

NeuroLux Bio — Pitch Deck Content Extract

Redefining Precision in Aesthetic Neurotoxins

Company Overview — Confidential 2025

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)

Botox®: Onset 2-3 days; Duration 3-4 months; Albumin-free: No; Notes: Category leader; broad KOL base.

Dysport®: Onset 1-2 days; Duration 3-4 months; Albumin-free: No; Notes: Dilution flexibility; spread profile.

Xeomin®: Onset 2-4 days; Duration 3-4 months; Albumin-free: Yes; Notes: Naked toxin (no complexing proteins).

Jeuveau®: Onset 2-3 days; Duration 3-4 months; Albumin-free: No; Notes: Value positioning in some accounts.

Daxxify®: Onset 1-2 days; Duration ≈6 months; Albumin-free: Yes (peptide-stabilized); Notes: Longest labeled effect; peptide excipient.

NeuroLux (proposed): Onset <2 days (target); Duration 6-9 months (target); Albumin-free: Yes (target); Notes: 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: 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

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

Phase 1 (FIH, glabellar lines): safety, PK/PD, dose-ranging (n≈60-80).

Phase 2: pivotal dose selection; endpoints: ≥2-grade improvement at Week 4; duration to loss of effect.

Phase 3: two randomized, placebo-controlled trials + open-label safety extension.

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):

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

Year 1 revenue: \$456M

Year 3 revenue (includes modest international): \$1.46B

Note: these are placeholders for diligence and will be refined with price/volume testing.

Team

Founder/CEO: aesthetics biotech operator; prior exits in injectables.
CMO: board-certified dermatologist; PI on ≥ 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.
Clear clinical and practice unmet needs; room for a premium, durable option.
Team with toxin, CMC, and KOL launch experience.
NeuroLux Bio aims to become the long-duration, rapid-onset standard.

Global Market Growth

2023: 11.0 USD Billion -> 2030: 21.0 USD Billion (headline figure cited: \$32.0B).
Source: Grand View Research, 'Botulinum Toxin Market Size & Trends Report' (2023 baseline, forecast to 2030).

U.S. Market Growth

2023: 4.5 USD Billion -> 2030: 9.0 USD Billion (headline figure cited: \$13.5B).
Source: Grand View Research, 'U.S. Botulinum Toxin Market Size & Forecast' (2023 baseline, forecast to 2030).

U.S. Share of Global (2023)

U.S.: 42% of global market.
Rest of World: 58%.
Source: Grand View Research (global & U.S. estimates, 2023).

Neuromodulator Demand in the U.S.

2023: 9.5 million patients.

2024: 9.9 million patients.

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

Positioning

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

Economic 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.

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

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

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

Competitive Watch: Claruvis 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 (NCT06481475).

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

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

FDA BLA Review Timelines

Priority Review: 6 months.

Standard Review: 10 months.

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

FDA User Fees (FY2025, PDUFA VII) - Biologics

Application fee (requiring clinical data): ~\$4.31M.

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

Program fee (per marketed product): ~\$403,889 annually.

Note: waivers/reductions may apply (e.g., small business, orphan).

Feature Comparison (Aesthetic Indication)

Claravis YY003*: Formulation - Liquid, pre-filled syringe; Onset - 2-3 days (est.); Duration - 3-4 months (est.); Stabilizer - Recombinant process, proprietary; Storage - Refrigerated.

Daxxify®: Formulation - Lyophilized, reconstitution; Onset - 1-2 days; Duration - ~6 months; Stabilizer - Peptide; Storage - Refrigerated.

Botox®: Formulation - Lyophilized, reconstitution; Onset - 2-3 days; Duration - 3-4 months; Stabilizer - Albumin; Storage - Refrigerated.

NeuroLux (target): Formulation - Liquid or ready-to-use; Onset - <2 days; Duration - 6-9 months; Stabilizer - Albumin-free (novel); Storage - Room temp stable (target).

*Claravis 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)

Preclinical: 18 months from start.

Phase 1: 12 months.

Phase 2: 18 months.

Phase 3: 10 months.

BLA Review: 10 months.

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

Cash Requirements by Stage (Illustrative)

Preclinical/IND: ~\$15M.

Phase 1: ~\$12M.

Phase 2: ~\$24M.

Phase 3: ~\$50M.

BLA/Launch Prep: ~\$20M.

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

Company Overview

Next-Generation Botulinum Therapy

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 Claravis Pharma. Claravis 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 Ph3 trials, and the liquid formulation (YY003) has shown comparable potency and long-term stability in Ph2 trials.

Advantages of Liquid Formulation

- 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: Claruvis Pharmaceutical Co.

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

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

NeuroLux Bio holds global rights (excluding China) to the liquid recombinant asset, YY003, and plans to initiate a multi-national Ph3 trial in 2026. The company also plans to leverage Claruvis' 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:

YY003 - Recombinant Botulinum Toxin A, Liquid: Target use - Glabellar Lines & Lateral Canthal Lines; Commercialization - 2H 2028.

YY003 - Recombinant Botulinum Toxin A, Liquid: Target use - TBD; Commercialization - 1H 2029.

