A Phase 1a/b study of SAT-3247 in healthy volunteers and adult participants with Duchenne muscular dystrophy

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satellos

REGENERATING MUSCLE FROM WITHIN™

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Satellos: Restoring Muscle Regeneration in Duchenne Muscular Dystrophy

Duchenne is Driven by Failed Muscle Regeneration

Muscle growth exceeds loss.
Functional capacity is preserved

Tipping Point
Muscle loss > gains

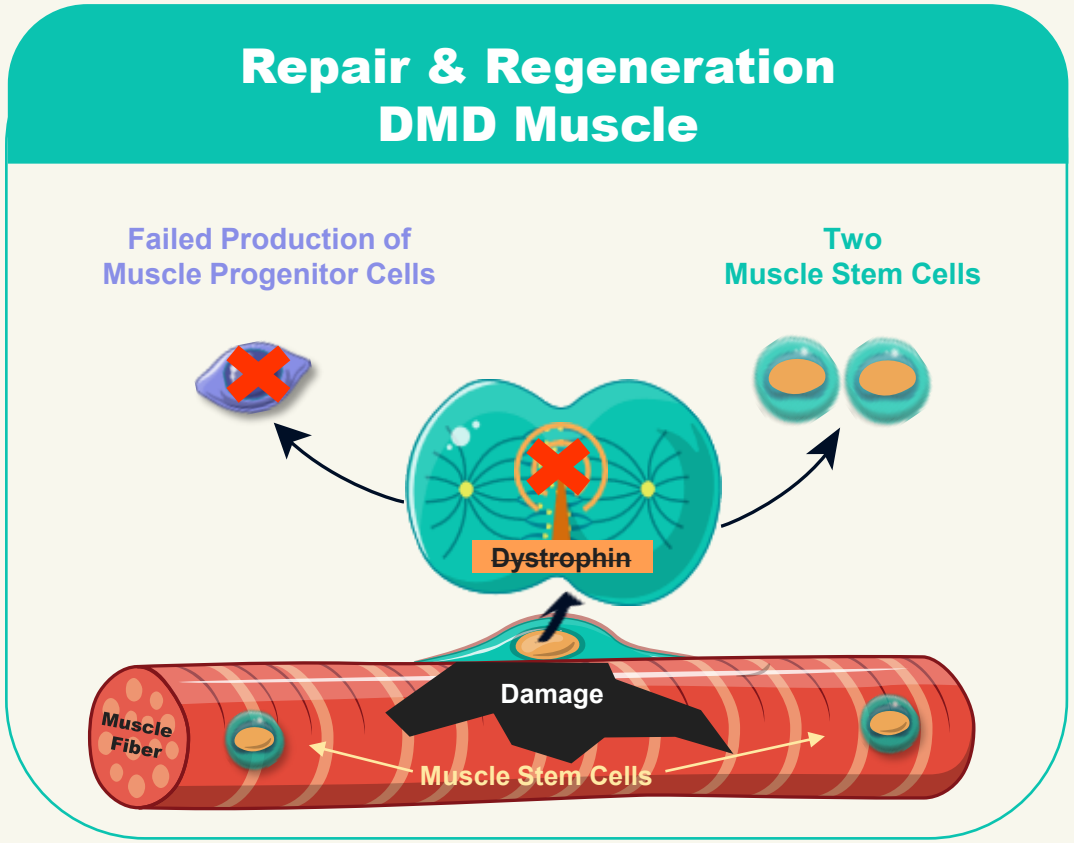
Regeneration Fails
Progressive and continuous muscle loss

Satellos discovered why muscle regeneration fails in DMD and invented SAT-3247 to potentially address the problem

