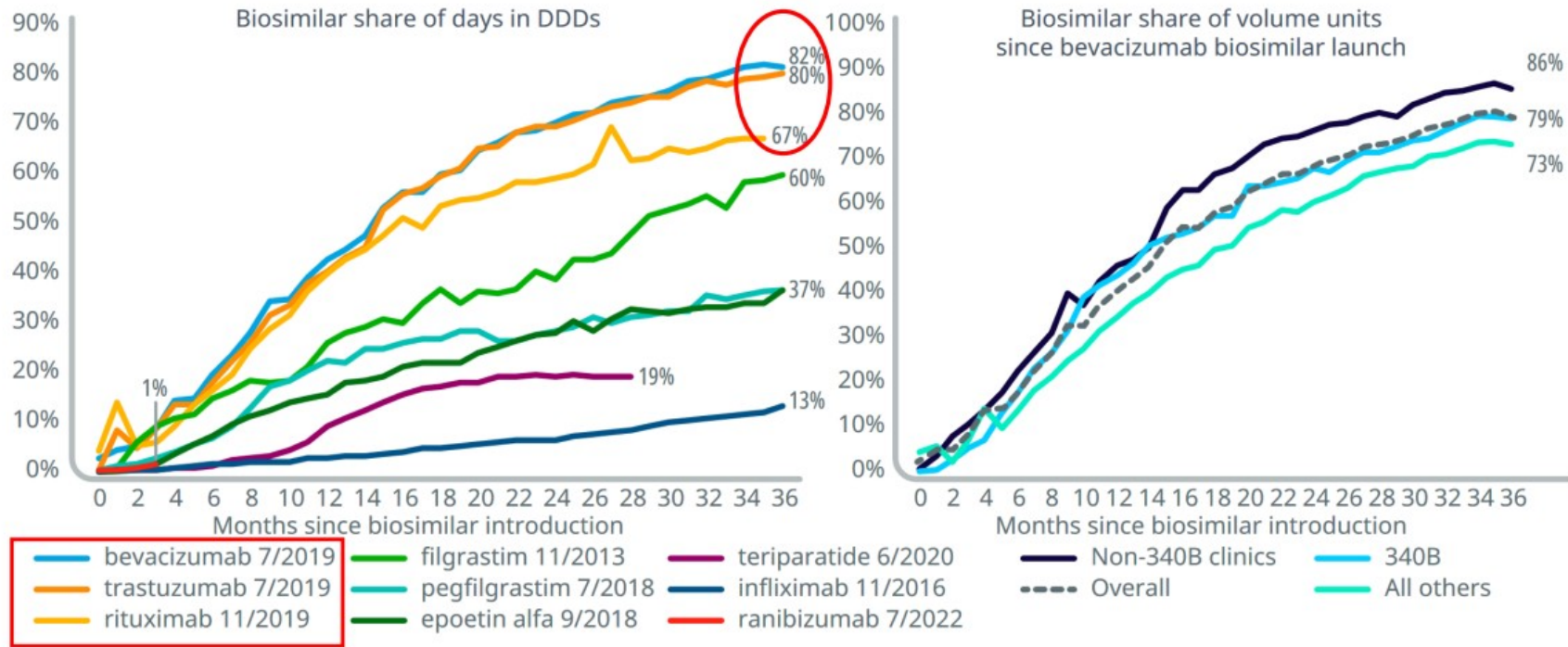
# New Biosimilar Development is Driven by Smaller Companies

