UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 05, 2025

Larimar Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-36510**	**20-3857670**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
Three Bala Plaza East **Bala Cynwyd, Pennsylvania**		**19004**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (844) 511-9056

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	LRMR	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On May 5, 2025, Larimar Therapeutics, Inc. (the "Company") posted on its website an updated slide presentation, which is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. Representatives of the Company will use the presentation in various meetings with investors, analysts and other parties from time to time.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Below is a list of exhibits included with this Current Report on Form 8-K.

Exhibit No.	Document
99.1	Larimar Therapeutics, Inc. Corporate Presentation, dated May 5, 2025*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith

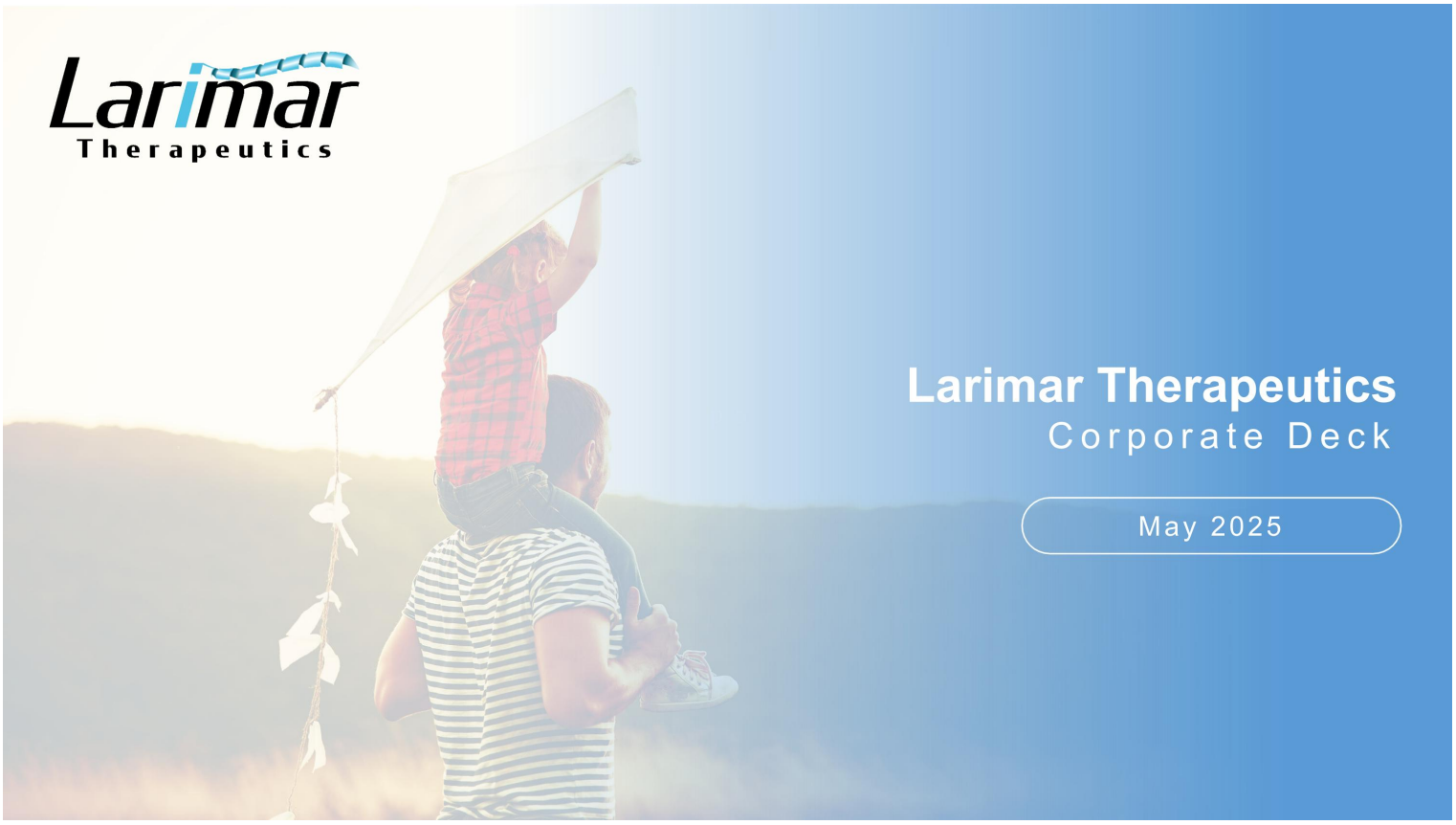
SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Larimar Therapeutics, Inc.