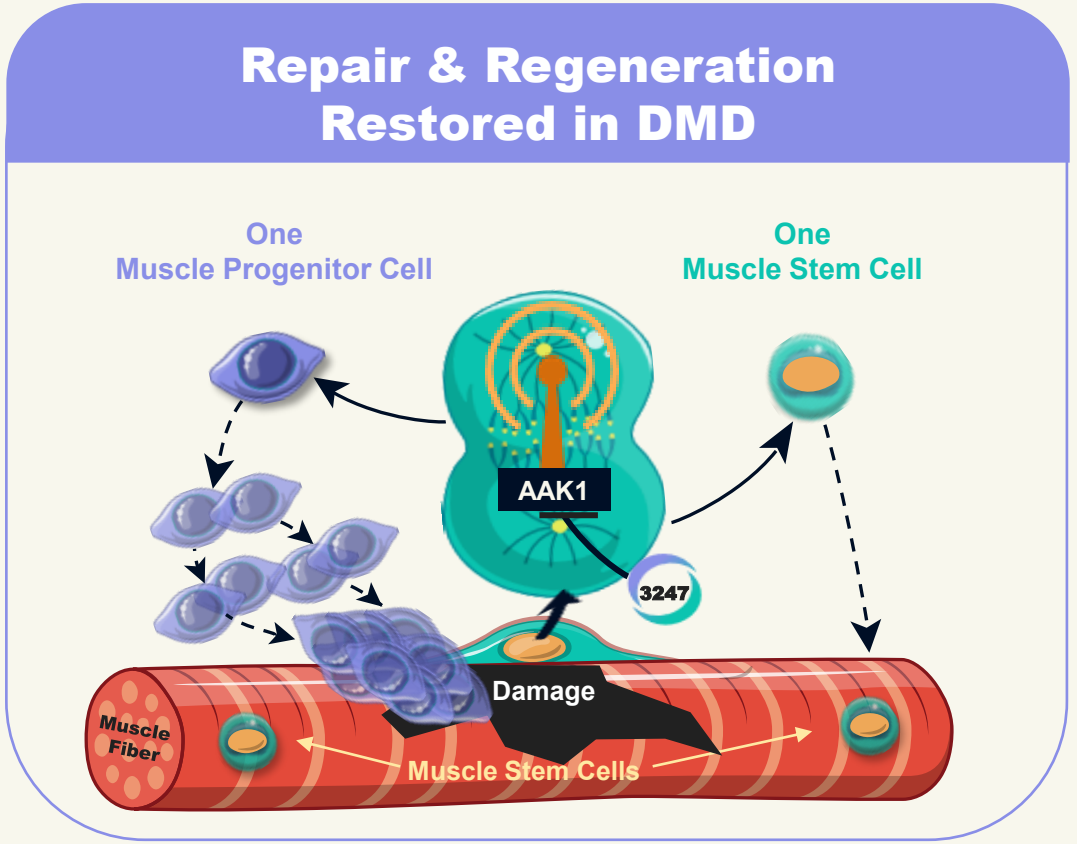
- ☑ Oral tablet
- ☑ Once Daily
- ☑ Well tolerated
- ☑ Non-Invasive

Satellos Discovery: Progenitor Formation & Regeneration Can Be Restored

Inhibition of AAK1 with SAT-3247 Replaces Missing Dystrophin Signal



Symmetric division without Dystrophin Signal
0 progenitors + 2 stem cells



Asymmetric division with AAK1 inhibition
1 progenitor + 1 stem cell

SAT-3247-CL-101

First in Human SAD/MAD Safety, PK, PD and Efficacy Study With Healthy Volunteers and Adult DMD Participants

TRAILHEAD

Open-Label Safety, PD and Efficacy Study in Adult DMD Participants

SAT-3247 Phase 1 First-in-Human Clinical Trial

Ph 1a: Healthy Volunteers (n=72)		Ph 1b: DMD Adults
SAD* Study	MAD* Study	28-day, Open-Label Study
▪ 10 - 400 mg ▪ 5 cohorts of 8 ▪ Single dose / 1 day	▪ 60 - 240 mg ▪ 4 cohorts of 8 ▪ Single dose / 7 days	▪ 60 mg daily dose, weekdays only for 4 weeks ▪ 5 patients enrolled and completed ▪ Age range 20 – 27, all on steroids

SAT-3247 was well tolerated with a favorable safety profile across Ph 1a & 1b studies

Endpoints

Primary (Ph 1a & 1b): Safety & tolerability [labs, vitals, ECG, physical exam]

Secondary (Ph 1a & 1b): Pharmacokinetic exposure (PK)

Exploratory (Ph 1b only): Grip/pinch strength, upper body effort, lung function (FVC), serum markers

