

**neurolux**  
**bio**

Redefining Precision in Aesthetic  
Neurotoxins

# The Opportunity

±\$11.1B

Global botulinum toxin market is large and growing (**±\$11.1B** in 2023; **~9–10%** CAGR through 2030).

±\$4.7B

U.S. is the largest region (**±\$4.7B** in 2023) with strong aesthetics adoption and cash-pay dynamics.

~9.9M

Injectables are the #1 minimally invasive procedure in the U.S. with **~9.9M** neuromodulator injections in 2024.

## Unmet needs:

Faster onset, longer duration, improved stability, and reduced immunogenicity.

# The Problem

## **Patients:**

want natural results, quicker onset, and fewer office visits per year.

## **Clinics:**

need differentiated products, efficient prep (less reconstitution), and durable outcomes to reduce follow-ups.

## **Payers:**

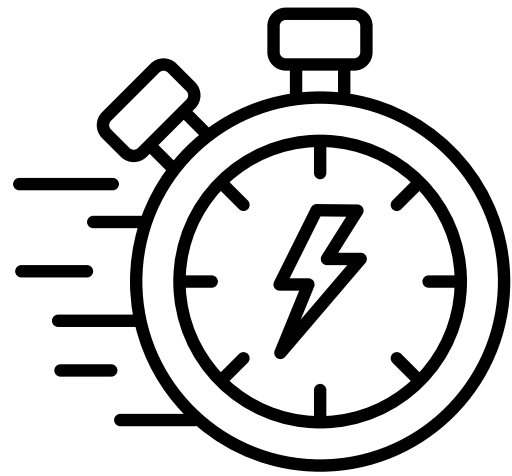
rarely involved in aesthetics; practices compete on experience and product innovation.

## **Duration:**

Existing options show similar 3–4 month duration and albumin-based formulations.

# Our Solution

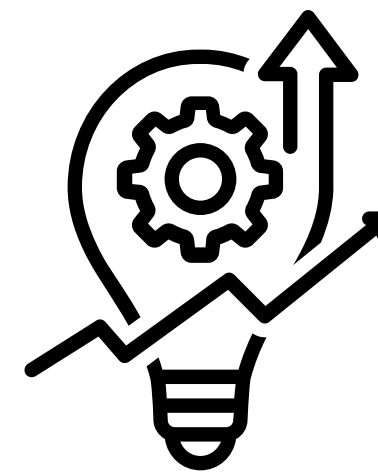
Next-gen botulinum toxin Type A designed for:



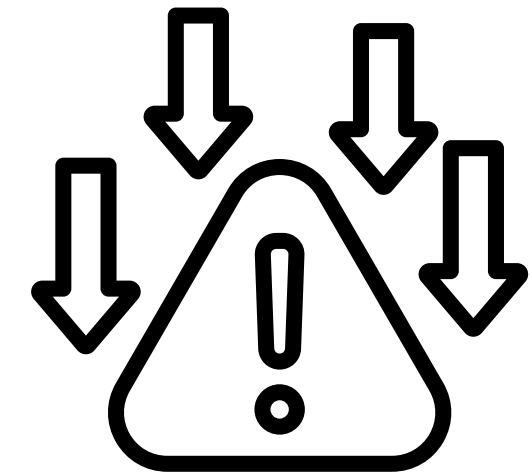
Rapid onset (<24–48 hours target).



Extended duration (6–9 months target).



Enhanced stability for simplified logistics.



Optimized complexing proteins to lower immunogenicity risk.

Platform enables aesthetic lead indication → therapeutic line extensions.

# Competitive Landscape (Cosmetic)

| Brand                  | Onset<br>(typical)  | Duration<br>(typical)  | Albumin-<br>free?        | Notes                                     |
|------------------------|---------------------|------------------------|--------------------------|-------------------------------------------|
| Botox®                 | 2–3 days            | 3–4 months             | No                       | Category leader; broad KOL base           |
| Dysport®               | 1–2 days            | 3–4 months             | No                       | Dilution flexibility; spread profile      |
| Xeomin®                | 2–4 days            | 3–4 months             | Yes                      | Naked toxin (no complexing proteins)      |
| Jeuveau®               | 2–3 days            | 3–4 months             | No                       | Value positioning in some accounts        |
| Daxxify®               | 1–2 days            | ≈6 months              | Yes (peptide-stabilized) | Longest labeled effect; peptide excipient |
| NeuroLux<br>(proposed) | <2 days<br>(target) | 6–9 months<br>(target) | Yes (target)             | Room-temp stability (target)              |

Sources: FDA-approved product labels (Botox®, Dysport®, Xeomin®, Jeuveau®, Daxxify®); Revance, Allergan, Ipsen data; company targets.

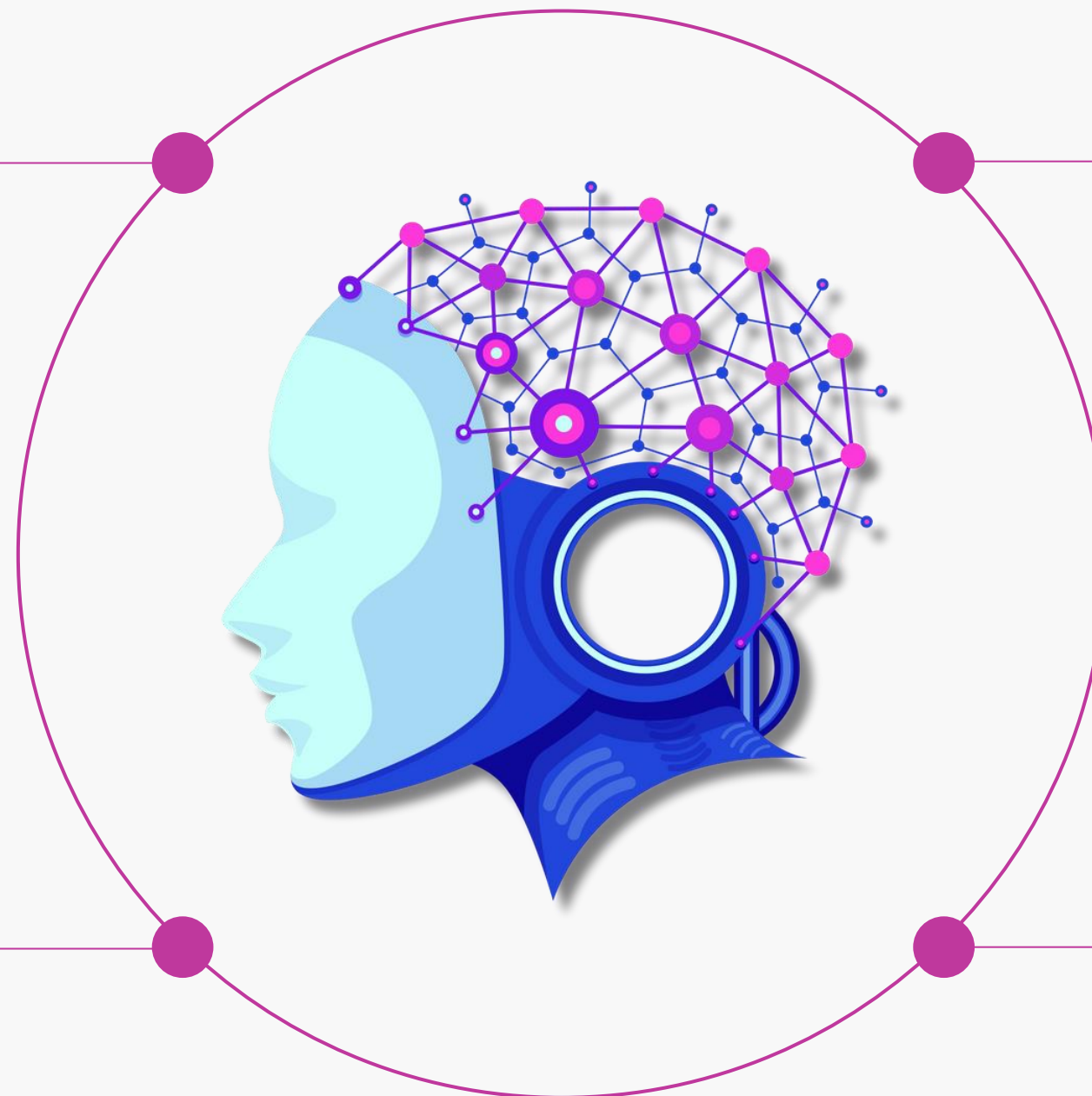
# Technology & IP

## Specific activity

Recombinant manufacturing and purification steps tuned for consistent specific activity.

## Stabilizer system

Stabilizer system designed to maintain potency under refrigerated or controlled room temp conditions.



## IP plan

Composition-of-matter (stabilizers & ratios), methods of use (dosing/intervals), and process patents (yield & purity).

## Trade secrets

Process conditions, excipient sourcing, QC assays.

# Clinical Development Plan

**Reclinical:** GLP tox, potency assays, and stability underway; IND-enabling in 12–18 months.

- |                                                                                                                                                                |                                                                                                                             |                                                                                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| <p>1. <b>Phase 1</b><br/>(FIH, glabellar lines):<br/>Safety, PK/PD, dose-ranging (n≈60–80). (FIH, glabellar lines): safety, PK/PD, dose-ranging (n≈60–80).</p> | <p>2. <b>Phase 2</b><br/>Pivotal dose selection; endpoints: ≥2-grade improvement at Week 4; duration to loss of effect.</p> | <p>3. <b>Phase 3</b><br/>Two randomized, placebo-controlled trials + open-label safety extension.</p> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|

**Regulatory:** FDA BLA (505(b)(1)); EU MAA after U.S. approval.

# Go-to-Market Strategy



- ✓ **Launch focus:** top 5,000 U.S. aesthetic injectors; KOL seeding and hands-on training programs.
- ✓ **Value proposition:** fewer annual visits with rapid onset → premium pricing justified by convenience.
- ✓ Digital demand gen with before/after data; practice economics tools for ROI per patient.
- ✓ International expansion (EU, select APAC) post-Year 2.

# Financial Model (Illustrative)

Assumptions (U.S. aesthetic use only, post-approval):

These are placeholders for diligence and will be refined with price/volume testing.

## Toxin patients

Addressable toxin patients at launch: ~12M (based on injector growth and ASPS trends).

## Target accounts

Capture 1.0% / 2.5% / 4.0% share Years 1/2/3 in target accounts.

## ASP

ASP per treatment vial: \$380; gross margin target: 80%.

**\$456M**

Year 1 revenue

**\$1.46B**

(includes modest international)

Year 3 revenue

# Team

## Founder/CEO

Aesthetics  
biotech operator;  
prior exits in  
injectables.

## CMO

Board-certified  
dermatologist; PI  
on  $\geq 10$   
neuromodulator  
trials.

## CTO

Bioprocess lead;  
scaled toxin  
biologics to  
commercial GMP.

## Advisors

Regulatory  
(ex-CBER), top  
KOL injectors,  
supply chain  
veterans.

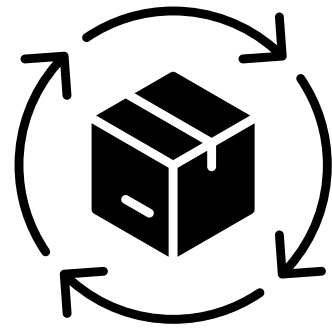
# Traction & Milestones

## Data



Accelerated stability at 25°C shows  $\geq 90\%$  potency at 6 months (in-house).

## Supply



LOI with GMP toxin manufacturer; pilot lots Q4.

## IP



2 provisional filings; PCT within 12 months.

## Next 18 months



Complete IND-enabling, submit IND, start FIH; finalize CMO selection.

# Funding Ask



## Raising:

\$XXM Series  
Seed/Series A.

## Use of proceeds:

IND-enabling (35%),  
manufacturing scale-up  
(25%), Phase 1 (30%), G&A  
(10%).

## Runway:

24 months to IND and FIH  
data; value inflections at  
IND acceptance and  
Week-4 readout.



# Why Now / Why Us

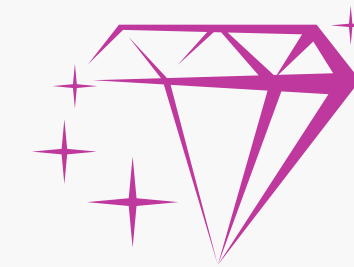
## #1 Procedure

### Category tailwinds:

Double-digit aesthetics growth;  
toxins still **#1** procedure.



Team with toxin, CMC, and  
KOL launch experience.