Date: May 5, 2025

By: /s/ Carole S. Ben-Maimon, M.D.
Name: Carole S. Ben-Maimon, M.D.
Title: President and Chief Executive Officer



Larimar Therapeutics

Corporate Deck

May 2025

Forward-Looking Statements

This presentation contains forward-looking statements that are based on the beliefs and assumptions of Larimar Therapeutics, Inc. ("Company") and on information currently available to management. All statements contained in this presentation other than statements of historical fact are forward-looking statements, including but not limited to Larimar's ability to develop and commercialize nomlabofusp (CTI-1601) and any other planned product candidates, Larimar's planned research and development efforts, including the timing of its nomlabofusp clinical trials and non-clinical investigations and overall development plan expectations with respect to the FDA START pilot program, interactions with FDA, expectations regarding potential for accelerated approval or accelerated access and time to market and other matters regarding Larimar's business strategies, ability to raise capital, use of capital, results of operations and financial position, and plans and objectives for future operations.

In some cases, you can identify forward-looking statements by the words "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks, uncertainties and other factors include, among others, the success, cost and timing of Larimar's product development activities, nonclinical studies and clinical trials, including nomlabofusp clinical milestones and continued interactions with the FDA; that preliminary clinical trial results may differ from final clinical trial results, that earlier non-clinical and clinical data and testing of nomlabofusp may not be predictive of the results or success of later non-clinical or clinical trials, and assessments; delays in patient recruitment, including as a result of changes in clinical protocols and adverse events; that the FDA may not ultimately agree with Larimar's nomlabofusp development strategy; the potential impact of public health crises on Larimar's future clinical trials, manufacturing, regulatory, nonclinical study timelines and operations, and general economic conditions; Larimar's ability and the ability of third-party manufacturers Larimar engages, to optimize and scale nomlabofusp's manufacturing process; Larimar's ability to obtain regulatory approvals for nomlabofusp and future product candidates; Larimar's ability to develop sales and marketing capabilities, whether alone or with potential future collaborators, and to successfully commercialize any approved product candidates; Larimar's ability to raise the necessary capital to conduct its product development activities; and other risks described in the filings made by Larimar with the Securities and Exchange Commission (SEC), including but not limited to Larimar's periodic reports, including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the SEC and available at www.sec.gov. These forward-looking statements are based on a combination of facts and factors currently known by Larimar and its projections of the future, about which it cannot be certain. As a result, the forward-looking statements may not prove to be accurate. The forward-looking statements in this presentation represent Larimar's management's views only as of the date hereof. Larimar undertakes no obligation to update any forward-looking statements for any reason, except as required by law.

Clinical-Stage Novel Protein Replacement Therapy Platform

First potential disease modifying therapy for FA	Nomlabofusp is designed to directly address frataxin deficiency in patients with Friedreich's ataxia (FA) by delivering a recombinant fusion protein to mitochondria. Granted Orphan Drug (US & EU), Rare Pediatric Disease (US), Fast Track (US), PRIME (EU) and ILAP (UK-MHRA) designations. Selected by FDA to participate in its START pilot program
Seeking FDA accelerated approval pathway	FDA stated as part of a START pilot program meeting that it is open to considering skin FXN concentration as a reasonably likely surrogate endpoint (RLSE) in support of an accelerated approval. The acceptability of FXN concentrations as an RLSE to support approval will be a matter of review in a future marketing application
Positive initial data from long-term OLE study	Daily nomlabofusp 25 mg was generally well-tolerated and increased and maintained tissue FXN concentrations over time with early trends in improvements across multiple clinical outcomes with some participants having received daily dosing for up to 1 year. Continuing to enroll with active patients currently receiving 50 mg dose
Adolescent PK run-in Study	Completed dosing in adolescent cohort of PK run-in study which was initiated in early 2025 Participants will be eligible to screen for entry into the OLE study after assessment of safety and PK data
Near-term catalysts	Topline 50 mg data from OLE study planned for Sept 2025 Data in adolescent cohort of PK run-in study planned for Sept 2025 On track to initiate global Phase 3 study in mid-2025 Biologics License Application (BLA) submission to seek accelerated approval targeted by year-end 2025

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$157.5 million in cash and investments as of March 31, 2025, with projected cash runway into Q2 2026

Potential for Accelerated Approval Pathway Based on Skin FXN Concentrations as a Surrogate Endpoint

FDA is open to considering the use of FXN concentration as a **reasonably likely surrogate endpoint** (RLSE)