**SAD: single ascending dose; *MAD: multiple ascending dose.*

SAT-3247: Well Tolerated With Favorable Safety Profile and Desired PK Profile in Phase 1

Key Demographics

Characteristic	SAD/FE (n=40)	MAD (n=32)	Ph 1b (n=5)
Age at screening (years)			
Mean	33.2	37.5	23.4
SD	12.7	15.1	2.7
Min, Max	20, 65	18, 64	20, 27
Sex at birth n (%)			
Female	23 (57.5)	7 (21.9)	0
Male	17 (42.5)	25 (78.1)	5 (100)
Weight at screening (kg)			
Mean	74.39	76.98	51.72
SD	15.23	13.89	12.19
Min, Max	47.6, 107.1	50.6, 105.3	36.3, 65.3
Concomitant steroid use n(%)	N/A	N/A	5 (100)
Concomitant exon skipping n(%)	N/A	N/A	0

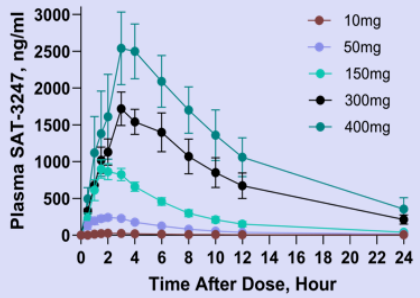
Safety Summary

AE Category	SAD (n=40)	MAD (n=32)	FE (n=8)	Ph 1b (n=5)
Any TEAE	9	18	4	4
Any related TEAE	1[a]	2[b]	0	2[d]
Any serious TEAE	0	0	0	2
Any related serious TEAE	0	0	0	0
Any TEAE leading to withdrawal	0	1[c]	0	0
Any TEAE leading to death	0	0	0	0

[a] Mild nausea/abdominal pain (resolved)
[b] Mild somnolence (resolved), mild abdominal pain (resolved)
[c] Covid-19 (unrelated, resolved)
[d] Mild nausea (resolved), elevated ALT ((ref range (5, 40) – baseline(29), day 28(47) - resolved))