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



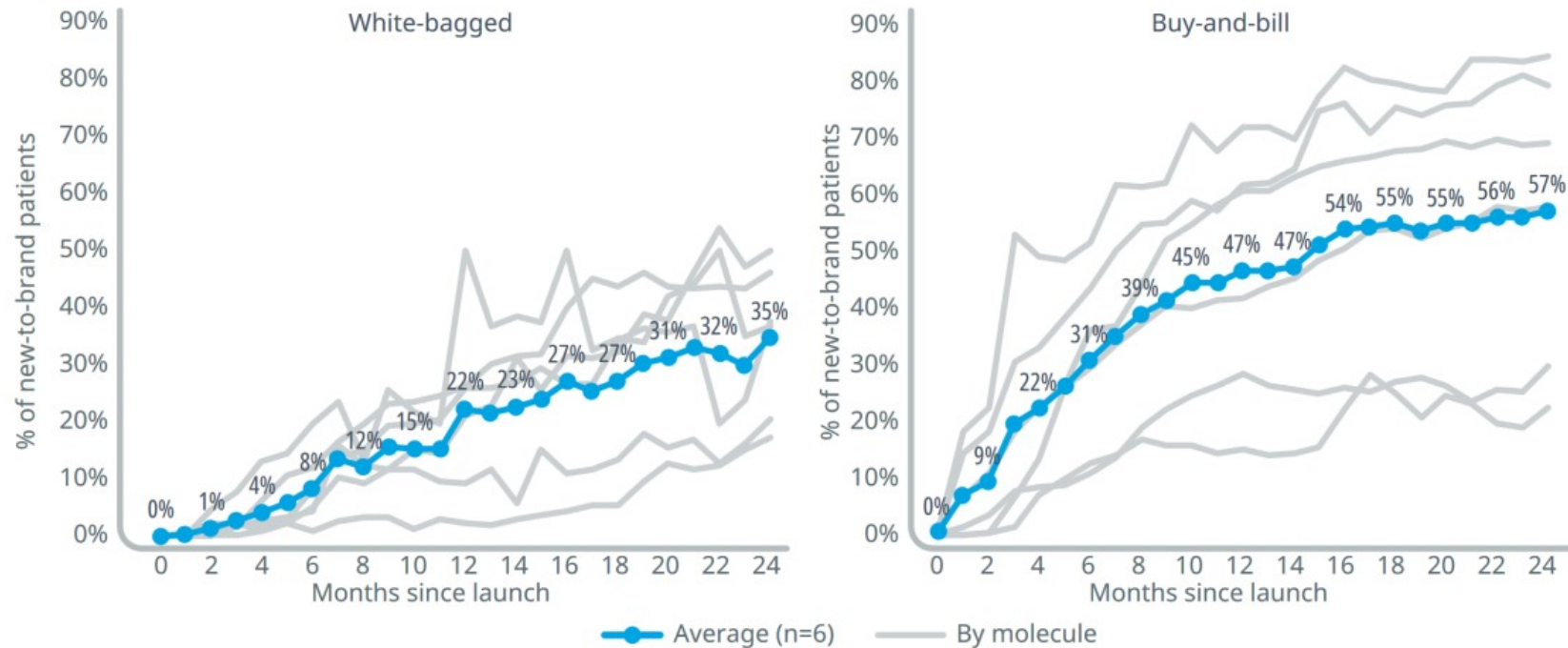
# More Recent Biosimilar Launches are Achieving Higher Shares

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



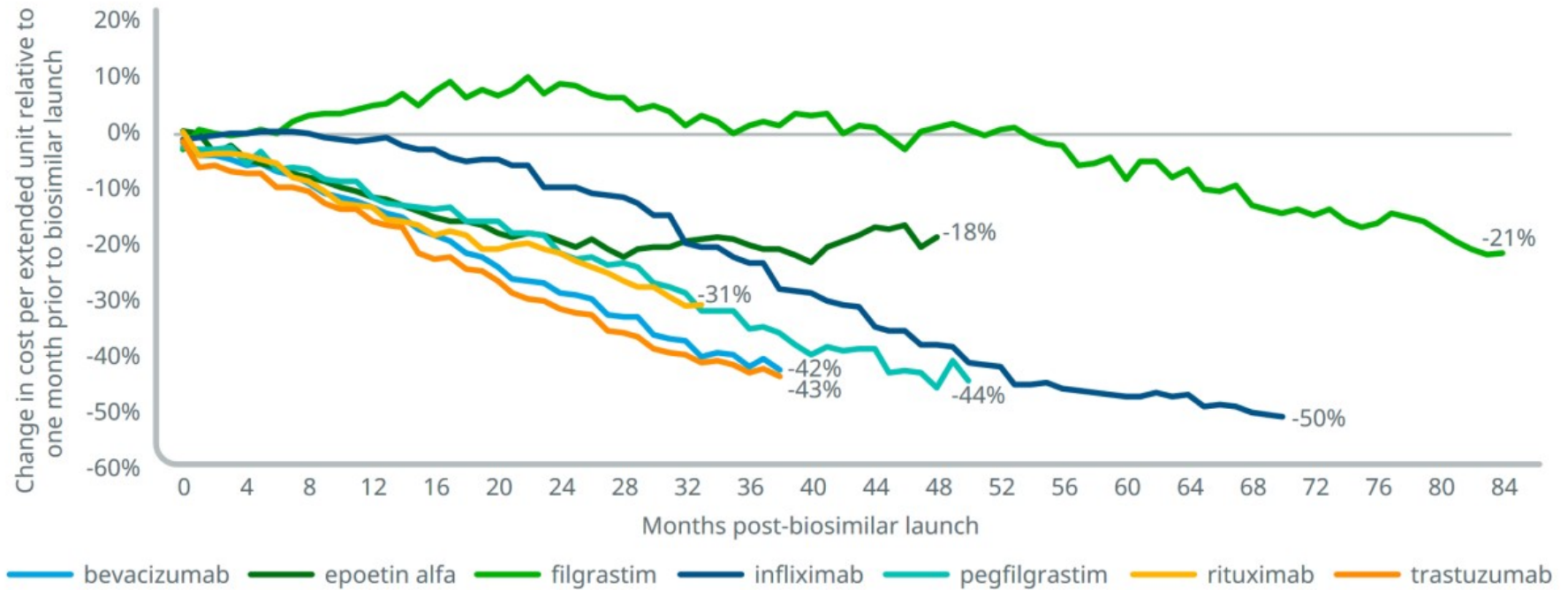
# Stronger Uptake of Biosimilars in Buy-and-Bill Markets