Skin FXN concentrations recommended by FDA as a RLSE to **support evidence of effectiveness** for accelerated approval

FDA noted submitted data appear sufficient to support relationship between increased skin FXN concentrations and relevant tissues such as heart, dorsal root ganglia and skeletal muscle

FDA acknowledged nonclinical studies were **done at relevant doses**

BLA submission to seek accelerated approval targeted by year-end 2025

Potential Path to Bring Nomlabofusp to Patients Worldwide

OLE Study

Completed dosing of 25 mg dose with positive initial data

Continuing to enroll with active subjects on 50 mg dose

Plan to introduce the lyophilized dosage form (formulation intended for commercialization) into clinical studies in mid-2025

Long-term 50 mg data expected Sept 2025

Adolescent PK Run-In Study

Completed dosing of adolescents (12-17 yrs of age) at weight-based dose expected to match PK of adult 50 mg dose

Participants eligible to transition into OLE after assessment of safety and PK data

Adolescent data expected Sept 2025

Global Phase 3 Study

Received feedback from FDA and EMA on study protocol for global double-blind placebo-controlled study

Potential sites in the U.S., E.U., U.K., Canada, and Australia

Plan to include children (2-17 yrs of age)

Plan to initiate mid-2025

Next Steps

Seeking feedback from FDA to determine adequacy of the safety data set to support the BLA submission

BLA submission to seek accelerated approval targeted by year-end 2025

Friedreich's Ataxia (FA): A rare and progressive disease

Genetic defect on both alleles lowers frataxin levels

Most patients with FA only produce ~20-40% of normal frataxin levels depending on the tissue, sampling technique, and assay considered*

Affects ~20,000 patients globally

~5,000 patients in the U.S., with most remaining patients in the Europe
~70% of patients present before age 14

Progressive disease

Initial symptoms include unsteady posture and frequent falling, and patients are eventually confined to a wheelchair
Life expectancy of 30-50 years with an early death usually caused by heart disease

No approved therapies increase frataxin levels

Only treatment approved for FA does not address frataxin deficiency

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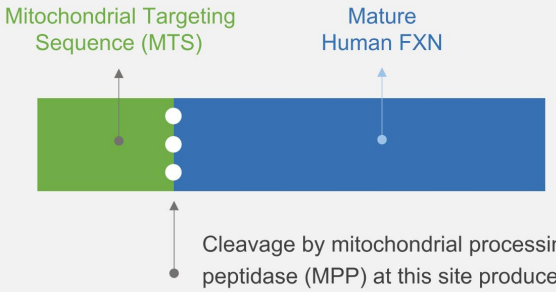
* E.C. Deutsch et al. Molecular Genetics and Metabolism 101 (2010) 238–245.

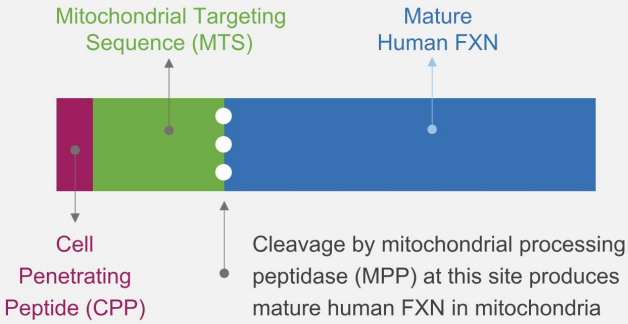
Nomlabofusp is Designed to Deliver Additional Frataxin

Nomlabofusp (CTI-1601) maintains the cleavage site between the MTS and mature human frataxin (FXN)

STRUCTURE OF ENDOGENOUS FXN



STRUCTURE OF NOMLABOFUSP



The presence of the cleavage site allows the CPP and MTS to be removed by mitochondrial processing peptidase to produce mature human FXN in the mitochondria

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FXN Levels Clearly Predict Disease Progression in FA

Lower FXN levels are associated with earlier onset of disease, faster rate of disease progression, and shorter time to loss of ambulation

Median Age of Onset and Rate of Disease Progression in Relation to FXN Levels

FXN Level* (% of Normal Level)	Age of Onset (Years)	FARS** (Change/Year)
11.2	7	2.9
22.0	11	2.1
31.0	16	2.0
48.7	19	1.6

Adapted from H.L.Plasterer et al. PLoS ONE 2013 8(5):e63958

Median Age of Onset Predicts Time to Loss of Ambulation

Age of Onset (Years)	Median Time to Loss of Ambulation (Years)
< 15	11.5
15 to 24	18.3
> 24	23.5

Adapted from C. Rummey et al. EClinicalMedicine. 2020 18:100213

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*FXN levels measured in peripheral blood mononuclear cells (PBMCs). FXN levels as measured by % of normal demonstrated to be equivalent in PBMCs, buccal cells, and whole blood.
**FARS: Friedreich's ataxia rating score, measures disease progression with a higher score indicating a greater level of disability.