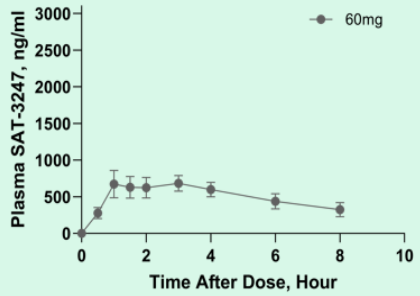
Pharmacokinetic Profiling

Healthy Volunteers



✓ Dose proportional exposure levels
✓ Drug clearance within 24 hours

Adult Duchenne

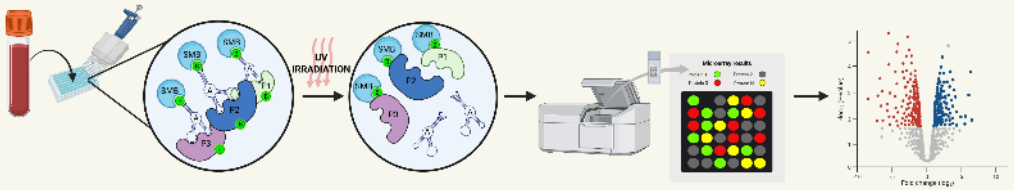


✓ Desired exposure met in patients

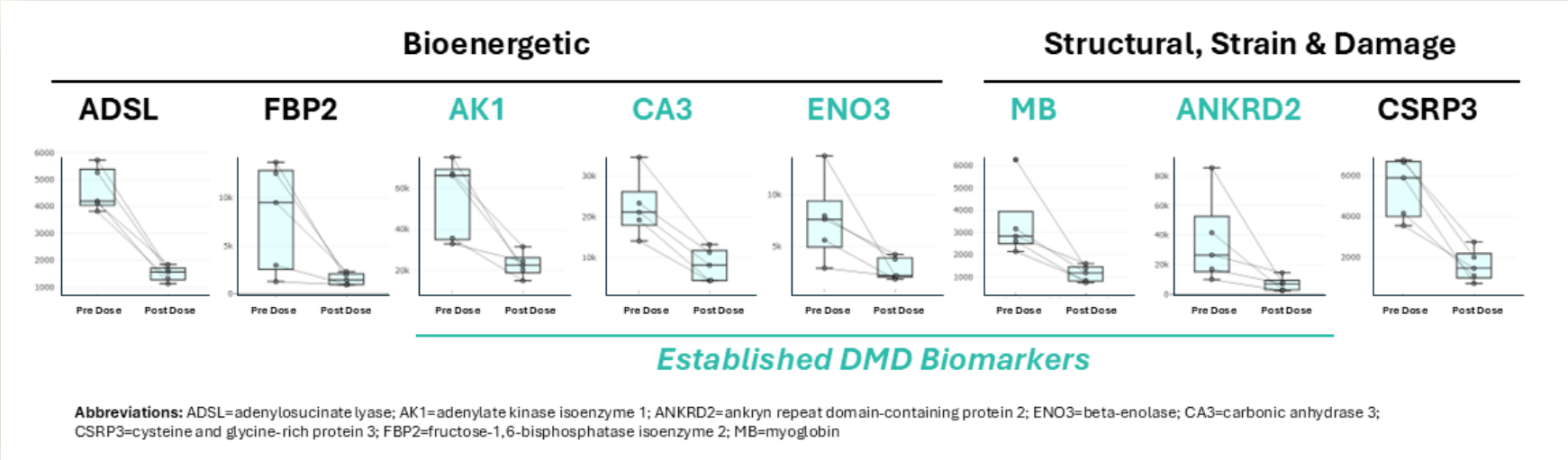
Phase 1 Takeaway

SAT-3247 demonstrated a favorable safety profile with predictable, dose-proportional pharmacokinetics in healthy volunteers and adults with Duchenne.

Proteomic Analyses: Consistent Declines Across Established DMD Biomarkers



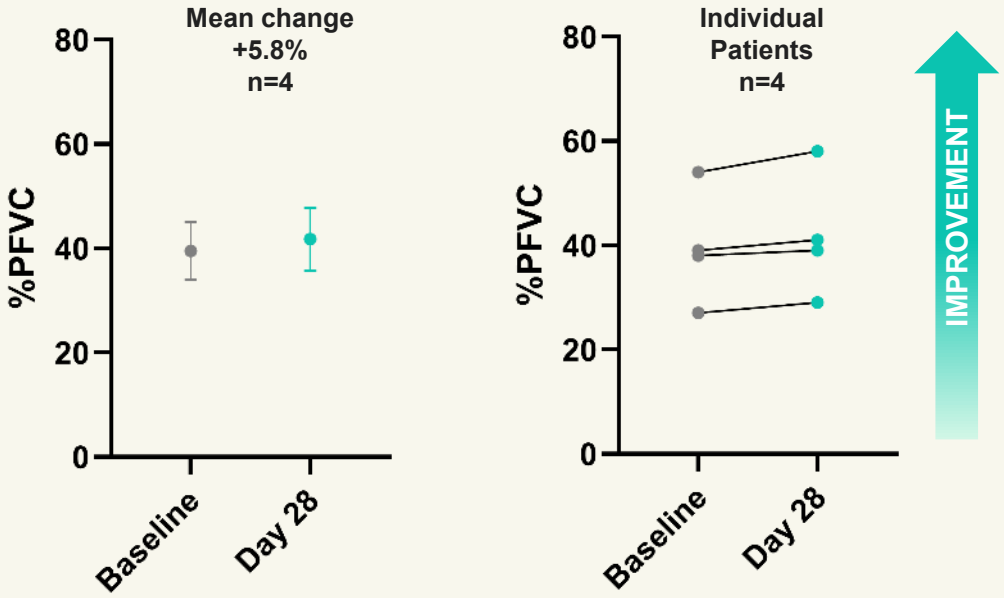
The SomaScan® proteomic tool employs single-stranded DNA aptimers to capture and measure concentrations of ~11,000 proteins in biologic samples