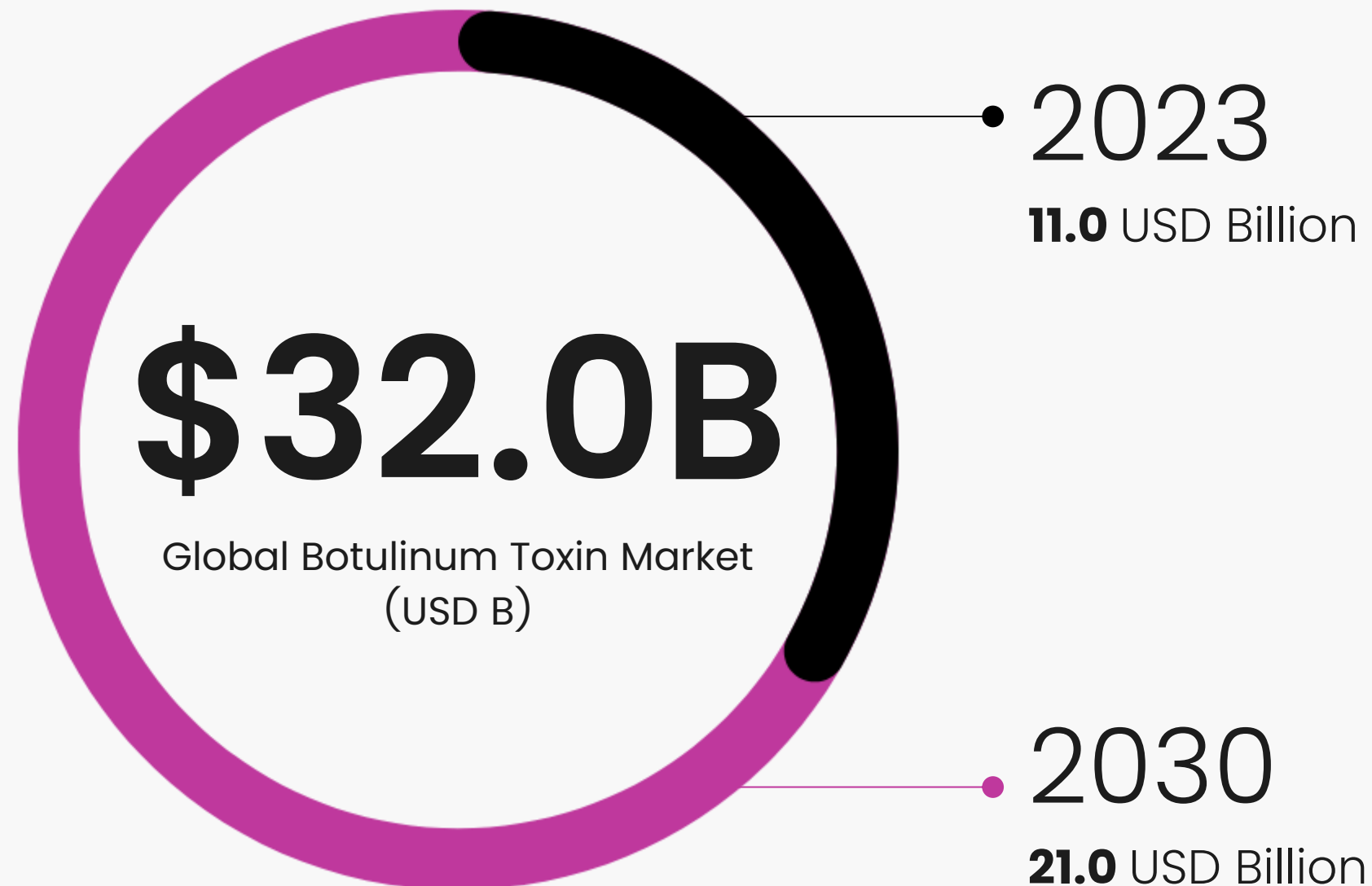


Clear clinical and practice  
unmet needs; room for  
premium, durable option.



NeuroLux Bio aims to  
become the long-duration,  
rapid-onset standard.

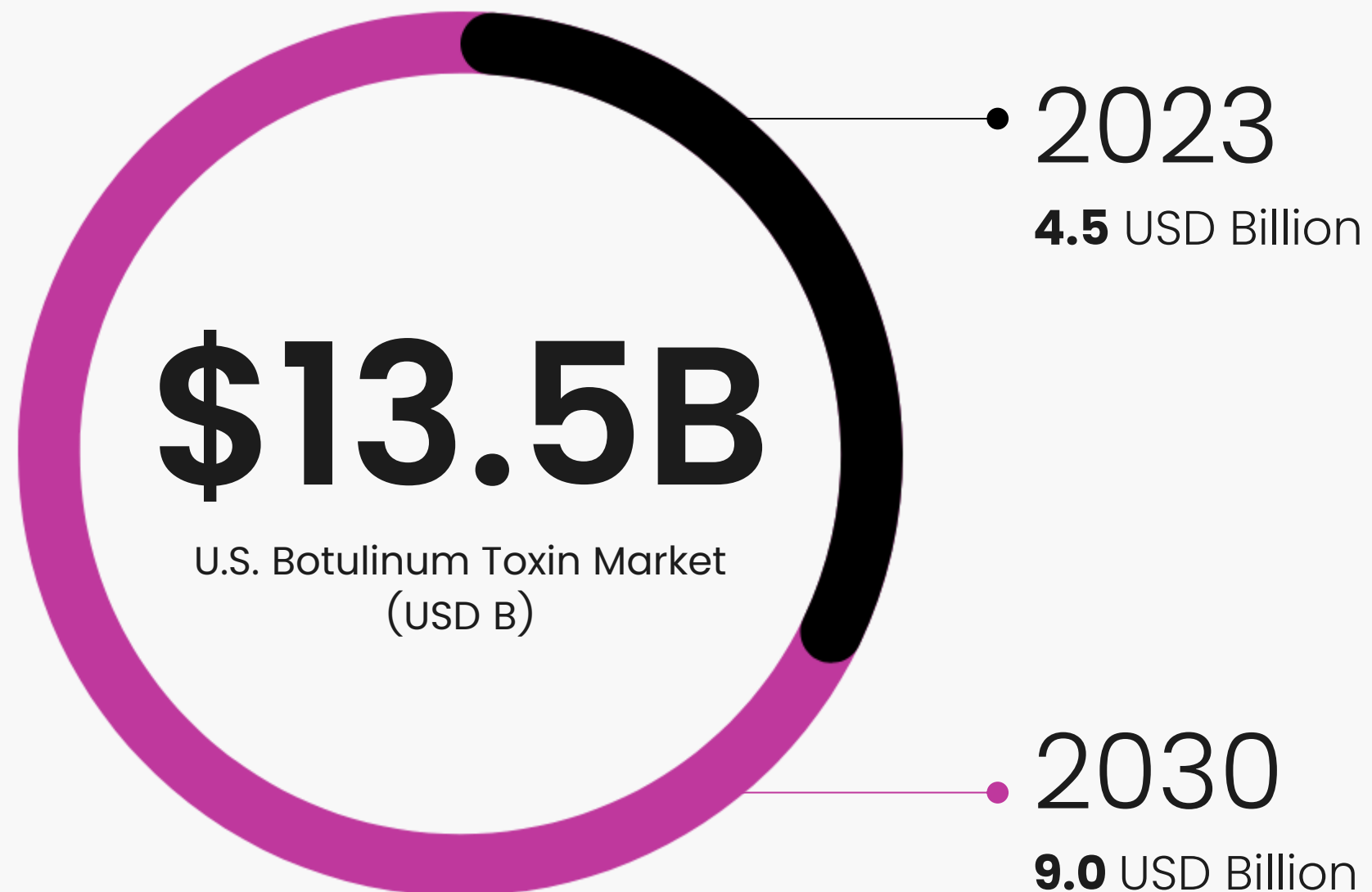
# Global Market Growth



**Source:** Grand View Research (2023 base; forecast to 2030).

Source: Grand View Research, 'Botulinum Toxin Market Size & Trends Report' (2023 baseline, forecast to 2030).

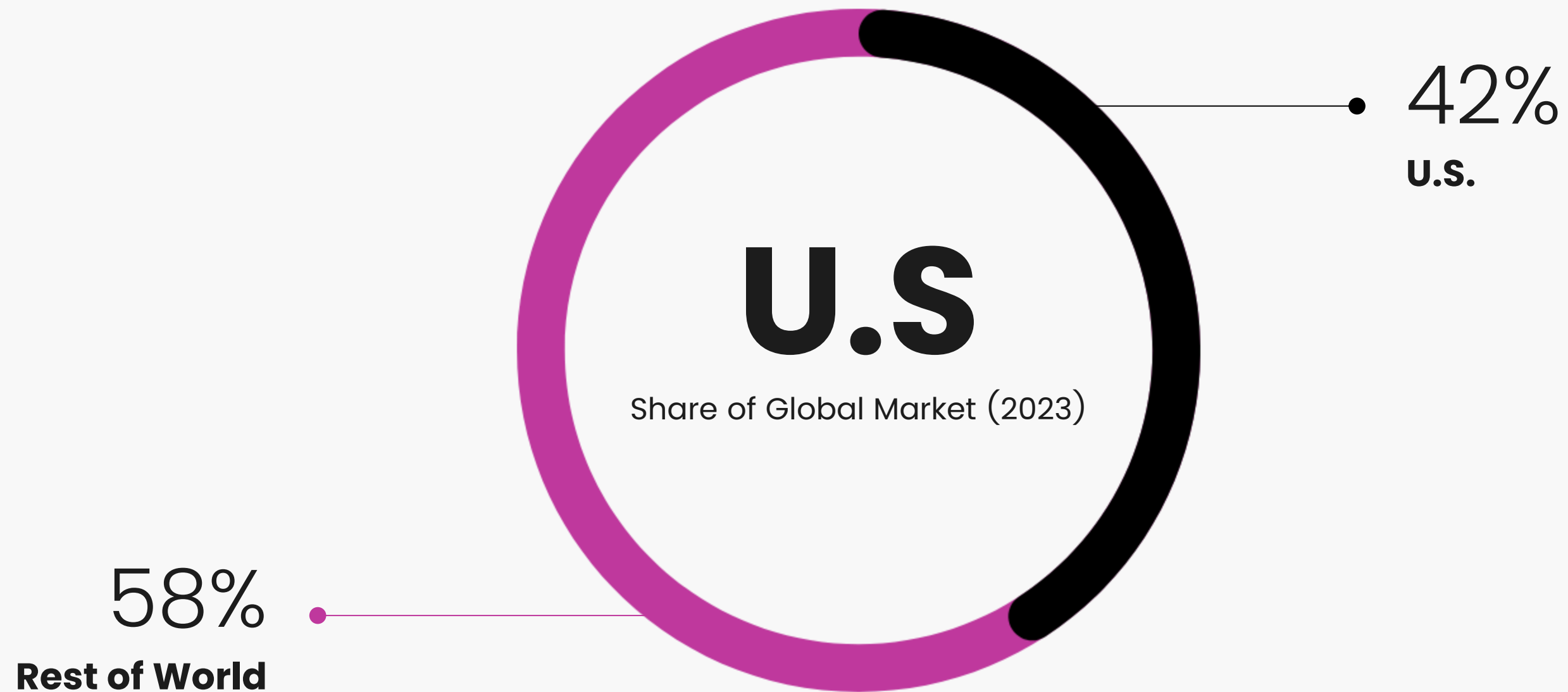
# U.S. Market Growth



**Source:** Grand View Research U.S. Outlook (2023 base; forecast to 2030).

Source: Grand View Research, 'U.S. Botulinum Toxin Market Size & Forecast' (2023 baseline, forecast to 2030).

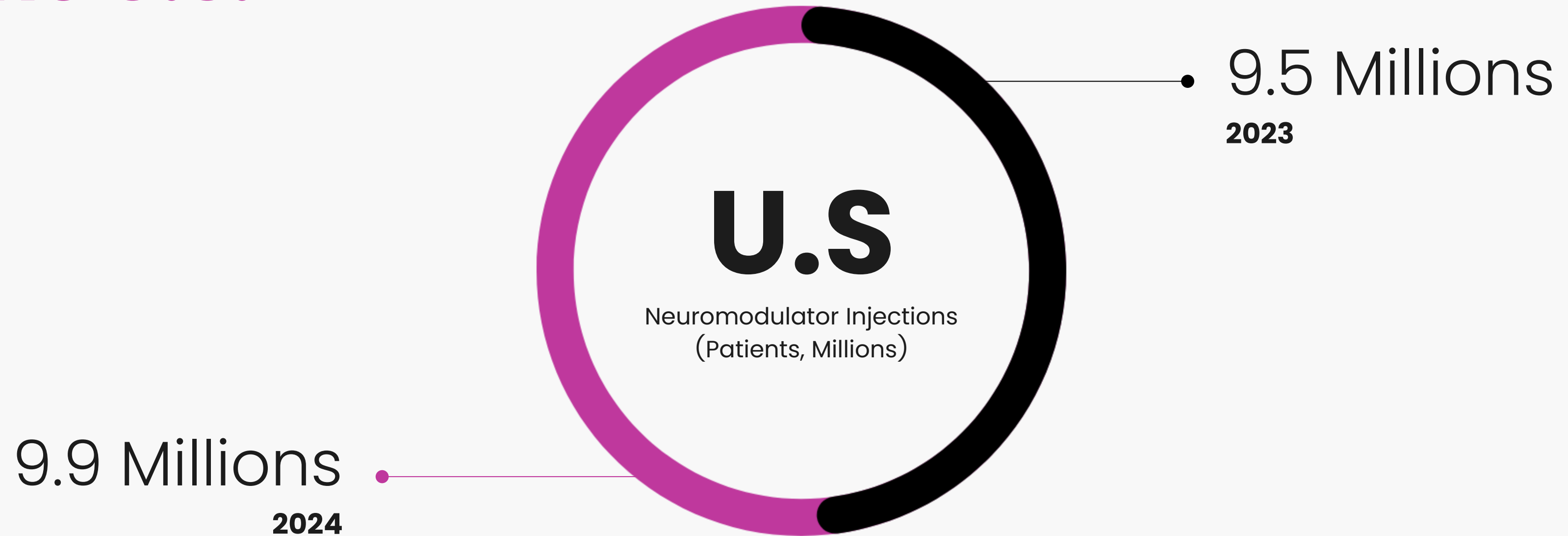
# U.S. Share of Global (2023)



Source: Grand View Research (global & U.S. estimates, 2023).