Physicians have incentive to select one product over another



# Biosimilar Pricing Dynamics

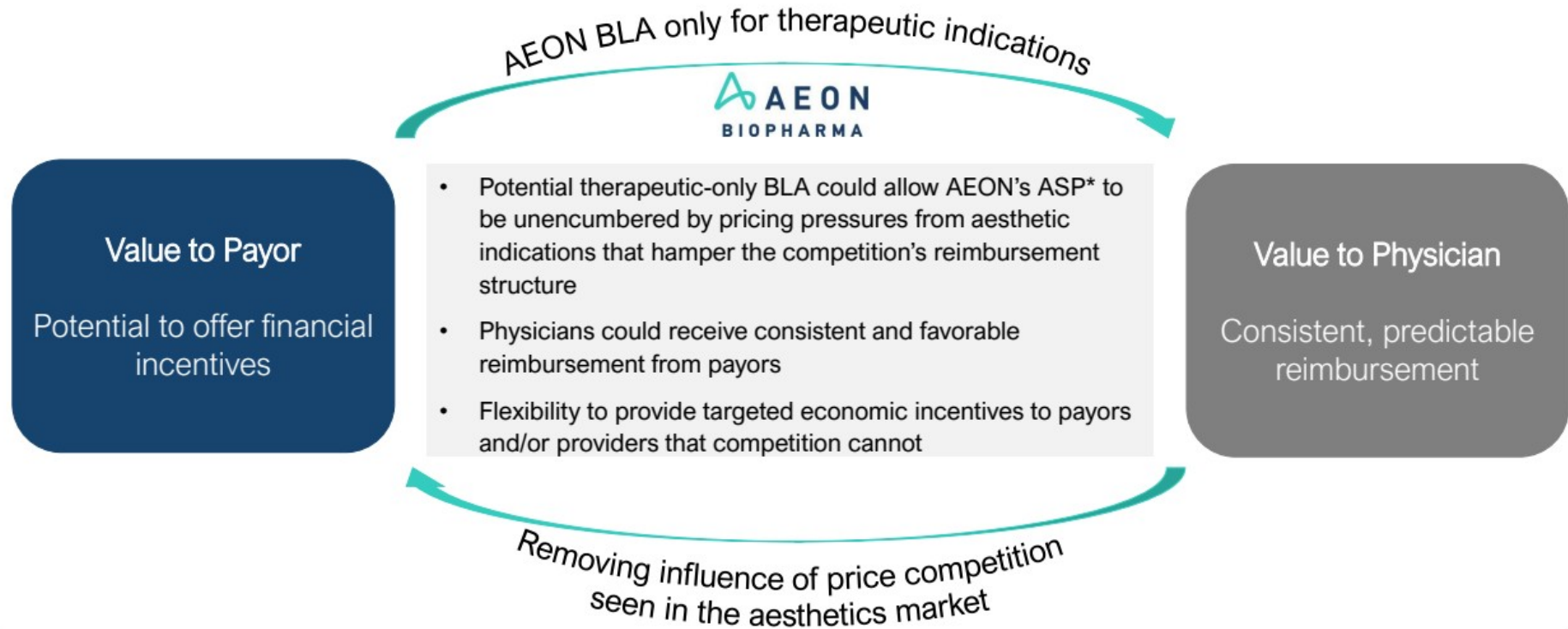
Price discounts in the 18-50% range within 3 years of launch



Reproduced with permission; IQVIA "Biosimilars in the United States 2023-2027"  
 IQVIA National Sales Perspective, US Market Access Strategy Consulting, Dec 2022.

# AEON Model Could Allow Reimbursement Based Solely on Therapeutic Pricing

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



# 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