YY003 - Recombinant Botulinum Toxin A, Liquid: Target use - TBD; Commercialization - 1H 2030.

Overview: 3 Year Plan

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 through 2028.

Financing allows for development and market readiness: 2H 2028.

Forecast tested against industry benchmarks to validate the reasonableness of our assumptions.

Natural BoNT/A

Botulinum toxin is a neurotoxic protein produced by *Clostridium botulinum*, a gram-positive anaerobic bacterium. The natural complex is composed of the BoNT/A neurotoxin together with accessory proteins NTNHA, HA70, HA17, and HA33 (L-Complex HA-NTNH-BoNT).

Well-Known Mechanism of Action

The light chain of the botulinum toxin cleaves specific sites on the SNARE proteins (including SNAP-25 and synaptobrevin/syntaxin). This cleavage inhibits the release of the neurotransmitter acetylcholine, which leads to a neuromuscular blocking effect and paralysis of muscle activity.

Natural Botulinum: Little Innovation Since the 1970s

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

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.

Contamination risk associated with nBoNT manufacturing leads to high maintenance costs and stringent quality control measures.

SDS-PAGE analysis of the BoNT/A complex (non-reduced and reduced) identifies: BoNT/A (full length), NTN1, NTN1 (C-term.), BoNT/A (heavy chain), Peptidase (M20/M25/M40 family), BoNT/A (light chain), HA70 (C-term.), HA33, HA70 (N-term.), HA17, HA70 (C-term.).

Recombinant Botulinum

Claravis 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.

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

Structural features shown for BoNT/A YY001: 150kDa full protein, Light Chain (LC), Key Di-Sulfide Bond, and Zinc Binding Pocket (Heavy Chain, HC).

De-Risked, Superior, Clinical-Stage Asset

YY001 Summary (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 studies versus the market leader.

Ph1 trial for upper limb spasticity initiated.

YY003 Summary (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 the market leader.

Excellent stability: 24 months at 2-8°C.

Pre-filled syringe delivery provides a significant ease-of-use advantage.

FDA-approved Ph2 dose-escalation study for GL initiated in Australia.

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 Head-to-Head Clinical Summary - Trial Design

Randomized, 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 lines.

Phase 1: 50 participants; primary endpoint is safety profile of YY001 during a 4-week period following a single injection, plus 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, plus safety and immunogenicity within 12 weeks, and head-to-head comparison with Botox.

Phase 3: 526 participants; primary endpoint is efficacy of YY001 evaluated by both investigators and participants 4 weeks after a single injection, plus safety and immunogenicity within 12 weeks, and head-to-head comparison with Botox.

YY001: Botox Head-to-Head Summary - Clinical Development Timeline

March 2022: IND approved for Ph1/2 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 highlights

Quick onset, improved efficacy, higher satisfaction.

Lower incidence of adverse reactions; lower incidence of injection site reactions.

0% incidence of NAb; 0.3% incidence of YY001-related ADA.

Head-to-Head Clinical Study with Botox - Efficacy Score & Response Rate

Glabellar line treatment is scored on a Dynamic 4-point scale (0 = no visible lines, 1 = mild, 2 = moderate, 3 = severe). At baseline, patients scored 2-3 (moderate-severe). Post-dose, YY001-treated patients moved to scores of 0-1 (mild/no visible lines).

Ph1/2 Clinical Study Results - Score and Response Rate Evaluated on Day 28

Group of 10 cases per arm: response rates of 60% (YY001 10U), 80% (YY001 20U), 90% (YY001 30U), 70% (Botox 20U), and 0% (Placebo).

Larger group (51/30/9 cases per arm): response rates of ~84% (YY001 20U), ~73% (Botox 20U), and ~0% (Placebo).

Response Rate = [(A) Investigator score = 0 or 1 AND (B) Investigator score reduced by at least 2 points from Baseline score] / Number of participants in each group x 100%.

Ph3 Clinical Study Results - Primary Efficacy Endpoint

Primary endpoint: improved composite response rate, evaluated by investigators and participants at Week 4 post-treatment (**** p<0.0001).

N and composite response rate by arm: YY001 20U (N=300, ~87%), Botox® 20U (N=150, ~68%), Placebo (N=75, ~3%).

Ph3 Clinical Study Results - Safety Profile

Reduced incidence rate of adverse events (AEs); composite rates evaluated by investigators and participants at Week 4 post-treatment (**** p<0.0001).

Incidence rate of ADR: YY001 group 4.6%, slightly higher than placebo (2.7%) and lower than active control (9.3%).

Incidence of injection site reactions: YY001 group 2.6%, similar to placebo (2.7%), lower than active control (8.0%).

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, a positive rate of 0.3%.

ADA-positive samples were tested for NAb, all of which were negative - a 0% incidence rate of neutralizing antibody.