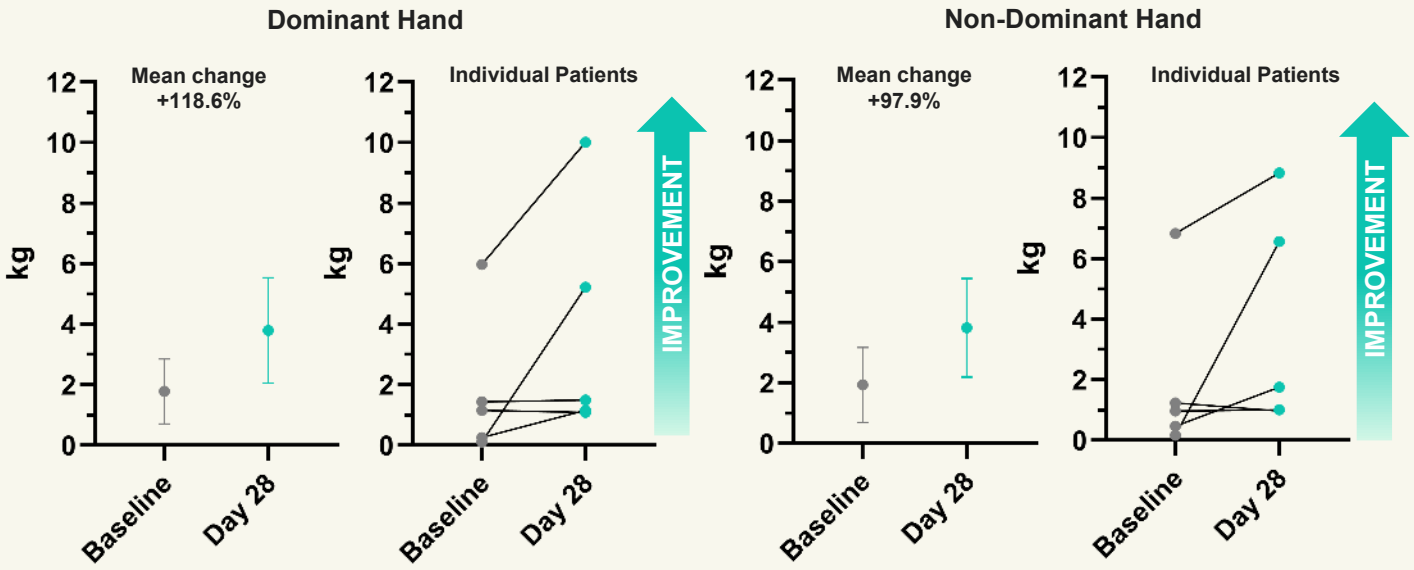
- **Reductions in recognized DMD biomarkers of muscle injury** after 15 days of dosing
- Additional work ongoing to further characterize the relationship between SAT-3247 and potential biomarkers identified with proteomic profiling

SAT-3247: Promising Indications of Functional Effect in 28 Days

5.8% Increase in Predicted Forced Vital Capacity (FVC)



118.6% and 97.9% Increases in Grip Strength in Dominant and Non-Dominant hands



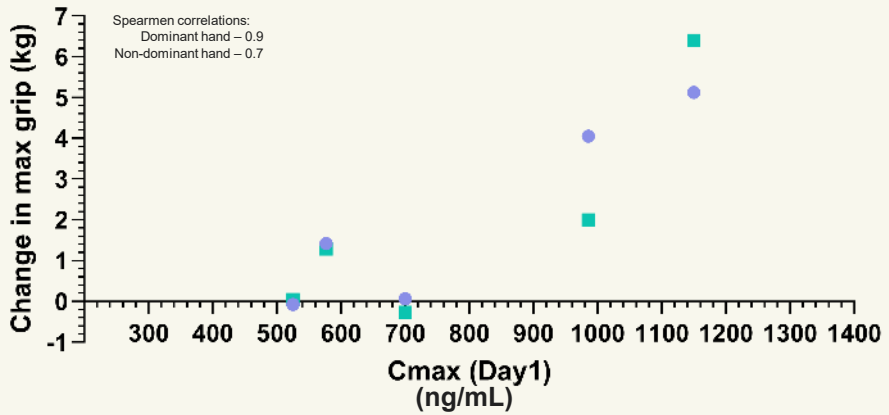
Typically, DMD patients in this age group experience a 5% annual decrease in FVC

Improvements seen with SAT-3247 are beyond reported experimental variability with the grip device