**Source:** Grand View Research global and U.S. estimates, 2023.

# Neuromodulator Demand in the U.S.



Source: Grand View Research (global & U.S. estimates, 2023).

**Source:** Grand View Research global and U.S. estimates, 2023.

# Positioning

## Promise

'Fewer visits. Faster glow.' Long-duration results with onset patients feel next-day.

## Economic case for clinics

Case for clinics: higher patient satisfaction, reduced chair time, premium vial economics.

## Medical case

Albumin-free stabilization, tight dose precision, consistent effect window.

# Key Risks & Mitigations

**CMC scale-up:** mitigate with dual-source critical excipients and staged PPQ runs.

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**Clinical duration:** power studies for durability and include responder analyses by dose.

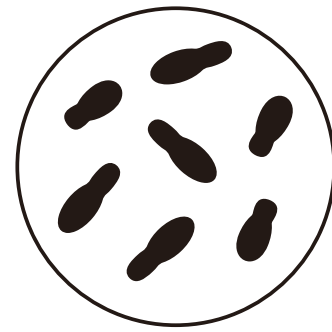
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**Regulatory:** early Type C meetings; align on endpoints and immunogenicity assays.

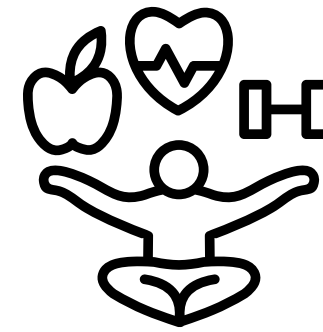
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**Commercial adoption:** KOL consortia, peer-led trainings, practice ROI calculators.

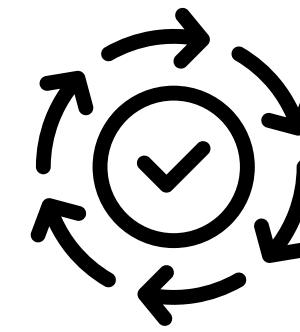
# Competitive Watch: Claruvivis YY003



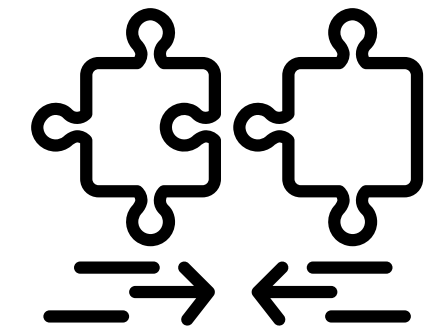
Liquid,  
recombinant  
Botulinum  
Neurotoxin  
Type A in a  
pre-filled  
syringe (first  
of its kind).



FDA cleared  
IND for  
glabellar  
lines in Sept  
2024; U.S.  
clinical  
program  
underway  
(NCT0648147  
5).



**Positioning  
themes:**  
convenience  
(no  
reconstitution)  
, potential  
safety/  
consistency  
claims.



**Implication for  
NeuroLux:**  
validate  
demand for  
ready-to-use  
formats;  
emphasize our  
durability/  
onset  
differentiation.

# FDA BLA Review Timelines



**Goal review times:** Standard  $\approx$  **10 months**; Priority  $\approx$  **6 months** (from BLA filing acceptance).

# FDA User Fees (FY2025, PDUFA VII) – Biologics

~\$4.31M

Application fee (requiring clinical data)

~\$403,889 *Annually*

Program fee (per marketed product)

~\$2.155M

Application fee (not requiring clinical data):  
~\$2.155M (not typical for toxin BLAs).

## Note:

Waivers/reductions may apply (e.g., small business, orphan).

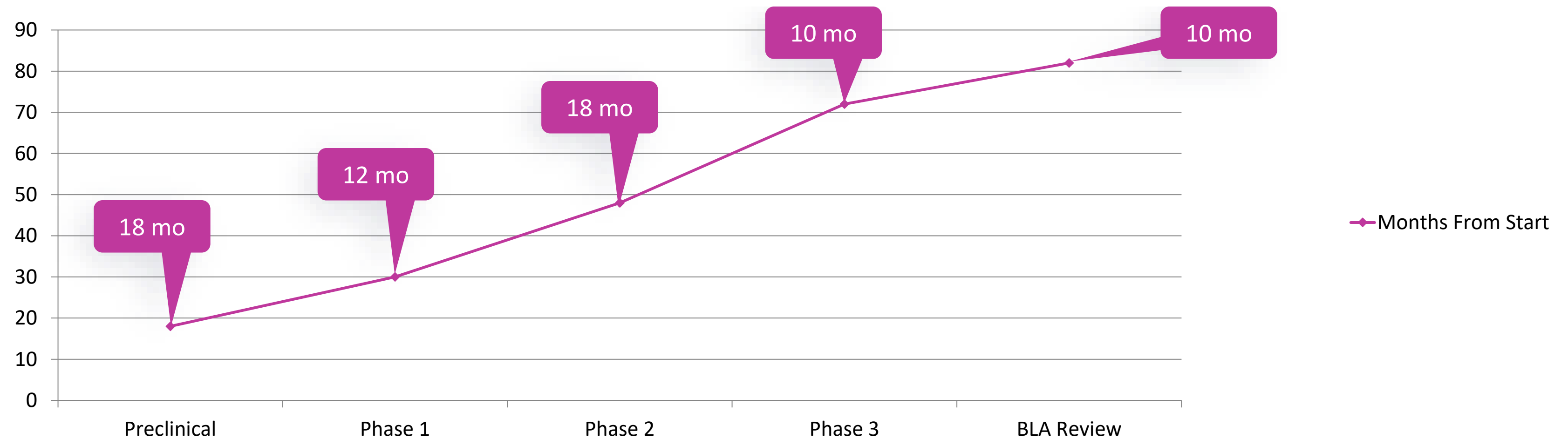
# Feature Comparison (Aesthetic Indication)

| Feature     | Claruviv<br>YY003*               | Daxxify®                    | Botox®                      | NeuroLux<br>(target)      |
|-------------|----------------------------------|-----------------------------|-----------------------------|---------------------------|
| Formulation | Liquid, pre-filled syringe       | Lyophilized, reconstitution | Lyophilized, reconstitution | Liquid or ready-to-use    |
| Onset       | 2–3 days (est.)                  | 1–2 days                    | 2–3 days                    | <2 days                   |
| Duration    | 3–4 months (est.)                | ≈6 months                   | 3–4 months                  | 6–9 months                |
| Stabilizer  | Recombinant process; proprietary | Peptide                     | Albumin                     | Albumin-free (novel)      |
| Storage     | Refrigerated                     | Refrigerated                | Refrigerated                | Room temp stable (target) |

\*Claruviv YY003 clinical program: NCT06481475; FDA IND cleared Sept 2024. Daxxify® data per Revance prescribing info; Botox® per Allergan label.

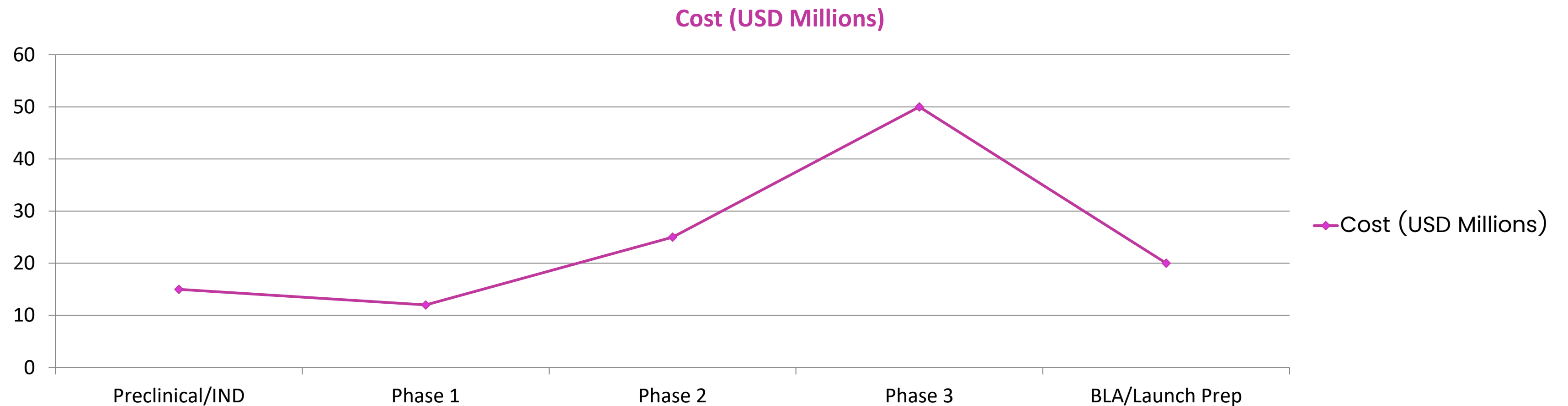
# Development Timeline

Illustrative IND to BLA Timeline (Neurolux)



Timelines are estimates; assume IND filing at Month 18, BLA submission at Month 84; FDA standard review ≈ **10 months**.

# Cash Requirements by Stage (Illustrative)



Estimates include CMC, clinical ops, regulatory, and overhead; actuals depend on design, endpoints, and geographies.



Company Overview

# Next-Generation Botulinum Therapy

## Advantages of Liquid Formulation

Founded in 2025, NeuroLux Bio is a venture-backed biotech company that has in-licensed a next-generation, fully recombinant, botulinum-based asset from Chongqing, China-based Claruvis Pharma

Claruvis has spent the last decade leveraging a depth of experience in botulinum toxin R&D and manufacturing to develop a fully recombinant, liquid formulation (YY003) – an innovation long sought after by market leaders

A lyophilized formulation of the recombinant drug (YY001) has shown improved efficacy, safety and decreased immunogenicity versus market leader in Ph 3 trials and the liquid formulation (YY003) has shown comparable potency and long-term stability in Ph 2 trials

Ease of use, no reconstitution step

Avoidance of potential contamination

Easy to refine dose specifications

Reduction of medical waste

Avoidance of needle tip passivation

## The Source:

Claruvivis

Pharmaceutical Co.

Claruvivis was founded in 2018 by a market leading scientific team with a depth of experience in botulinum R&D, clinical development and manufacturing

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The lyophilized recombinant asset, YY001, recently completed successful Ph3 trials and the company is now pursuing regulatory approval and commercial launch in China

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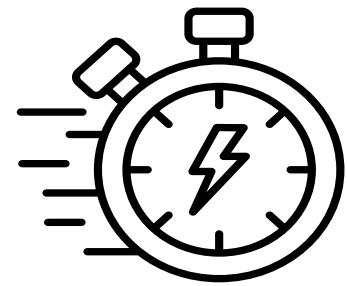
NeuroLux Bio holds global rights (excluding China) to the liquid recombinant asset, YY003, and plans to initiate multi-national Ph3 trial in 2026. The company also plans to leverage Claruvivis' world-class, commercial-scale facility in Chongqing, China, with its 2 million vial per year capacity, to provide a key strategic advantage towards global supply needs

# Focused Pipeline: Product Differentiation & Most Commonly Used Area(s) for Injectable Toxin to Maximize Market Attractiveness

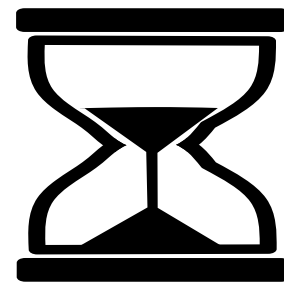
| PRODUCT                                                | TARGET USE                              | DISCOVERY DEVELOPMENT | FORMULATION DEVELOPMENT | CLINICAL VALIDATION | COMMERCIALIZATION |
|--------------------------------------------------------|-----------------------------------------|-----------------------|-------------------------|---------------------|-------------------|
| <b>YY003</b><br>Recombinant Botulinum Toxin A – Liquid | Glabellar Lines & Lateral Canthal Lines |                       |                         |                     | 2H 2028           |
| <b>YY003</b><br>Recombinant Botulinum Toxin A – Liquid | TBD                                     |                       |                         |                     | 1H 2029           |
| <b>YY003</b><br>Recombinant Botulinum Toxin A – Liquid | TBD                                     |                       |                         |                     | 1H 2030           |

# Overview: 3 Year Plan

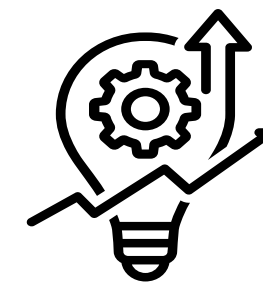
## KEY HIGHLIGHTS



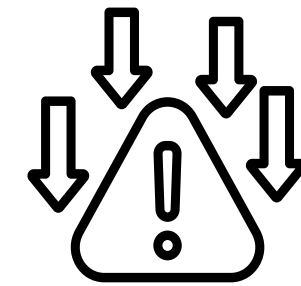
2-3 year plan allows for efficient development program with path to FDA + approval by 2H 2028



Opportunity in 2028 – 2029 enhanced by our differentiated product opportunity for current market players or interested new players



Series financing of \$70M in 2025 gets us thru 2028



Financing allows for development and market readiness: 2H 2028

FORECAST TESTED AGAINST INDUSTRY BENCHMARKS TO VALIDATE THE REASONABLENESS OF OUR ASSUMPTIONS.