Completed Ph 2 Dose Exploration Study (25 & 50 mg Cohorts)

Goal: Further characterize PK/PD and assess safety to inform long-term dose and dose regimen

28-day Treatment Period - nomlabofusp (CTI-1601) or placebo

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28

= Subcutaneous administration of nomlabofusp (CTI-1601) or placebo

= No Administration

Study Details	
Population	Ambulatory and non-ambulatory Friedreich's ataxia patients ≥18 years of age Nomlabofusp (CTI-1601) treatment naïve or participated (if eligible) in a previous Larimar study
Dose	**Cohort 1:** 25 mg **Cohort 2:** 50 mg
Key Endpoints	Frataxin levels in peripheral tissue, PK, safety and tolerability; other exploratory endpoints include lipids and gene expression levels
Number of Patients	**Cohort 1:** Enrolled 13 participants (9 on nomlabofusp; 4 on placebo) **Cohort 2:** Enrolled 15 participants (10 on nomlabofusp; 5 on placebo)
Key Results	Generally well tolerated; most common adverse events were mild and moderate injection site reactions Dose dependent increases of frataxin levels in tissues tested (skin and buccal cells) Baseline FXN levels in skin cells in the 50 mg cohort were < 17% of the average of healthy volunteers. After daily dosing for 14 days, FXN levels increased to 33% to 59% of the average of the healthy volunteers

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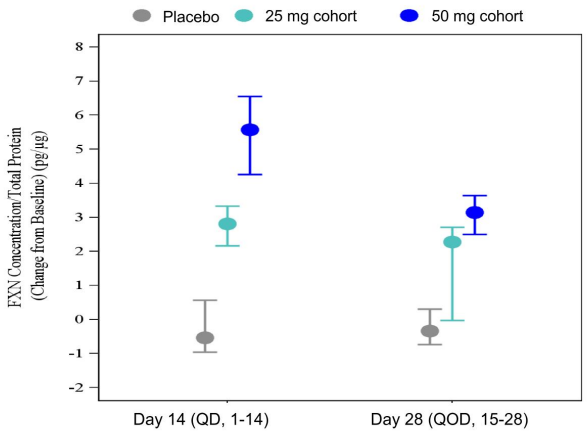
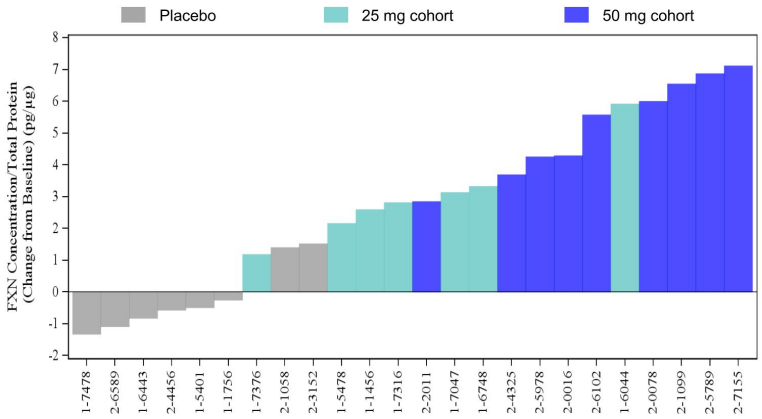
Dose-Dependent Increase in FXN Levels in Skin Cells

