

CLINICAL TRIAL OUTCOME DATA

Protocol Phase III Summary Report

STUDY ID CT-2024-8842

PRINCIPAL INVESTIGATOR Dr. Elena Richards

COMPLETION DATE October 14, 2023

SAMPLE SIZE (N) 450 Participants

STUDY ARM Double-Blind Placebo

STATUS Peer Review Pending

ENDPOINT CATEGORY	PRIMARY METRIC	INTERVENTION (N=225)	CONTROL (N=225)	P-VALUE
Efficacy	Symptom Reduction >50%	78.2%	34.1%	< 0.001
Safety	Adverse Events (Grade 3+)	4.2%	3.8%	0.82
Pharmacokinetics	Mean Serum Conc. (\hat{I} g/mL)	14.5 (\hat{A} \pm 2.1)	0.0	N/A
Patient Reported	QoL Index Improvement	+22.4 pts	+5.1 pts	< 0.01

Key Findings: The intervention met the primary superiority endpoint with a statistically significant margin. Safety profile remains consistent with previous Phase II observations. No significant variance in biomarkers across demographic subgroups.

Signature of Lead Statistician

Date of Authentication