**neuro**lux  
**bio**

Confidential 2025

# Next-Generation Botulinum Therapy

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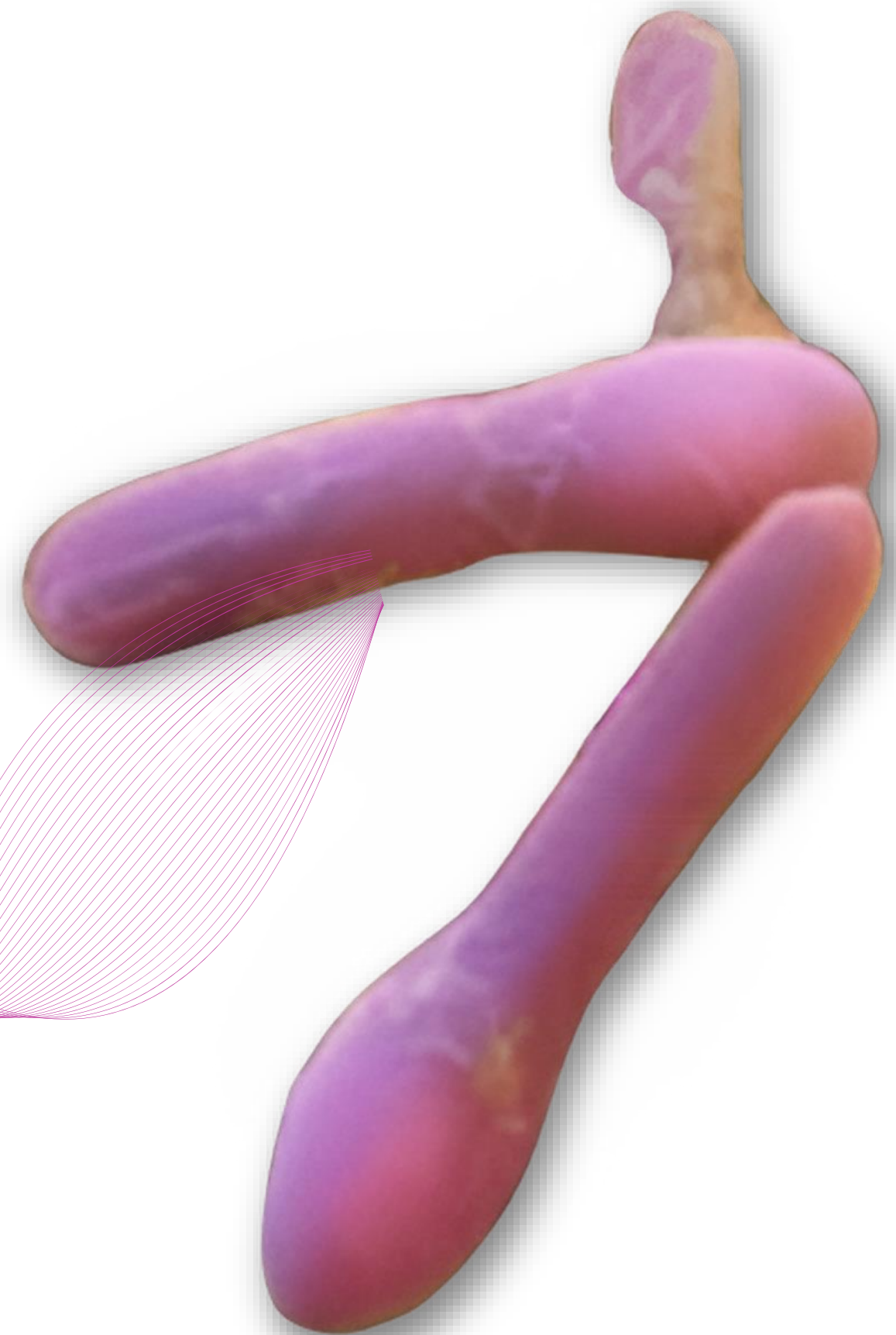
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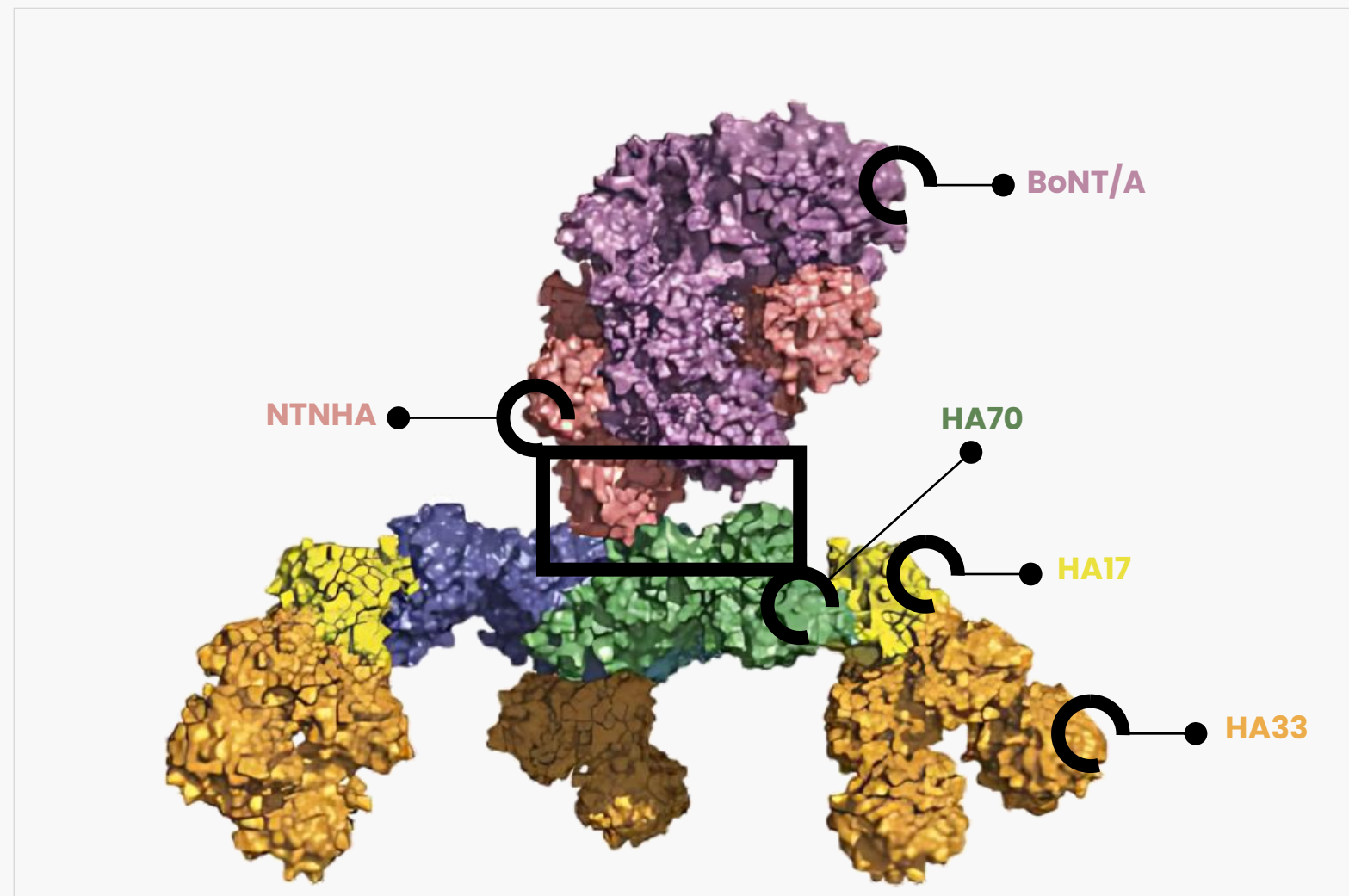
# Natural BoNT/A

Botulinum toxin is a neurotoxic protein produced by Clostridium Botulinum, a gram-positive anerobic bacterium



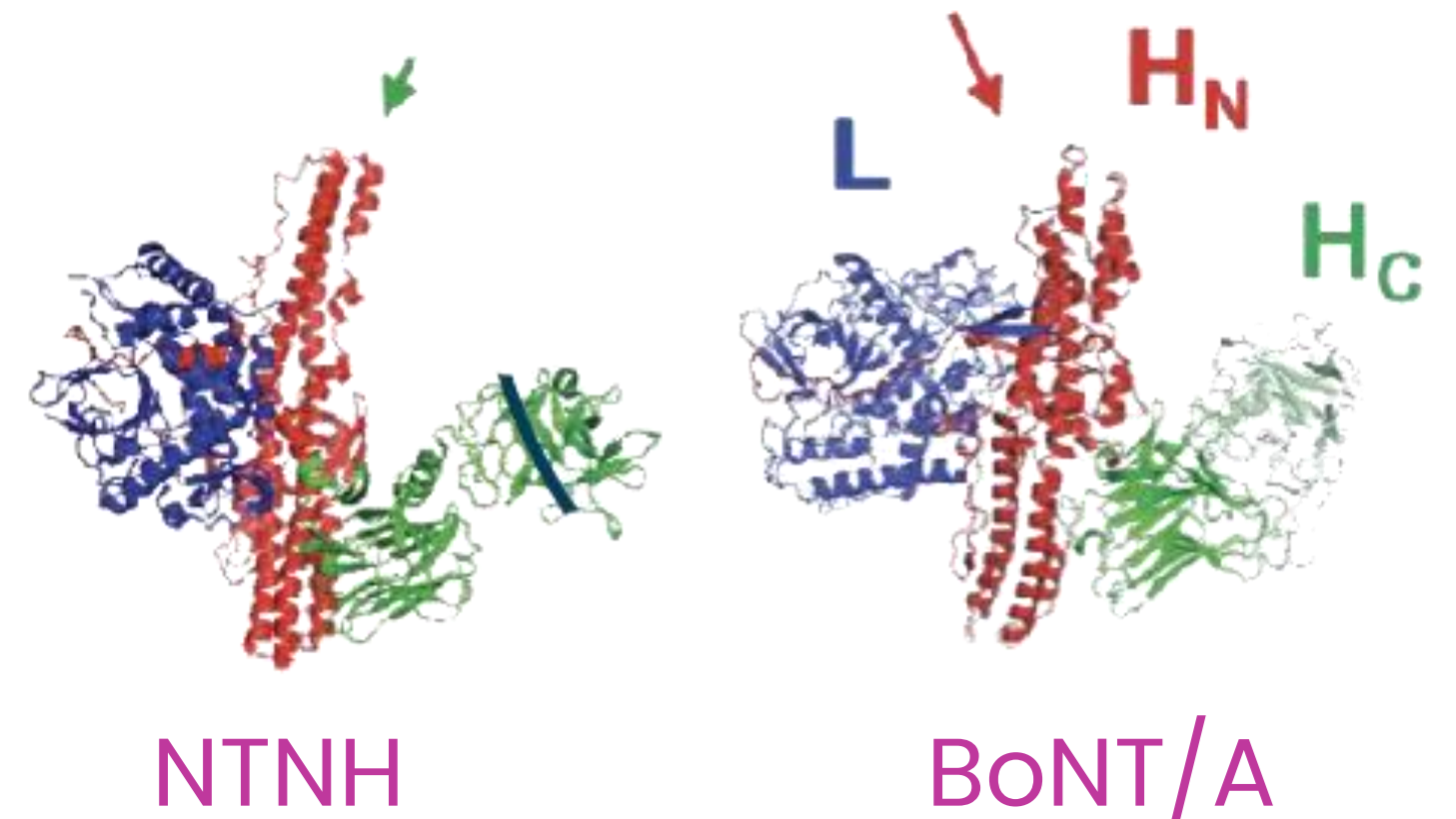
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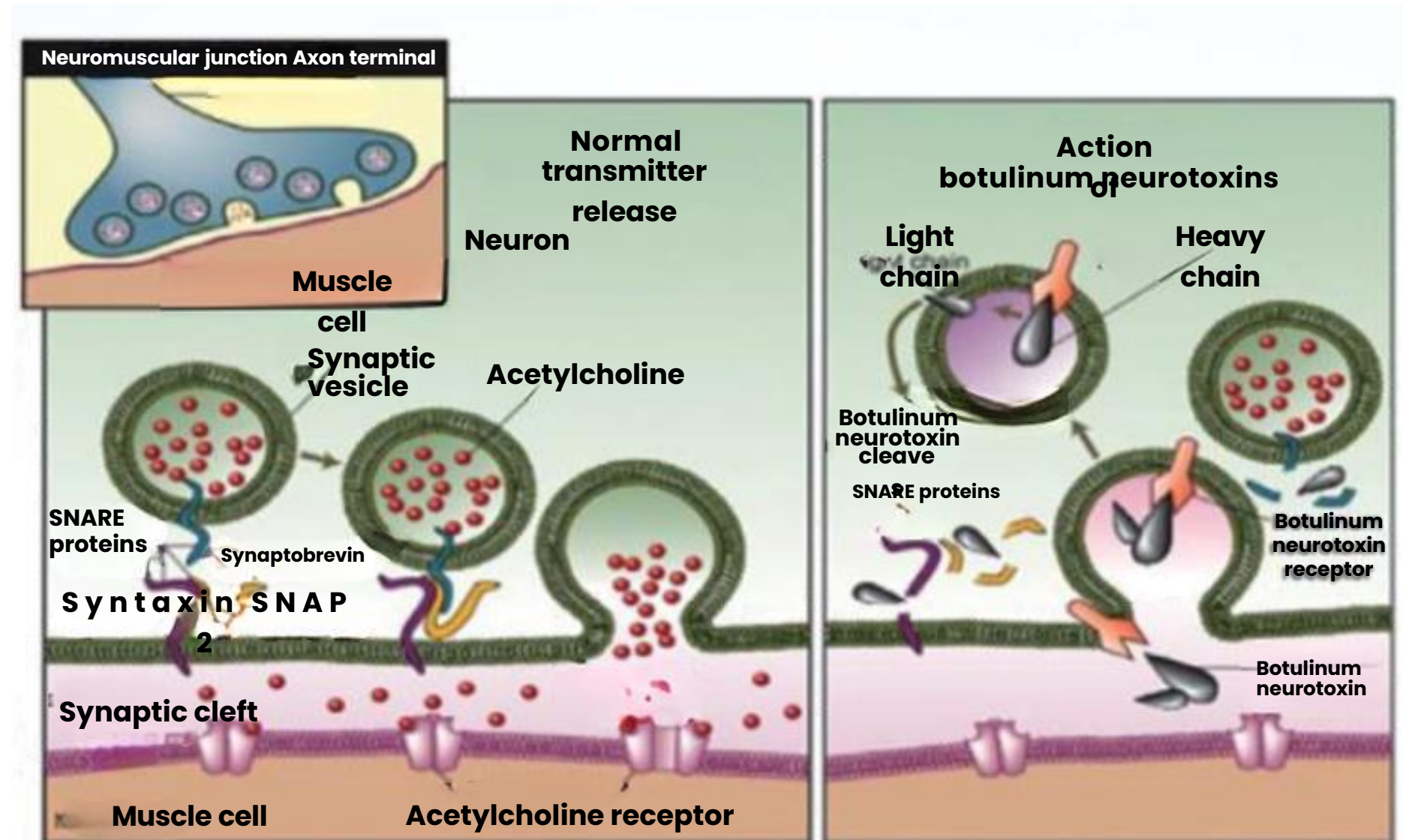
L-Complex HA-NTNH-BoNT