Participants dosed daily for 14 days, then every other day until day 28

FXN Levels* in Skin Cells Change from Baseline**



FXN Levels* in Skin Cells Change from Baseline at Day 14



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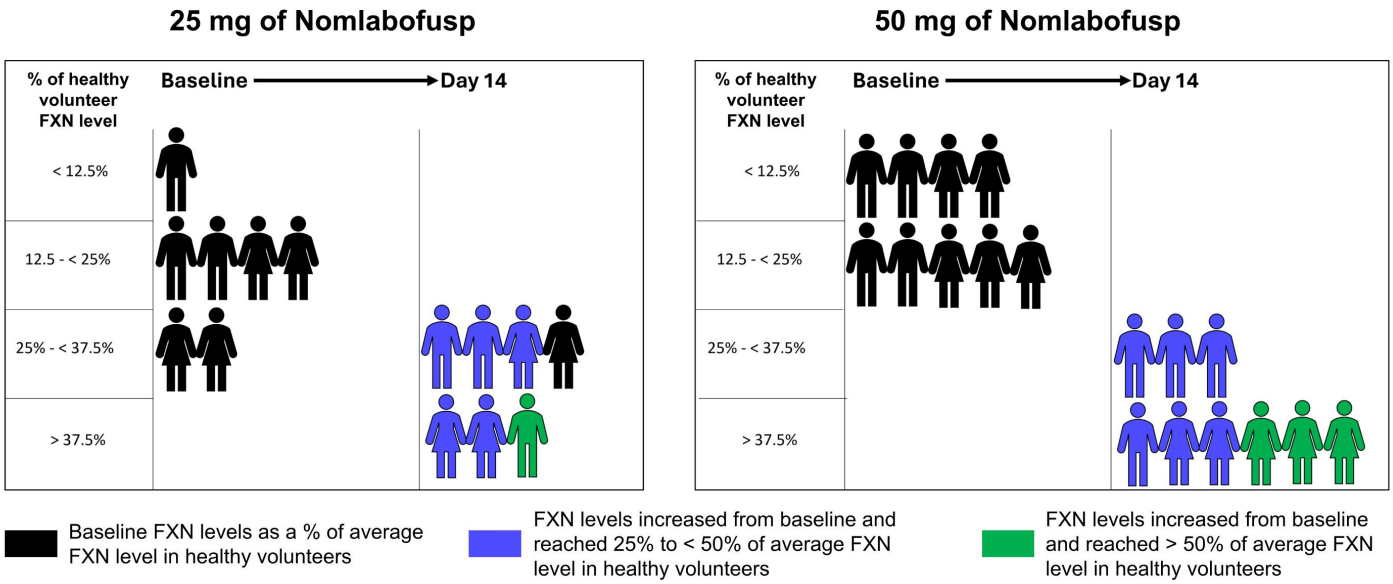
*FXN levels measured via detection of peptide derived from mature FXN; FXN concentrations are normalized to total cellular protein content in each sample. Data represent median and 25th and 75th percentiles. Only participants with quantifiable levels at both baseline and Day 14 are included in the figures.
**Median baseline FXN levels in patients were 3.5 pg/µg for the placebo, 3.7 pg/µg for the 25 mg cohort and 2.1 pg/µg for the 50 mg cohort.

Skin Cell FXN Levels Achieve Higher % of Healthy Volunteers* Following 14 days of Daily Nomlabofusp



Baseline FXN levels as a % of average FXN level in healthy volunteers

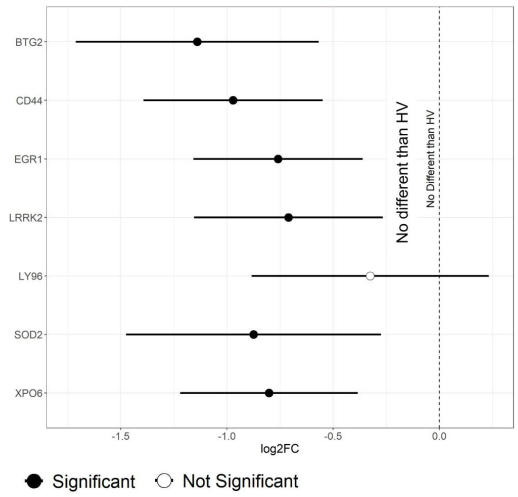
FXN levels increased from baseline and reached 25% to < 50% of average FXN level in healthy volunteers

FXN levels increased from baseline and reached > 50% of average FXN level in healthy volunteers

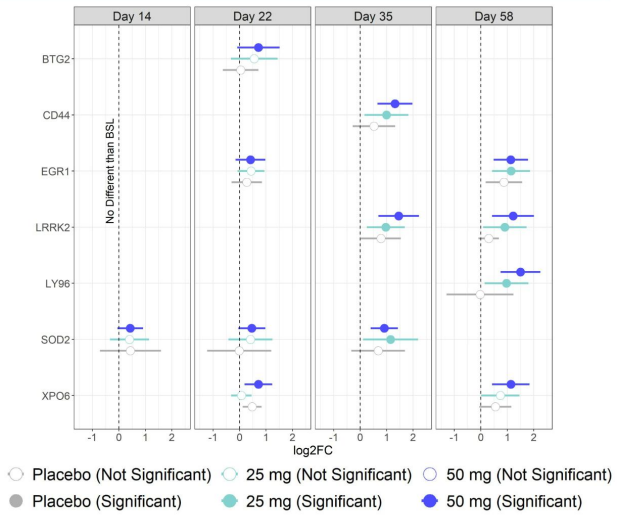
Only participants with quantifiable levels at baseline and day 14 are included in the figures.
*% of healthy volunteer FXN level is calculated by dividing each participant's FXN level by the average FXN level (16.34 pg/µg) from the noninterventional healthy volunteer study (N=60).