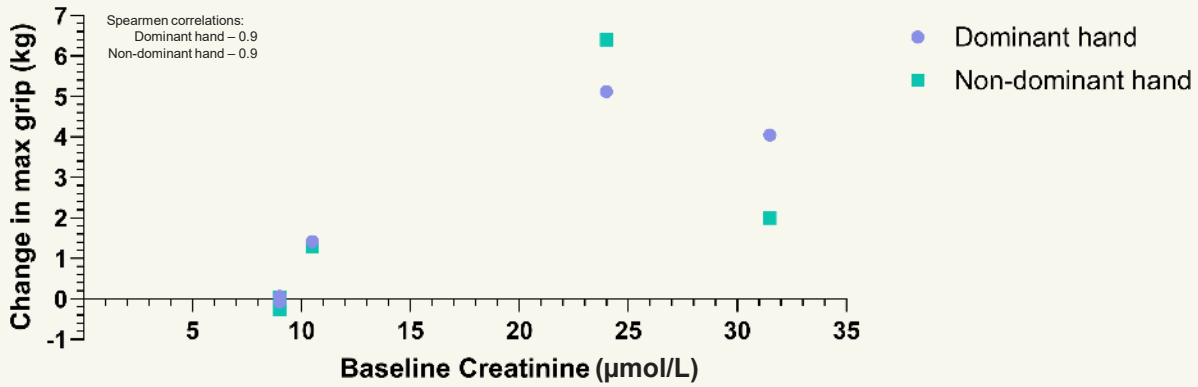
Grip Strength Improvements Correlate with Cmax and Creatinine Levels

Supports rationale that results seen are drug related

Maximum Grip Strength vs Cmax



Maximum Grip Strength vs Baseline Creatinine



- **Greatest improvements** in grip strength occurred in participants with:
  - **Highest Cmax on Day 1;** and
  - **Highest baseline creatinine** (surrogate marker for muscle mass)

TRAILHEAD

- TRAILHEAD is an open-label, Phase 2 study evaluating the long-term safety, tolerability, and potential efficacy of orally-administered SAT-3247
- TRAILHEAD will enroll up to 30 male adult participants with DMD, who will receive 60 mg SAT-3247 administered orally using a 5-days-on/2-days-off (weekday) dosing regimen for up to 12 months.

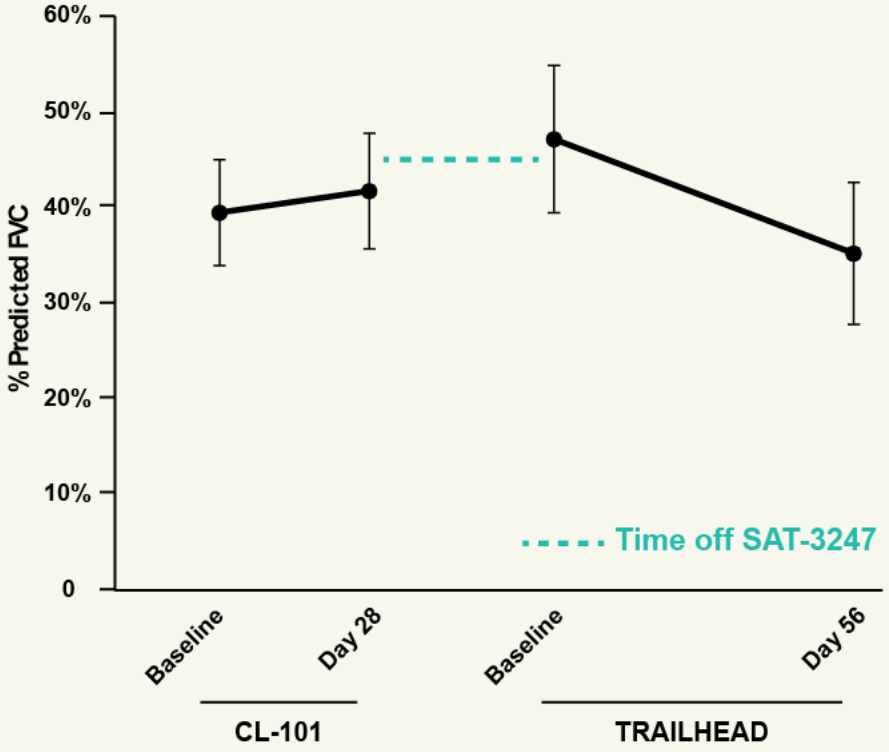
Baseline Characteristics	Group A (n = 4)
Age **Mean (SD)** **Min, Max**	 24.8 (2.99) 21, 28
Time from DMD diagnosis to SAT-3247 treatment initiation in TRAILHEAD (years) **Mean (SD)** **Min, Max**	 20.671 (4.8127) 16.07, 26.94
Ambulatory Participants (n)	2
Time between last dose in CL-101 & first dose in TRAILHEAD (days) **Mean (SD)** **Min, Max**	 255.5 (54.43) 205, 328
Baseline PUL2.0 **Mean (SD)** **Min, Max**	 21.8 (14.89) 10, 41
Participants with concomitant steroid use (n)	4