## BoNT/A1



# Well-Known Mechanism of Action

The light chain of the botulinum toxin cleaves specific sites on the snare proteins. The cleavage inhibits the release of neurotransmitter acetylcholine, which leads to a neuromuscular blocking effect and paralysis of muscle activity



# Natural Botulinum:

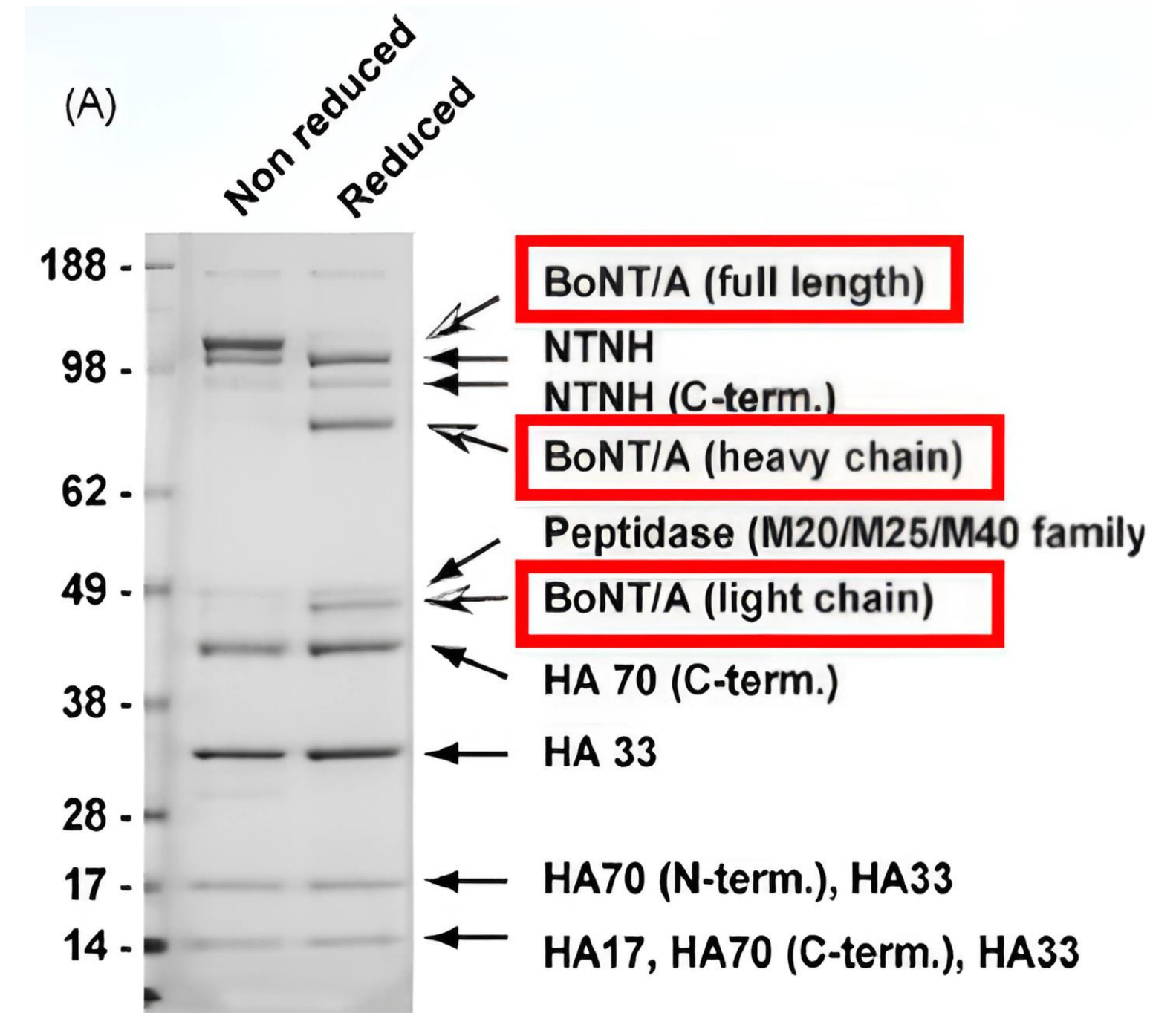
Today's natural BoNT/A complex has had little innovation since the 1970's

All approved and clinical-stage natural botulinum (nBoNT) products today are produced from *Clostridium botulinum* with little process innovation over the last few decades

*Clostridium*-derived nBoNT products on the market contain accessory proteins that are pharmacologically inactive and pose immunogenicity risk

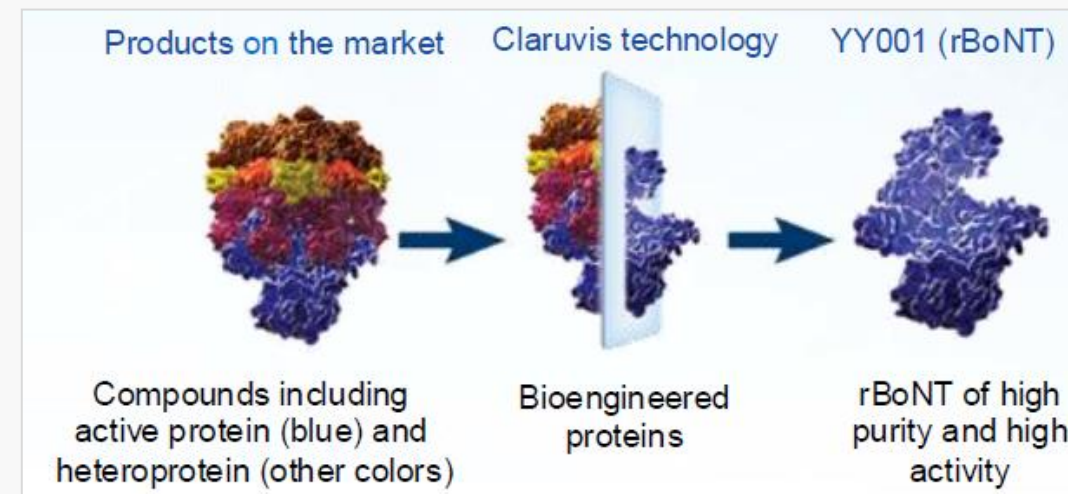
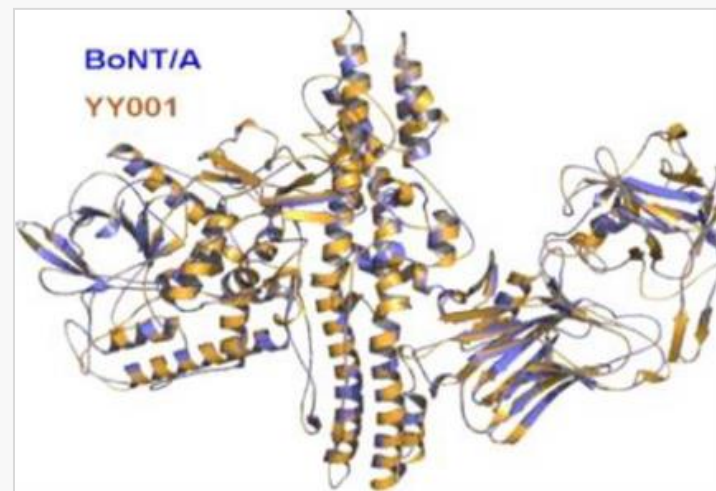
Additionally, contamination risk associated with nBoNT manufacturing leads to high maintenance costs and stringent quality control measures

## SDS-PAGE analysis of BoNT/A complex



# Recombinant Botulinum

Claruviv has developed a recombinant form of botulinum neurotoxin type A (rBoNT/A), a significant innovation in the field and a highly compelling, next-generation botulinum asset



Structural comparisons show rBoNT/A to be highly consistent with nBoNT/A (see figure below)

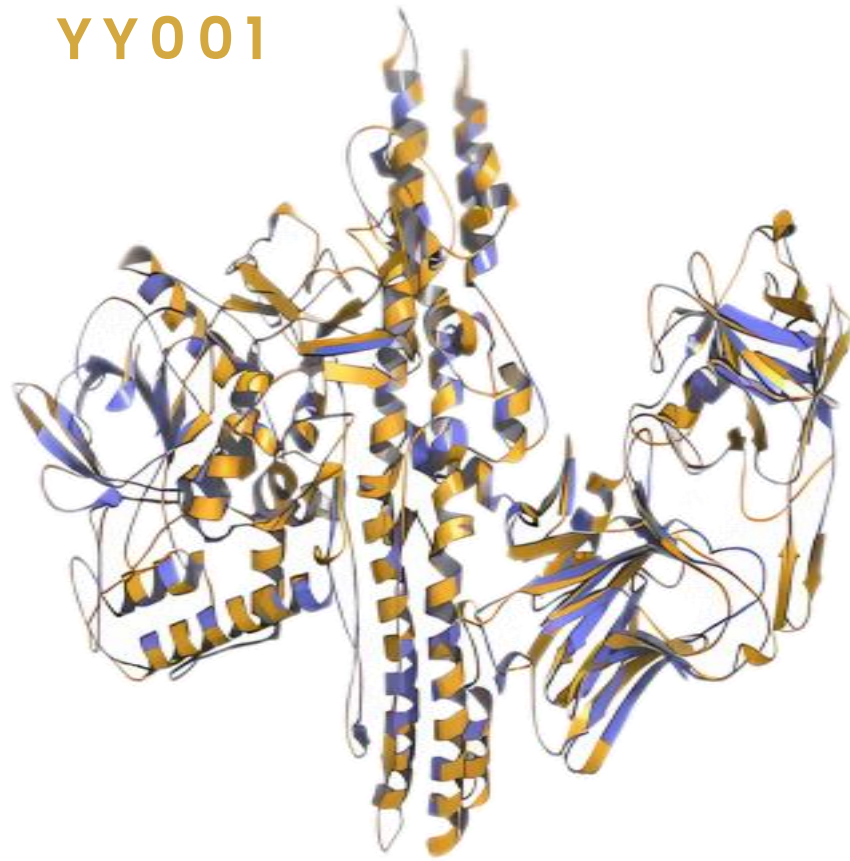
Due to its recombinant nature, rBoNT has improved purity, activity and stability versus Clostridium-derived products. The recombinant manufacturing process also significantly reduces biosafety concerns, while improving consistency and quality

Enormous commercial value and potential in an easier-to-use, less immunogenic, cosmetic application, as well as additional untapped value in therapeutic indication expansion

Recombinant formulation is homogeneous protein with higher purity, resulting in decreased immunogenicity risk, particularly for therapies needing repeated, high dose administration (i.e., large muscle disorders)