Increase Towards Normal Gene Expression in Adults with FA* Observed After Nomlabofusp Treatment

Select Baseline Gene Expression
Patients with FA* vs. Healthy Volunteers (HV)**



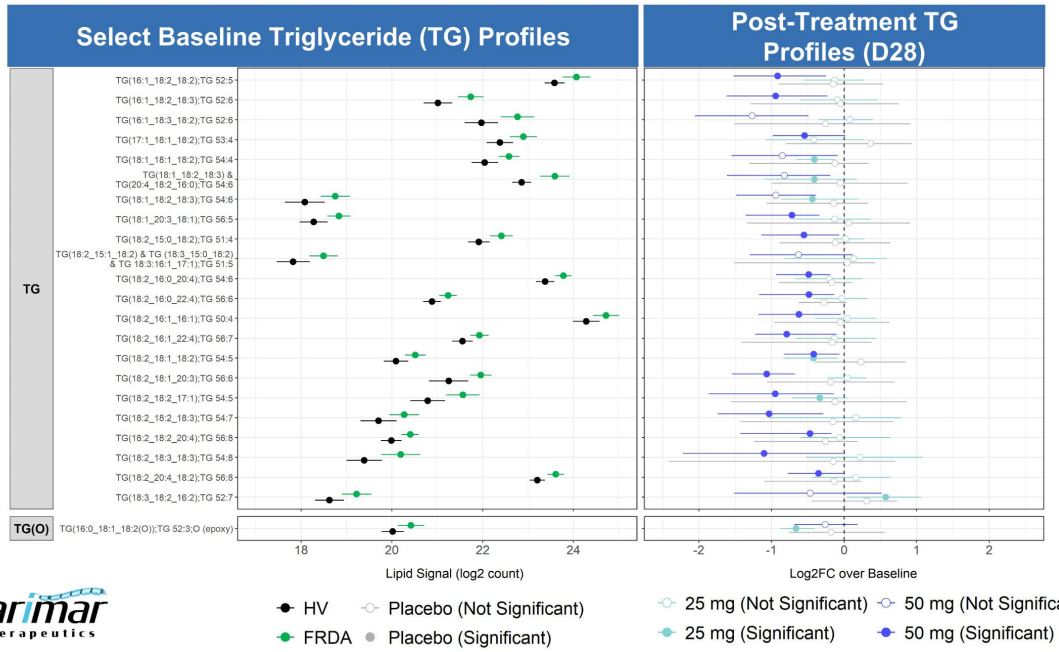
Post-treatment Changes in Gene Expression From Baseline



Data presented at the International Congress for Ataxia Research, November 2024
**Samples from Phase 2 dose exploration study evaluating nomlabofusp 25 mg (Cohort 1) and 50 mg (Cohort 2) or placebo via subcutaneous injection daily for 14 days followed by alternate day administration for 14 days. Buccal samples were collected before, during, and after treatment for gene expression profiling*
***Data from Larimar's non-interventional healthy volunteer study*

Interest from FDA in Exploring the Correlation Between Lipids and FXN Concentrations

Decreases in elevated lipids in adults with FA* observed after nomlabofusp treatment



**Samples from Phase 2 dose exploration study evaluating nomlabofusp 25 mg (Cohort 1) and 50 mg (Cohort 2) or placebo via subcutaneous injection daily for 14 days followed by alternate day administration for 14 days. Plasma samples were collected before, during, and after treatment for lipid profiling. Healthy volunteer (HV) data is from Larimar's non-interventional HV study*

Data presented at the International Congress for Ataxia Research, November 2024

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Nomlabofusp Long-term Open Label Extension Study

Open-label Extension: 25 mg Completed, Dosing at 50 mg Continues

Long-term data from 50 mg dose expected September 2025

Key Eligibility Criteria

Previous participation in Phase 1 or Phase 2 trials

Daily subcutaneous injections self-administered or by a caregiver

25 mg nomlabofusp

50 mg nomlabofusp

- All 7 sites activated and enrolling
- Following assessment of safety and PK data of cohorts in the PK run-in study, adolescents (12-17 yrs of age) and children (2-11 yrs of age) will be eligible to screen for the OLE