Safety	Group A (n = 4)
Any TEAE	2
Any related TEAE	0
Any serious TEAE	0
Any TEAE leading to withdrawal	0
Any study withdrawals	0

Data as of 23-Feb-2026

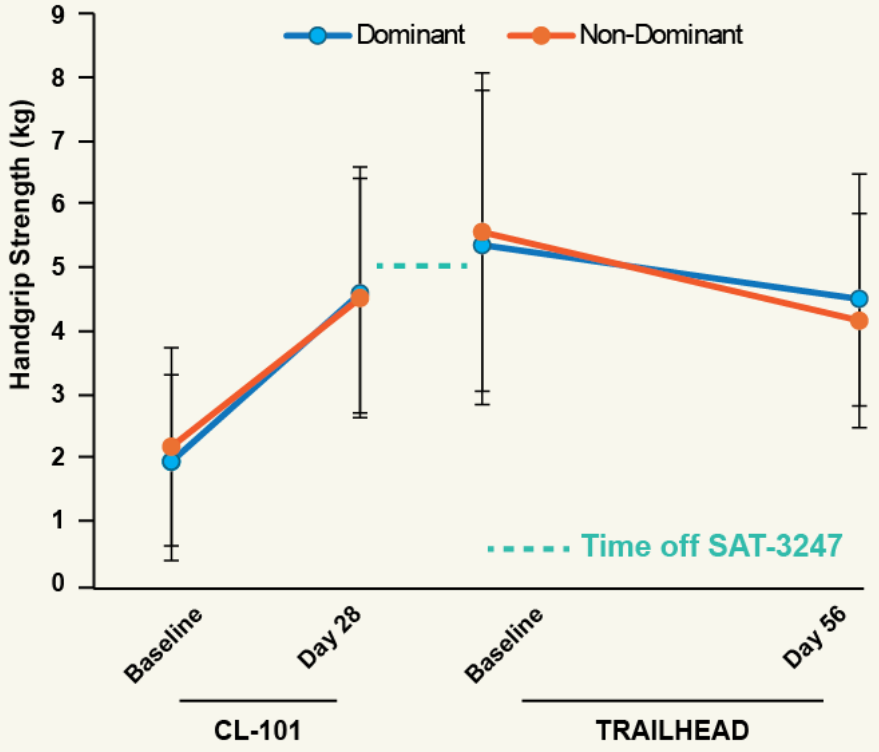
TRAILHEAD: FVC and Handgrip

Forced Vital Capacity (FVC)