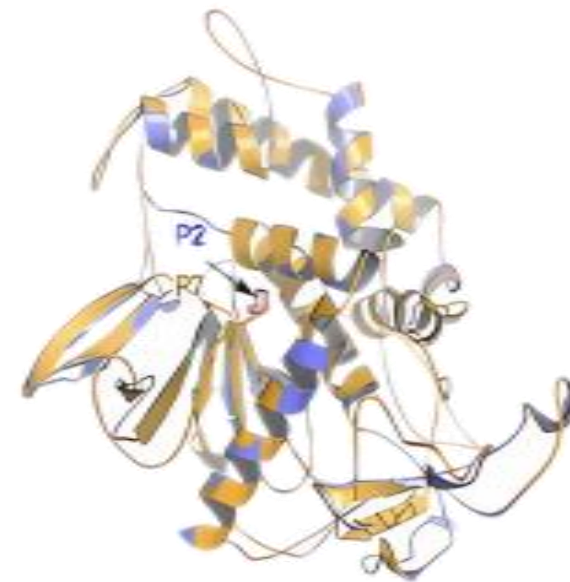
# Recombinant Botulinum

BoNT/A  
YY001

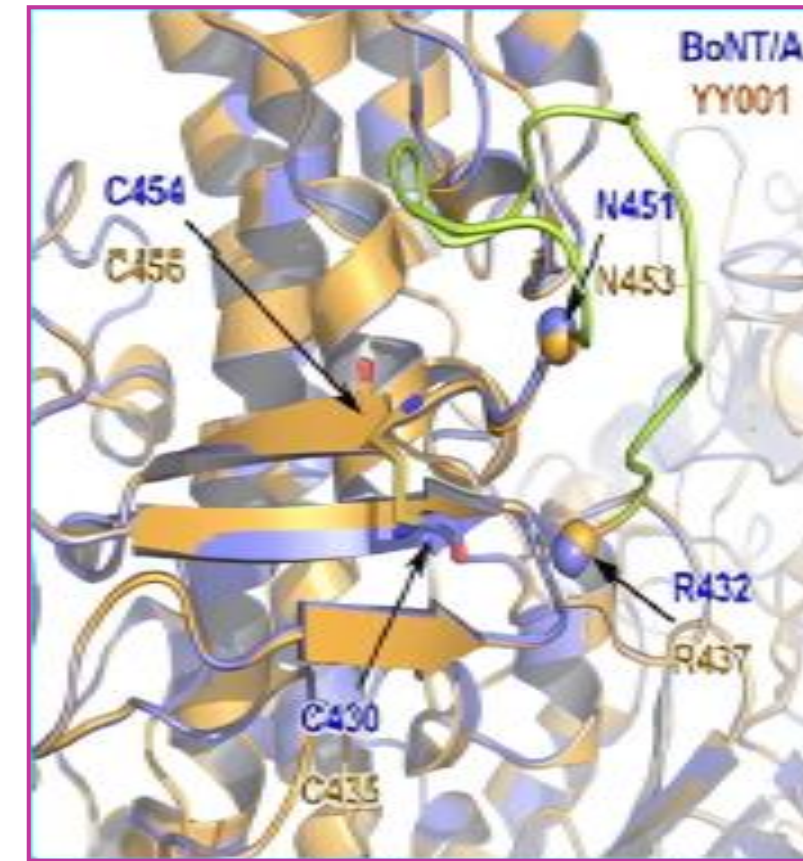


150kDa

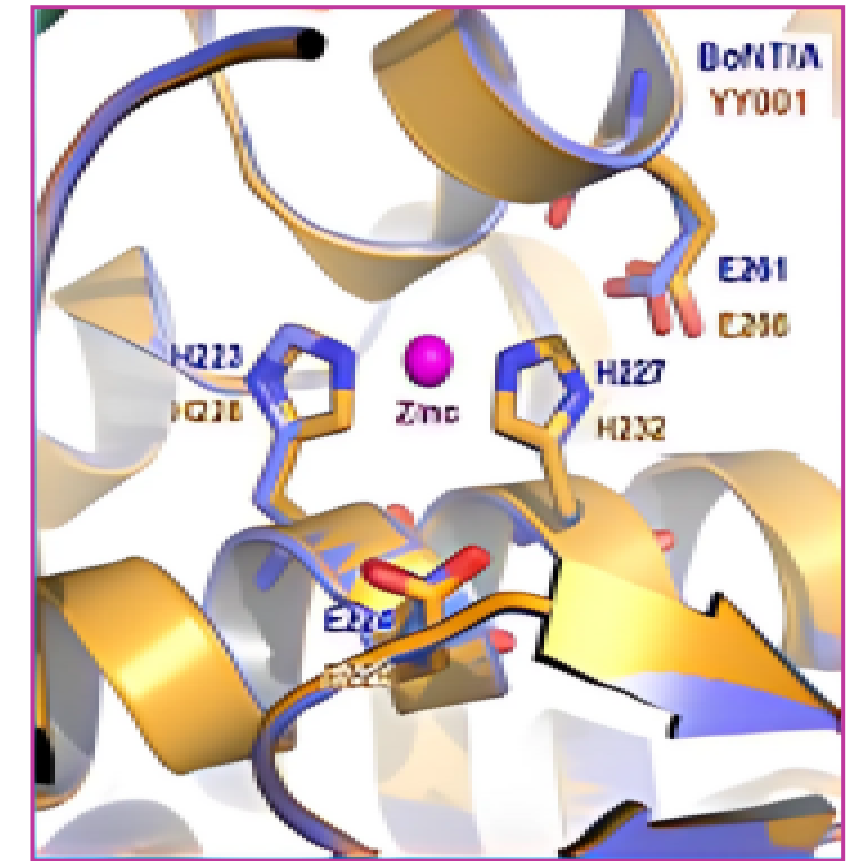
BoNT/A  
YY001



Light Chain



Key Di-Sulfide Bond



Zinc Binding Pocket



LC



HC

# De-Risked, Superior, Clinical-Stage Asset

## YY001 Summary

- ✓ YY001: lyophilized rBoNT/A
- ✓ Non-clinical pharmacology, safety and tox studies show no allergic reaction following local injection
- ✓ YY001 has successfully completed Ph1, 2 and 3 clinical studies in China for glabellar lines (GL)
- ✓ YY001 showed improved efficacy, satisfaction, safety and immunogenicity in head-to-head versus market leader
- ✓ Ph1 trial for upper limb spasticity initiated

## YY003 Summary

- ✓ YY003: liquid rBoNT/A
- ✓ YY001 and YY003 are formulated from the same drug substance, with comparable dose-related inhibitory effects as shown in non-clinical studies
- ✓ Novel formulation is animal and human derived component free, including human serum albumin, improving upon market leader
- ✓ Excellent stability, 24 months at 2-8 C
- ✓ Pre-filled syringe delivery provides significant ease of use advantage
- ✓ FDA-approved Ph2 dose escalation study for GL initiated in AUS

# Clinical Summary To Date

## YY001-001, lyophilized form

### Phase 1

single dose, 10, 20, and 30 U, with Botox 20U, GL (completed)

### Phase 2

single dose 20U, with Botox 20U, GL (completed)

### Phase 3

single dose 20U, with Botox 20U, GL (completed)

## YY001-002, lyophilized form

### Phase 2a

dose 200, 300, 400U, upper limb spasm, with Botox 200U dose (on-going)

### Phase 2b

to be dosed with selected dose from Ph2a study (to be conducted)

### Phase 3

(to be conducted)

## YY003, liquid form, PFS

### Phase 2a

dose 20, 30, 40U, GL (initiated)

### Phase 2b

single dose with selected dose from Ph2a (to be conducted)

### Phase 3

international multiple center trial (to be conducted)

# YY001: Botox H2H Clinical Summary

## Trial Design

Random, double-blind, multiple ascending dose, placebo-and positive drug-controlled, multi-center Ph1, 2 and Ph3 clinical trial in China to evaluate the safety, immunogenicity and efficacy of YY001 for the improvement of glabellar line

### Phase 1

50 participants, primary endpoint is to assess safety profile of YY01 during 4-week period following single injection and head-to-head comparison with Botox

### Phase 2

90 participants, primary endpoint is efficacy of YY001 in treating glabellar lines evaluated by investigators 4 weeks after a single injection, as well as safety and immunogenicity within 12 weeks; and head-to-head comparison with Botox

### Phase 3

526 participants, primary endpoint is the efficacy of YY001 in treating glabellar lines evaluated by both investigators and participants 4 weeks after single injection, as well as safety and immunogenicity within 12 weeks; head-to-head comparison with Botox

# YY001: Botox H2H Summary

## Clinical Development Timeline

- March 2022, IND approved for Ph ½ clinical
- July 2022, Ph1 commenced
- Sept 2022, Ph2 commenced
- Dec 2022, completed enrollment and dosed all participants in Ph2
- March 2023, GMP facility commenced operation, production for Ph3 clinical trial and future commercialization
- May 2023, Ph2 completed
- July 2023, submitted application for Ph3
- Dec 2023, initiated enrollment of Ph3
- Sep 2024, Ph3 completed
- 2024, NDA application

### Phase 1

- Quick onset
- Improved efficacy
- Higher satisfaction

### Phase 1

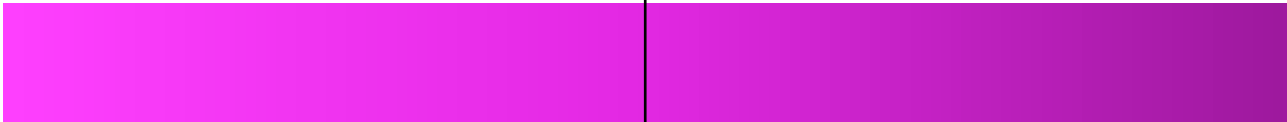
- Lower incidence of adverse reactions
- Lower incidence of injection site reactions

### Phase 1

- 0% incidence of Nab
- 0.3% incidence of YY001-related ADA

# Head-to-Head Clinical Study with Botox

Efficacy Score and Response Rate of Glabellar Line Treatment

| Dynamic 4<br>score Std. | <sup>3</sup><br>(severe)                                                                 | <sup>2</sup><br>(moderate)                                                                 | <sup>1</sup><br>(mild)                                                                         | <sup>0</sup><br>(no visible)                                                               |
|-------------------------|------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| Baseline                |        |                                                                                            |                                                                                                |                                                                                            |
| Post-dose               | <br>3 |        | <br>1 or 0 |                                                                                            |
|                         |                                                                                          | <br>2 |           | <br>0 |