Key Study Objectives

- Safety and tolerability
- Long-term PK
- Tissue FXN concentrations
- Clinical efficacy measures compared to FACOMS* database once enrollment is complete

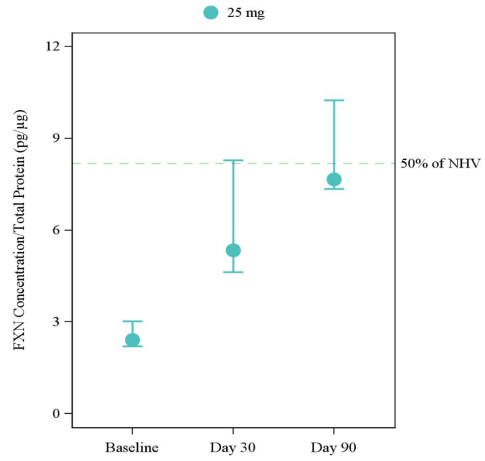
Screening Period ≤ 42 days** → Treatment Period Planned for ≥ 1 year → Potential extensions

*FACOMS: Friedreich's Ataxia Clinical Outcome Measures Study.
**Estimated screening period may be extended for those study participants who have not been on a stable regimen of omaveloxolone for at least six months.

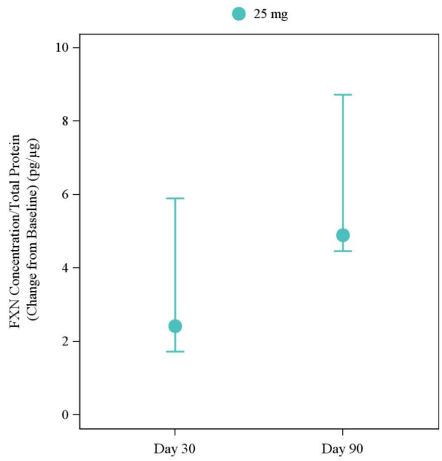
Increased FXN Levels in Skin Cells Sustained Over Time

Participants in the OLE dosed daily with 25 mg nomlabofusp for up to 90 days

Skin Cells - Absolute FXN Levels



Skin Cells - FXN Levels Change from Baseline

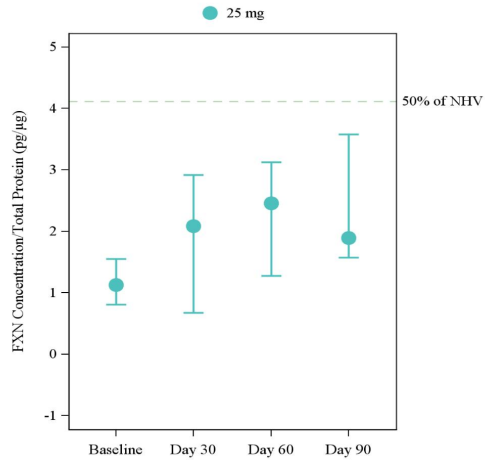


FXN levels measured via detection of peptide derived from mature FXN; FXN concentrations are normalized to total cellular protein content in each sample. Data represent median and 25th and 75th percentiles. Only participants with quantifiable levels at all measurement points are included in the figures. 50% of normal healthy volunteer (NHV) FXN level is 8.17pg/µg from the noninterventional healthy volunteer study (N=60).

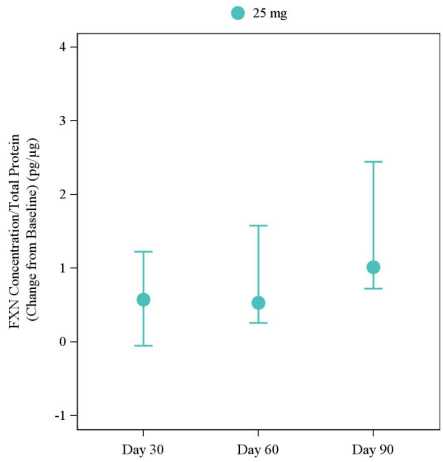
Increased FXN Levels in Buccal Cells Sustained Over Time

OLE participants dosed daily with 25 mg nomlabofusp for up to 90 days reached steady state by 30 days

Buccal Cells - Absolute FXN Levels



Buccal Cells - FXN Levels Change from Baseline



FXN levels measured via detection of peptide derived from mature FXN; FXN concentrations are normalized to total cellular protein content in each sample. Data represent median and 25th and 75th percentiles. Only participants with quantifiable levels at all measurement points are included in the figures. 50% of normal healthy volunteer (NHV) FXN level is 4.12 pg/µg from the noninterventional healthy volunteer study (N=60).