YY003: Novel Liquid Formulation

YY001 is a lyophilized formulation of recombinant botulinum toxin, successfully validated in the clinic with excellent efficacy, safety and low immunogenicity across Ph1, 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 eliminates the need for human serum albumin, making YY003 free from animal and human source proteins versus the 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 (Non-Clinical Studies)

YY001 and YY003 show comparable, dose-related inhibitory effect on Extensor Digitorum Longus muscles in mice (inhibition via gastrocnemius muscle), tested at 0.09U, 0.27U, and 0.80U (YY001) and 0.09U, 0.27U, and 0.81U (YY003), with closely matched response curves over 0-350/400 hours.

Comparable performance was also shown via Compound Muscle Action Potential (CMAP) assay:

YY001 and YY003 show comparable inhibitory effect on gastrocnemius muscle contraction; onset within 24 hours post-dosing.

YY001 CMAP ratio returns to baseline 27 days post-administration; YY003 CMAP ratio returns 22 days post-administration - reflecting 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 study (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 initiated in Australia.

H2 2026 - International multi-region clinical trial, Phase 3.

YY003 Data Set in US IND Application

Rec BoNT/A Drug Substance

Full CMC package.

Complete non-clinical profile (PD/Tox).

Ph1/2/3 clinical data (YY001 GL).

DP Liquid Form in PFS (YY003)

Activity comparison YY001 vs YY003.

Active systemic anaphylaxis test (GLP).

Local immunological 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 the 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 are in the proof-of-concept stage.

Recombinant Modified and Non-Modified Type A and Type E Toxins (Veterinary)

Development of type A and type E products for the veterinary market. Products are currently in the proof-of-concept stage, with use cases including canine and equine pain management and muscle spasms. Currently developing products in collaboration with an animal health partner.

IP Portfolio Overview

Key Patent Families

Patent Family 2: composition patent covering YY001, fully recombinant botulinum toxin.

Patent Family 3: covers method of making YY001.

Patent Families 6, 7, 8: cover formulation; Patent Family 6 specifically covers the 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.

Analytical Characterization Categories

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 external; near and far), thermal study.

Particle size: dynamic light scattering.

Non-Clinical Studies Conducted

Non-clinical evaluation of recombinant BoNT/A was submitted to FDA for IND Application and approved.

Pharmacology

Primary pharmacodynamics: mouse bioassay, DAS assay in mice, CMAP assay in rats.

Safety pharmacology.

Toxicology - Single-Dose

Single intramuscular injection dose-range-finding toxicity in rats, 4-week recovery (non-GLP).

Single-dose intramuscular injection toxicity and safety pharmacology study in rats, 12-week recovery (GLP).

Single intramuscular injection dose-range-finding toxicity in monkeys, 4-week recovery (non-GLP).

Single-dose intramuscular injection toxicity and safety pharmacology study in monkeys, 12-week recovery (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).

Toxicology - Repeated-Dose

13-week repeated intramuscular injection toxicity and safety pharmacology studies in monkeys, 8-week recovery (GLP).

39-week repeated intramuscular injection toxicity studies in monkeys, 26-week recovery (GLP).

Summary of repeated intramuscular injection dose toxicity studies.

Genotoxicity: not applicable.

Carcinogenicity: not applicable.

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).

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 and developmental toxicity.

Therapeutic Uses of Botulinum Toxin

FDA-Approved Indications

Chronic migraine; cervical dystonia; blepharospasm and strabismus; primary axillary hyperhidrosis; adult bladder dysfunction; pediatric detrusor overactivity associated with a neurologic condition; spasticity; cosmetic uses.

Off-Label Uses

Neurogenic thoracic outlet syndrome, epicondylitis, post-stroke pain, post-herpetic neuralgia, diabetic neuropathy, trigeminal neuralgia, neuropathic pain, spinal cord injury, myofascial pain, bladder pain.

Broader Clinical Categories Cited

Focal dystonia (involuntary/spasmodic muscle activity): cervical dystonia, laryngeal dystonia, limb dystonia, oromandibular dystonia, orolingual dystonia, truncal dystonia.

Spasticity (velocity-dependent increase in muscle tone): stroke, traumatic brain injury, cerebral palsy, multiple sclerosis, spinal cord injury, strabismus/nystagmus.

Non-dystonic disorders: hemifacial spasm, tremor, tics, myokymia and synkinesis, tinnitus (due to myoclonus), hereditary muscle cramps, nocturnal bruxism, trismus, anismus.

Chronic pain and localized muscle spasms: chronic low back pain, myofascial pain syndrome, tension headache, chronic migraine headache, medication overuse headache, lateral epicondylitis, knee pain, shoulder pain, neuropathic pain.

Smooth muscle hyperactive disorders: neurogenic bladder-detrusor, detrusor-sphincter dyssynergia, benign prostatic hypertrophy, achalasia cardia, Hirschsprung disease, sphincter of Oddi dysfunction, hemorrhoids, chronic anal fissures, Raynaud's phenomenon.

Sweating, salivary, and allergy disorders: axillary and palmar hyperhidrosis, Frey syndrome, drooling in cerebral palsy and other neuro disorders, nasal allergy and allergic rhinitis.

Cosmetic use: hyperkinetic facial lines, hypertrophic platysma muscle bands.