No  
glabellar lines

Mild  
glabellar lines

Moderate  
glabellar lines

Severe  
glabellar lines

0

1

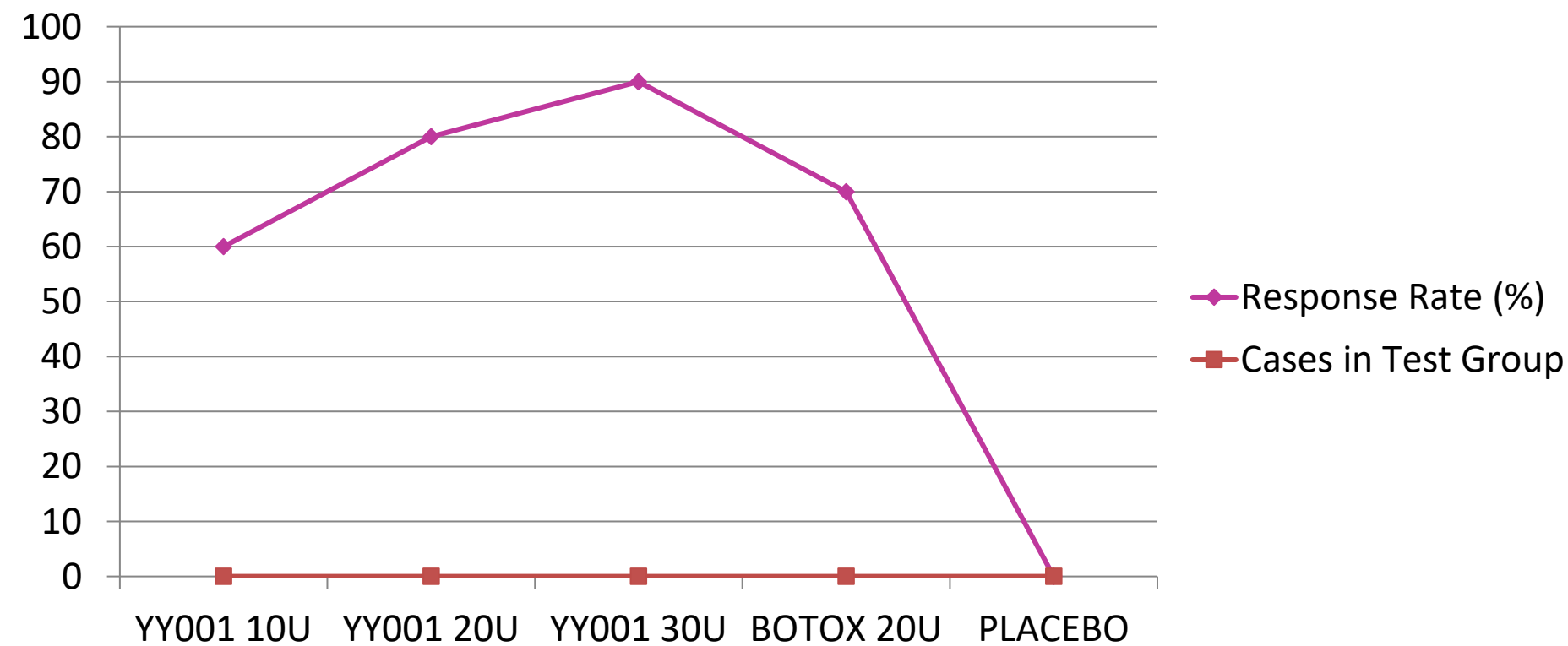
2

3

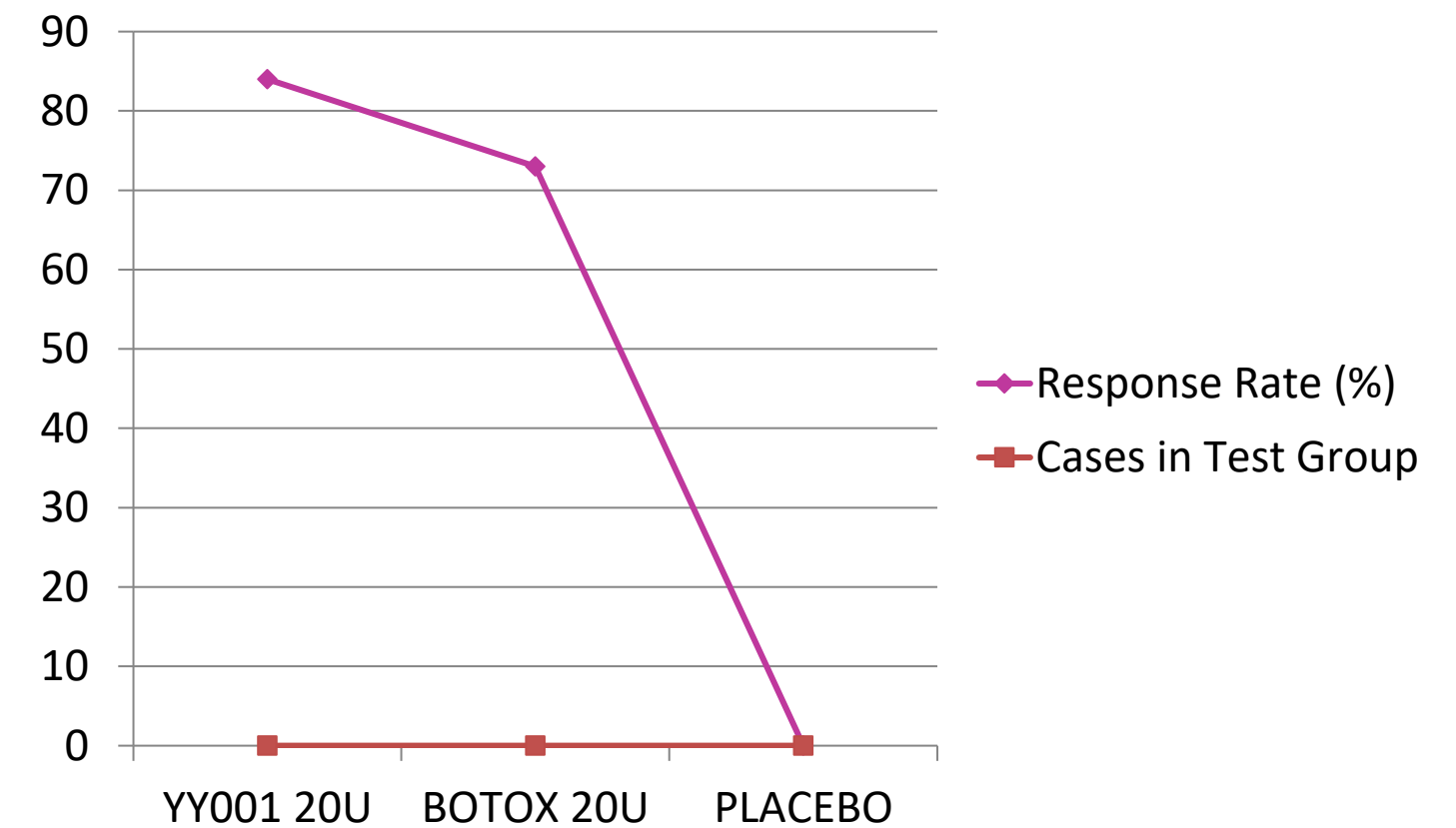
# Ph1/2 Clinical Study Results

Score and Response Rate Evaluated on Day 28

**10** cases in each test group



**51/30/9** cases in each test group

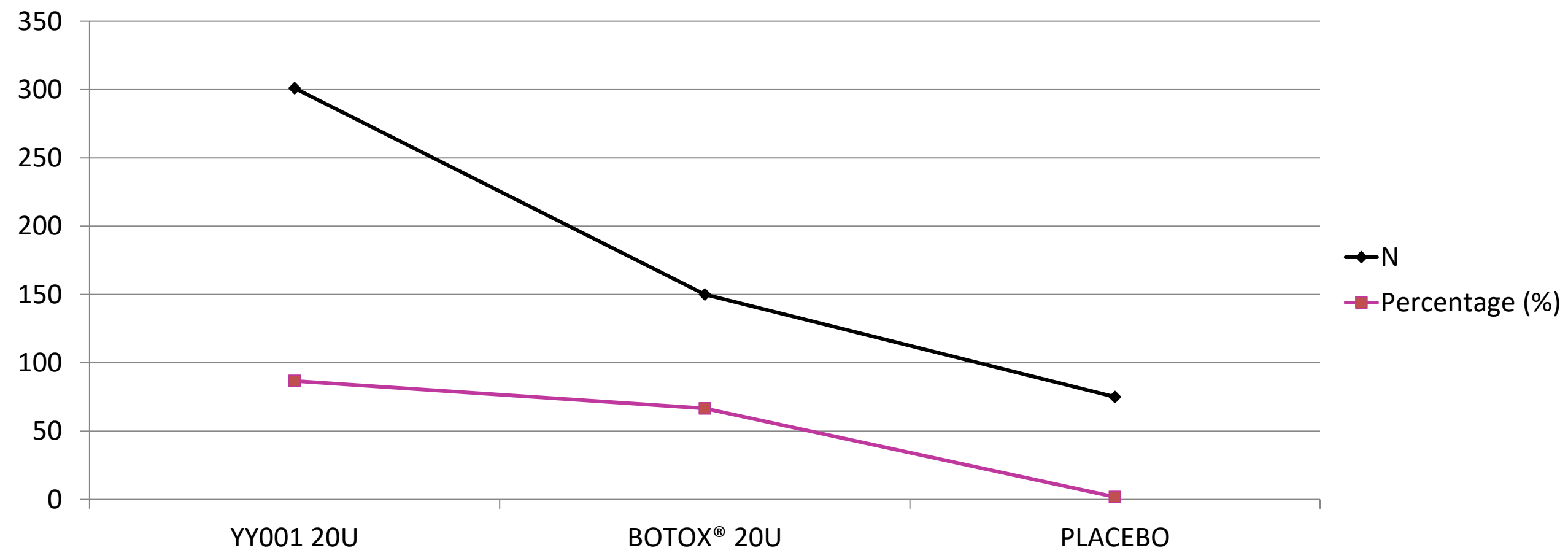


Response Rate =  $\frac{\text{(A) Investigator score = 0 or 1 AND (B) Investigator score reduced by AT LEAST 2 points from Baseline score}}{\text{No. of participants in each group}} \times 100\%$

# Ph3 Clinical Study Results

## Primary Efficacy Endpoint: Improved Composite Response Rate

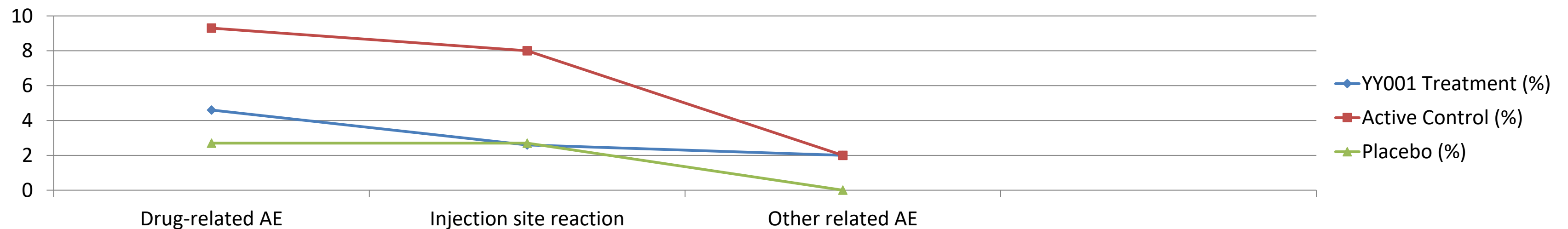
Composite response rates evaluated by investigators and participants at week 4 post-treatment (\*\*\*\*  $p < 0.0001$ )



# Ph3 Clinical Study Results

## High Safety Profile: Reduced Incidence Rate of AEs

Composite response rates evaluated by investigators and participants at week 4 post-treatment (\*\*\*\*  $p < 0.0001$ )



### Incidence rate of ADR

YY001 group was 4.6%, slightly higher than the placebo group (2.7%) and lower than the active control group (9.3%)

### Incidence of injection site reactions

YY001 group was 2.6%, similar to the placebo group (2.7%), and lower than the active control group (8.0%);

### Incidence rate of ADR

YY001 group was 4.6%, slightly higher than the placebo group (2.7%) and lower than the active control group (9.3%)

# Ph3 Clinical Study Results

## Immunogenicity Assessment

A total of 301 subjects of YY001 were tested for ADA at baseline, week 4 and week 12 after treatment

YY001-related ADA was positive in only 1 subject, with a positive rate of 0.3%

ADA positive samples were tested for Nab, all of which were negative. The incidence rate of neutralizing antibody was 0%

# YY003: Novel Liquid Formulation

**YY001 is a lyophilized formulation of recombinant botulinum toxin**

Has been successfully validated in the clinic with excellent efficacy, safety and low immunogenicity Ph 1, 2, and 3 studies for Glabellar Line Treatment

**YY003 is formulated from the same drug substance, and is a novel, animal and human protein-free, liquid formulation of recombinant botulinum toxin**

Novel liquid formulation, unique to YY003 and driving significant value, eliminates the need for human serum albumin, making YY003 free from animal and human source proteins versus market leader

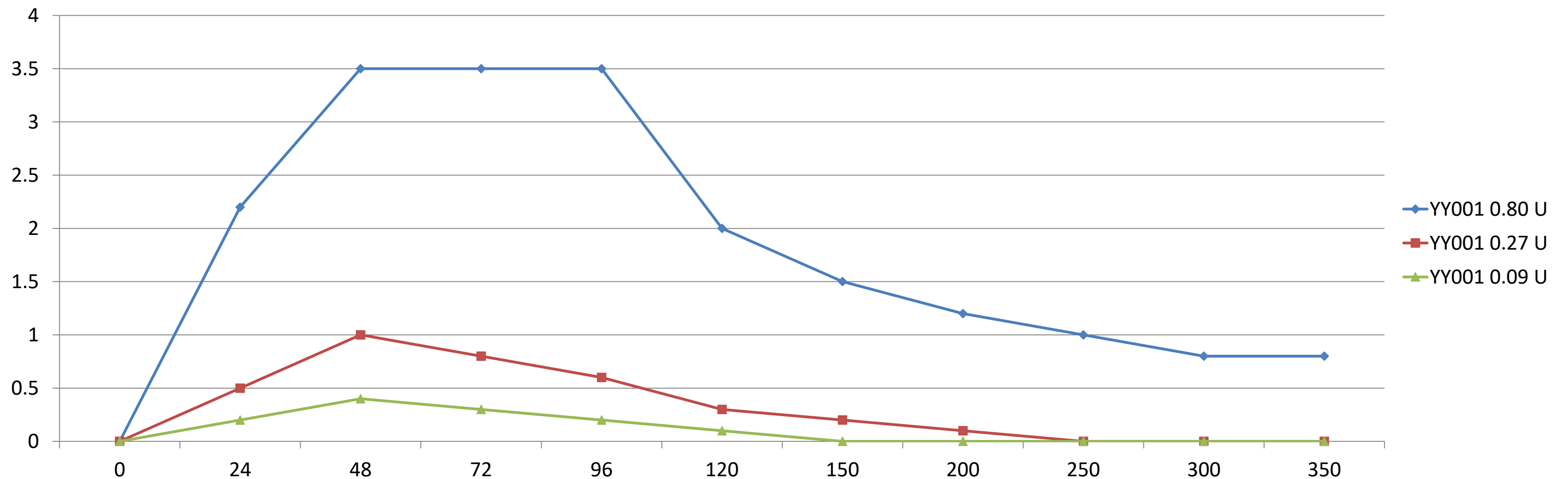
Excellent stability in liquid form, stable over 24 months at 2-8 C