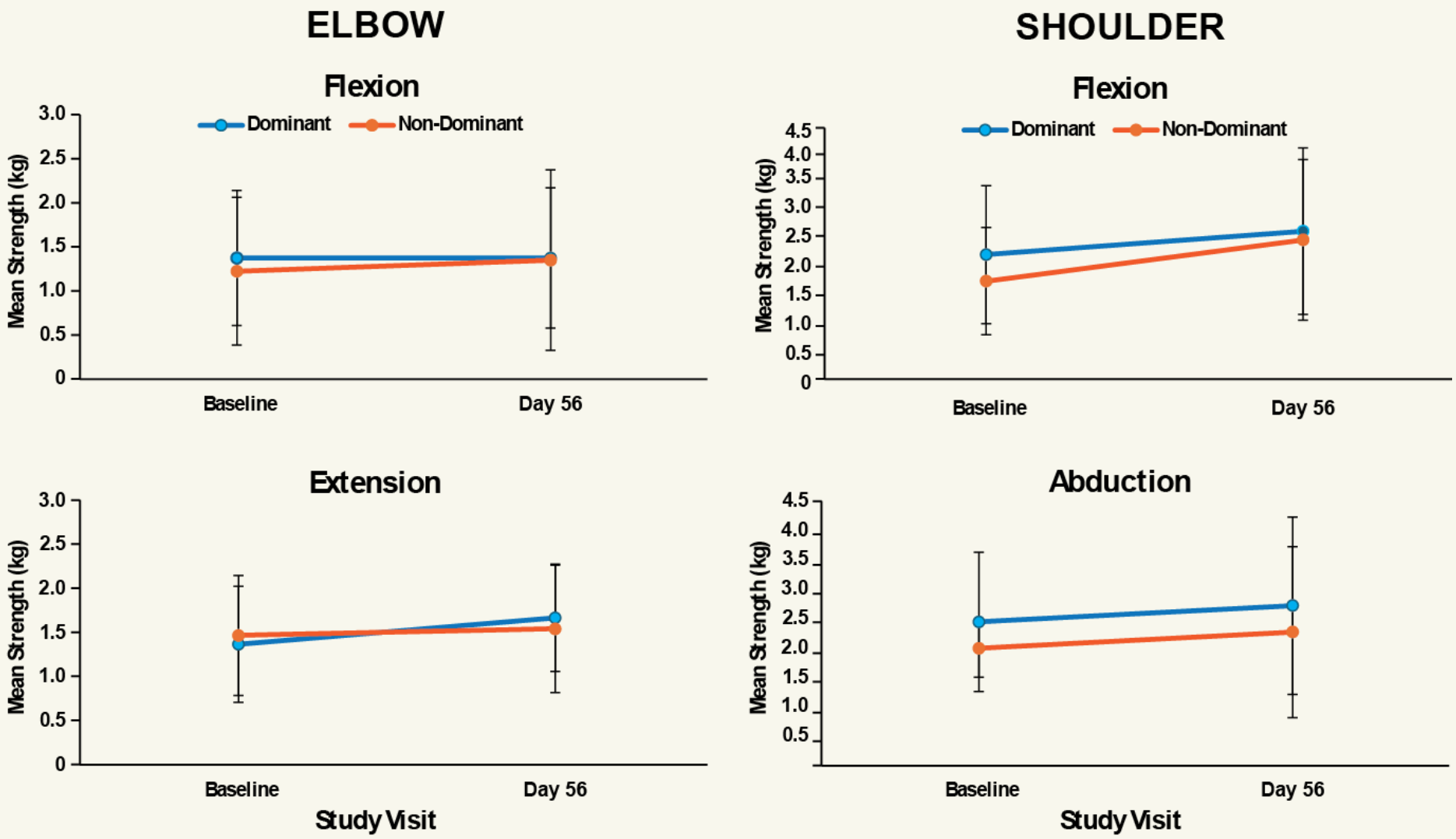
Stable since starting SAT-3247

Handgrip Strength



Improved since starting SAT-3247

TRAILHEAD: Dynamometry Appears Stable over 56 Days of Treatment



Current Clinical Trials to Evaluate SAT-3247 in People with DMD

	TRAILHEAD (LT-001)	BASECAMP (CL-201)
Participants	Up to 30 adults with DMD >=18 years	51 ambulatory DMD participants aged ≥ 7 and < 10 years of age
Summary	Will assess the long-term safety, tolerability and potential efficacy of a 60 mg dose of SAT-3247 with a weekday regimen in an 11-month, open-label study.	Will study 60 and 120 mg of SAT-3247 in a randomized, double-blind, placebo-controlled weekday regimen for 12 weeks to determine the optimal dose, safety, tolerability, and preliminary efficacy.
Locations	Australia: up to 10 participants USA: planning to file with FDA and enroll up to 20 additional participants	U.S., UK, EU (Belgium, Spain, Poland), Serbia, Canada, and Australia.
Current Status	1 site activated 4 participants dosed	5 sites activated in U.S. First participant dosed

Reimagine

how muscle degeneration is treated.

Regenerate

with small molecule medicines.

Realize

the next horizon to improve lives.