Evaluation of CNT201: A Novel Recombinant Collagenase Injection for the Treatment of Dupuytren's Contracture: P1/2 Clinical Trial

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INTRODUCTION

CNT201 is a high-purity, animal source-free recombinant collagenase developed to treat Dupuytren's contracture (DC), a condition characterized by collagen buildup under the skin of the palm, forming palpable cords. CNT201 comprises a 1:1 ratio of two microbial collagenases originated from *Clostridium histolyticum* and produced through a toxin-free, genetically engineered *Escherichia coli* process. This manufacturing technology enables high quality and may offer advanced safety profile over existing therapies. The study aims to evaluate the safety, tolerability, efficacy, pharmacokinetics (PK), and immunogenicity of CNT201 in adults with DC.

CNT201: PROFILE & DIFFERENTIATION

Established
Better quality
Animal source free and hemolytic toxins free

Established
Advanced formulation
Single vial presentation enabled by improved formulation technology

Under development
Clinical superiority
Differentiated safety profiles

		XIAFLEX®	CNT201	Expected Advantage
Origin and mixture ratio (Same)		Collagenase class I and class II originating from *Clostridium histolyticum* (same mixture ratio)		• Securing marketing authorization based on the same MoA
DS	Strain for manufacture	*Clostridium histolyticum* (hemolytic toxin)	Recombinant *E. coli* (no hemolytic toxin)	• Improved safety by eliminating hemolytic toxins • Minimized manufacturing costs through CDMO utilization
DS	Animal source	Yes	No	• Free from critical CMC issues
DP	Formulation	2 vials presentation (dedicated diluent required)	Single vial presentation (Aiming 4 years stability / fast dissolution)	• Minimized manufacturing and cold-chain distribution costs • Enhanced convenience for HCP

ELIGIBILITY CRITERIA

Men or women aged 18 to 75 years with primary Dupuytren's contracture involving at least one finger (excluding the thumb), characterized by a palpable cord and a positive Table Top Test, and presenting with a fixed flexion deformity of 20–100° at the MP joint or up to 80° at the PIP joint, who are treatment-naive to CNT201 and have no prior history of collagenase or surgical treatment for Dupuytren's contracture.

TRIAL OBJECTIVES

P1. Assess safety and tolerability of CNT201 in adults with DC.
P2. Evaluate efficacy in reducing joint contracture.

S1. Assess clinical improvement after first injection.
S2. Measure systemic exposure to CNT201 components.
S3. Characterize CNT201 immunogenicity in blood.

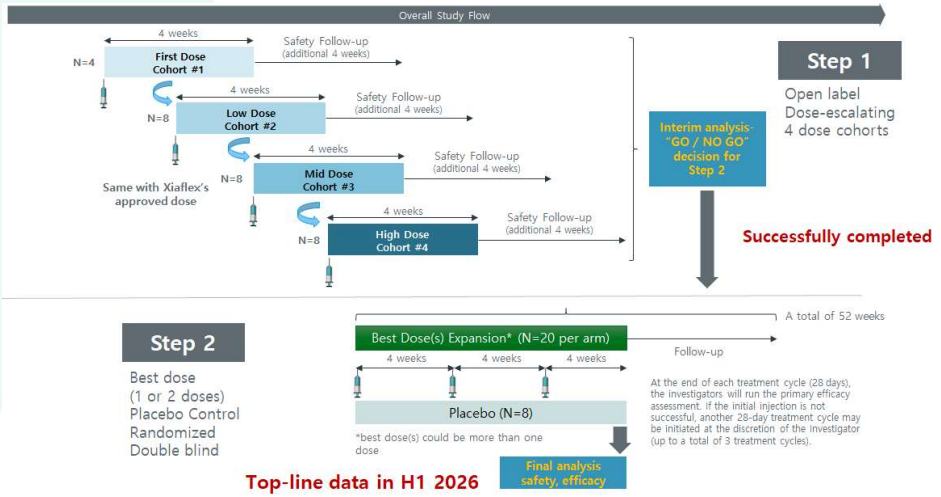
TRIAL DESIGN

This Phase 1/2 study is conducted in two parts:

- **Step 1 (Dose Escalation)**: Up to 36 participants will be enrolled at four Australian sites. Cohort 1 includes four participants, while Cohorts 2–4 each enroll eight participants, evaluating four dose levels of CNT201.
- **Step 2 (Dose Expansion)**: Up to 56 participants will be enrolled in a randomized, double-blind, placebo-controlled design at Australian and European sites. Participants will receive CNT201 or placebo in up to three treatment cycles.

Inclusion criteria require primary DC diagnosis with a palpable cord and specific degrees of joint contracture. Participants with prior collagenase or surgical treatments for DC are excluded. Primary endpoints assess contracture reduction to within 0–5° of normal extension within 29 days. Secondary endpoints include ≥50% contracture reduction, changes in range of motion, time to success, and patient/physician satisfaction. PK and immunogenicity assessments are also conducted.

SCHEMATIC DESIGN: PHASE 1/2 in DUPUYTREN'S CONTRACTURE



ACCURAL

Enrollment and treatment of 20 participants in the Step 1 dose-escalation phase have been completed.
In Step 2, 32 participants will be enrolled in the dose-expansion phase using the RP2D, with a 3:1 randomization ratio of CNT201 to placebo.

SUMMARY

- CNT201's novel recombinant collagenase injection and promising early data suggest potential advantages over existing therapies for DC.
- This study evaluates its comprehensive safety, efficacy, and pharmacological profile, aiming to advance treatment options for this challenging condition.

FUNDING

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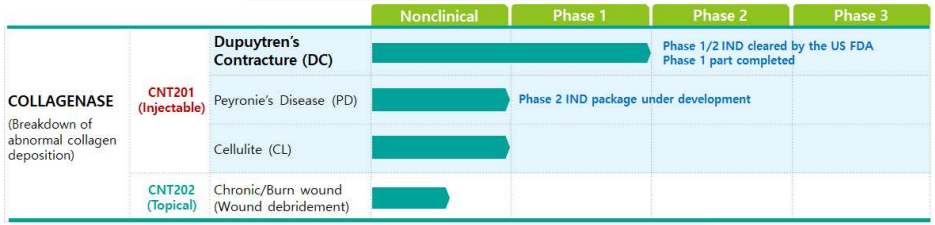
CONNEXT PIPELINE



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