Pre-filled syringe format significantly improves ease of use

# Comparable Performance

**YY003 has comparable performance to YY001, as shown in non-clinical studies**

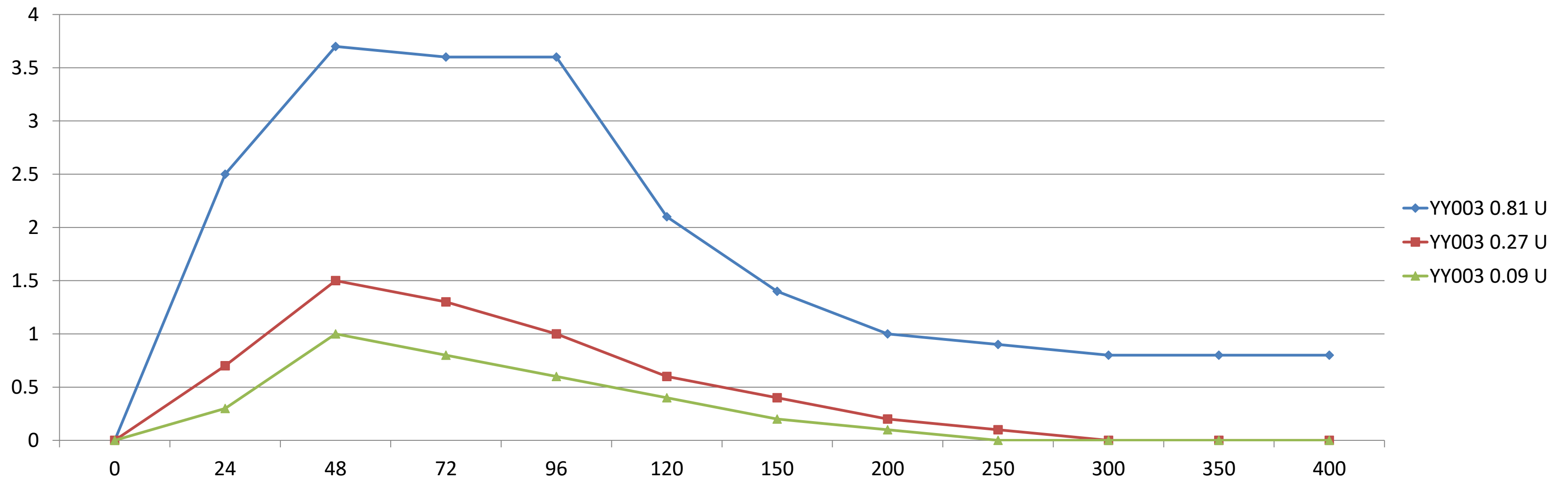
YY001 and YY003 show comparable, dose-related inhibitory effect on Extensor Digitorum Longus muscles in mice (inhibition via gastrocnemius muscle)



# Comparable Performance

**YY003 has comparable performance to YY001, as shown in non-clinical studies**

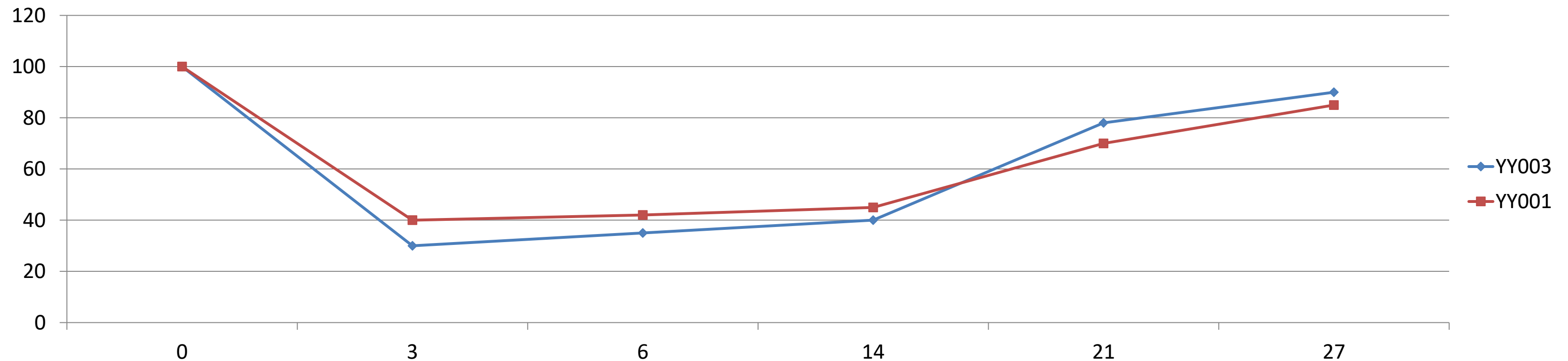
Additional data showing comparable inhibitory effect of YY001 and YY003 at same dose



# Comparable Performance

## Comparable performance shown via Compound Muscle Action Potential (CMAP) assay

- YY001 and YY003 show comparable inhibitory effect on gastrocnemius muscle contraction. Onset time within 24 hours post dosing
- YY001 CMAP ratio returning 27 days post administration and YY003 CMAP ratio returning 22 days post administration reflect reversibility of muscle inhibition



# YY003 R&D Timeline

**2024.01.20**

- Designed novel formulation, conducted patent search
- Conducted POC, formulation screening
- Started long-term stability 0-24 months

**2024.03.28**

- Filed first patent
- Formulation validation in house and in CRO
- Applied PCT, global filing

**2024.08.07**

- YY003 nominated for global development
- CRO (GMP) manufacturing of clinical samples
- Filed IND and approved
- Ph2 GL clinical trial in AUS

**H2 2026**

International multi-region clinical trial, Ph 3

# YY003 Data set in US IND Application

Rec BoNT/A  
Drug Substance

- Full CMC package
- Complete non-clinical profile (PD/Tox)
- PI/II/III clinical data (YY001 GL)

DP liquid form in  
PFS (YY003)

- Activity comparison YY001 vs YY003
- Active systemic anaphylaxis test (GLP)
- Local im. irritation test (GLP) Novel no HSA formulation component safety data (literature)
- Full formulation analysis package

# Pipeline Products

## Recombinant botulinum toxin type E

Type E potentially offers faster onset and shorter treatment duration compared to Type A toxin. Clinical use cases include scar and pain relief

Expressed Type E has been characterized, and manufacturing process is in development stage (cell bank established, preliminary process development and formulation completed enabling tox batch)

## Modified recombinant type A and type E

Leveraging protein engineering, to design a modified type A and type E to achieve longer duration of action as well as redirecting to different targets, including sensory neurons for neuropathic pain

AI tools are utilized to drive design. Products in proof-of-concept stage

# Pipeline Products

## Recombinant modified and non-modified type A and type E toxins

Development of type A and type E products for the veterinary market. Products are currently in proof-of-concept stage, and uses cases include canine and equine pain management and muscle spasms

Currently developing products in collaboration with a animal health partner

# IP Portfolio Overview

## Key Patent Families

### Patent Family 2, 3

- Composition Patent Family 2 covers YY001, fully recombinant botulinum toxin
- Patent Family 3 covers method of making YY001

### Patent Family 6, 7, 8

- Patent Families 6, 7, and 8 cover formulation
- Patent Family 6, specifically, covers novel formulation for YY003

## Previous IP activities conducted by Claruvis

- Patent due diligence review, including in US and EU jurisdictions
- FTO search and analysis for products in development, including YY003

# Non-Clinical Studies Conducted

## Non-clinical evaluation of recombinant BoNT/A

- Submitted to FDA for IND Application and approved

## Pharmacology

- Primary pharmacodynamics
  - Mouse bioassay
  - DAS assay in mice
  - CMAP assay in rats
- Safety Pharmacology

## Toxicology

- Full panel of animal toxicity assessment

# Non-Clinical Studies Conducted

## Toxicology

### Single-dose toxicity

- Single intramuscular injection dose range finding toxicity in rats with 4-week recovery period (non-GLP)
- Single dose intramuscular injection toxicity and safety pharmacology study in rats with 12-week recovery period (GLP)
- Single intramuscular injection dose range finding toxicity in monkeys with 4-week recovery period (non-GLP)
- Single dose intramuscular injection toxicity and safety pharmacology study in monkeys with 12-week recovery period (GLP)
- Summary of single intramuscular injection dose toxicity studies
- Intravenous injection maximum tolerated dose toxicity study in rats
- Single dose intravenous injection toxicity study in rats (GLP)

# Non-Clinical Studies Conducted

## Repeated-dose Toxicity

- 13-week repeated intramuscular injection toxicity and safety pharmacology studies in monkeys with 8-week recovery period (GLP)
- 39-week repeated intramuscular injection toxicity studies in monkeys with 26-week recovery period (GLP)
- Summary of repeated intramuscular injection dose toxicity studies

## Genotoxicity (NA)

## Carcinogenicity (NA)

# Non-Clinical Studies Conducted

## Reproductive Toxicity

- Intramuscular injection dose toxicity study on fertility and early embryonic development in rats (GLP)
- Intramuscular injection dose range finding study on embryo-fetal development toxicity in rats (non-GLP)
- Intramuscular injection toxicity study on embryo-fetal development in rats (GLP)
- Intramuscular injection dose range finding study on embryo-fetal development toxicity in rabbits (non-GLP)
- Intramuscular injection toxicity study on embryo-fetal development in rabbits (GLP)
- Intramuscular injection toxicity study on pre- and postnatal development in rats (GLP)

# Non-Clinical Studies Conducted

Local Tolerance and Other Studies (YY003, liquid formulation)

- Intramuscular irritation test of YY003 in rats (GLP)
- Active systemic anaphylaxis test of YY003 in guinea pigs (GLP)

HSA-replacement component safety data

- General toxicity
- Genotoxicity
- Carcinogenicity toxicity
- Reproductive toxicity and development toxicity

# IP Portfolio Overview

## Primary

- Molecular weight
- Sequence analysis
- Di-sulfide bond analysis
- Post-translational modification
- Infrared spectrum
- Free thiol group

## Polymerization

- Ultrafiltration

## Tertiary structure

- UV light analysis (Inner and Ext)
- UV light analysis (near and far)
- Therma Study

## Particle size

- Dynamic light scattering

# Therapeutic Uses of Botulinum Toxin

| FDA-Approved Indications                                               | Off-label Uses                      |
|------------------------------------------------------------------------|-------------------------------------|
| Chronic migraine                                                       | Neurogenic thoracic outlet syndrome |
| Cervical dystonia                                                      | Epicondylitis                       |
| Blepharospasm and strabismus                                           | Post-stroke pain                    |
| Primary axillary hyperhidrosis                                         | Post-herpetic neuralgia             |
| Adult bladder dysfunction                                              | Diabetic neuropathy                 |
| Pediatric detrusor overactivity associated with a neurologic condition | Trigeminal neuralgia                |
| Spasticity                                                             | Neuropathic pain                    |
| Cosmetic uses                                                          | Spinal cord injury                  |
|                                                                        | Myofascial pain                     |
|                                                                        | Bladder pain                        |

# Therapeutic Uses of Botulinum Toxin

| Focal Dystonia<br>involuntary, sustained,<br>or spasmodic patterned<br>muscle activity | Spasticity Velocity-<br>dep. increase in<br>muscle tone     | Non-dystonic<br>disorders<br>involuntary muscle<br>activity | Chronic pain and<br>disorders of<br>localized muscle<br>spasms | Smooth muscle<br>hyperactive<br>disorders        | Sweating,<br>salivary, and allergy<br>disorders              | Cosmetic use                             |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------|-------------------------------------------------------------|----------------------------------------------------------------|--------------------------------------------------|--------------------------------------------------------------|------------------------------------------|
| Cervical dystonia<br>(spasmodic torticollis)                                           | Stroke                                                      | Hemifacial spasm                                            | Chronic low back pain                                          | Neurogenic<br>bladder- Detrusor                  | Axillary and palmar<br>hyperhidrosis                         | Hyperkinetic<br>facial lines             |
| Laryngeal dystonia<br>(spasmodic dysphonia)                                            | Traumatic brain<br>injury                                   | Tremor                                                      | Myofascial pain<br>syndrome                                    | hyperreflexia Detrusor-<br>sphincter dyssynergia | Frey syndrome, also known<br>as auriculotemporal<br>syndrome | Hypertrophic<br>platysma<br>muscle bands |
| Limb dystonia (writer's<br>cramp)                                                      | Cerebral palsy                                              | Tics                                                        | Tension headache                                               | Benign prostatic<br>hypertrophy                  | Drooling in cerebral palsy<br>and other neuro disorders      |                                          |
| Oromandibular dystonia                                                                 | Multiple sclerosis                                          | Myokymia and<br>synkinesis                                  | Chronic migraine<br>headache                                   | Achalasia cardia                                 | Nasal allergy and allergic<br>rhinitis                       |                                          |
| Orolingual dystonia                                                                    | Spinal cord injury                                          | Tinnitus (due to<br>myoclonus of muscles)                   | Medication overuse<br>headache                                 | Hirschsprung disease                             |                                                              |                                          |
| Truncal dystonia                                                                       | Strabismus (disorder of<br>conjugate eye move)<br>nystagmus | Hereditary muscle<br>cramps                                 | Lateral epicondylitis                                          | Sphincter of Oddi<br>dysfunctions                |                                                              |                                          |
|                                                                                        |                                                             | Nocturnal bruxism                                           | Knee pain                                                      | Hemorrhoids                                      |                                                              |                                          |
|                                                                                        |                                                             | Trismus                                                     | Shoulder pain                                                  | Chronic anal<br>fissures                         |                                                              |                                          |
|                                                                                        |                                                             | Anismus                                                     | Neuropathic pain                                               | Raynaud's<br>Phenomenon                          |                                                              |                                          |

**neuro**lux  
**bio**

Thank you!