Tissue FXN Levels as a % of Healthy Volunteers are Higher at Day 90 Compared to Baseline in Subjects Treated with 25 mg Daily in the OLE

Buccal FXN Levels

Mean % of healthy volunteers

15% at baseline
(5.30% min, 26.67% max)

↓

30% at Day 90
(18.68 % min, 53.18 % max)

Skin FXN Levels

Mean % of healthy volunteers

16% at baseline
(9.33% min, 24.48% max)

↓

72% at Day 90
(43.86 % min, 160.61 % max)

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Only participants with quantifiable levels at each measurement point are included in the tables
Mean % of healthy volunteers is the mean of all the participants FXN levels relative to the mean FXN levels in skin cells (16.34 pg/µg) and in buccal cells (8.24 pg/µg) from the noninterventional healthy volunteer study (N=60).

Observed Increases in Tissue FXN Levels in OLE Are Comparable to the Phase 2 Dose Exploration Study

Absolute tissue FXN levels and increases from baseline after 25 mg nomlabofusp daily over time

	Open Label Extension					
	Buccal FXN levels (pg/µg)			Skin FXN levels (pg/µg)		
	n	Median	Mean	n	Median	Mean
Baseline	11	1.13	1.19	8	2.41	2.60
Day 30	11	2.08	3.62	8	5.34	7.45
Change from Baseline	**11**	**0.58**	**2.43**	**8**	**2.42**	**4.85**
Day 60	9	2.46	2.41			
Change from Baseline	**9**	**0.53**	**1.13**			
Day 90	6	1.89	2.48	5	7.65	11.73
Change from Baseline	**6**	**1.01**	**1.32**	**5**	**4.89**	**9.28**

	Phase 2 Dose Exploration					
	Buccal FXN levels (pg/µg)			Skin FXN levels (pg/µg)		
	n	Median	Mean	n	Median	Mean
Baseline	7	1.78	1.80	7	3.70	3.38
Day 14	7	2.24	2.22	7	5.53	6.4
Change from Baseline	**7**	**0.56**	**0.42**	**7**	**2.81**	**3.02**

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Skin samples not collected at Day 60 per study protocol
Only participants with quantifiable levels at each measurement point are included in the tables

Observed Trends Towards Improvement in Clinical Outcomes at Day 90 in OLE After Daily 25 mg Nomlabofusp

Visit	Statistic	**mFARS** 93-Point Scale	**FARS-ADL** 36-Point Scale	**Modified Fatigue Impact Scale** 84-Point Scale	**9 Hole Peg Test Dominant Hand** Time (Seconds)
		N = 8	N = 8	N = 8	N = 8
Baseline	Mean (SD)	55.81 (13.296)	18.13 (6.064)	27.1 (14.23)	130.91 (99.366)
	Median (IQR)	53.5 (47.5, 68.3)	17.0 (12.8, 23.8)	29.5 (18, 38)	89.5 (48.7, 227.8)
	(Min, Max)	(35.0, 73.0)	(11.0, 27.0)	(2, 45)	(38.0, 277.3)
Day 90	Mean (SD)	55.13 (14.829)	15.88 (6.249)	18.5 (15.68)	113.11 (95.586)
	Median (IQR)	53.3 (43.8, 66.0)	14.8 (11.0, 21.3)	17.0 (5, 32)	67.15 (48.4, 176.7)
	(Min, Max)	(35.3, 79.5)	(8.0, 25.0)	(0, 42)	(33.50, 287.00)
Change from Baseline at Day 90	**Mean (SD)**	**-0.69 (3.983)**	**-2.25 (3.082)**	**-8.6 (12.24)**	**-17.79 (27.450)**
	Median (IQR)	**-1.17 (-3.8, 1.2)**	**-2.25 (-3.8, 0.3)**	**-3.5 (-19, -3)**	**-9.00 (-32.0, 1.7)**
	(Min, Max)	**(-5.0, 7.0)**	**(-8.0, 1.5)**	**(-28, 9)**	**(-73.5, 9.8)**

Timed 25-Foot Walk is not presented due to participants' ambulatory status

Nomlabofusp has Been Generally Well-Tolerated in OLE

Safety Data from OLE Update in Dec 2024

14 participants with FA were included in the safety data

Two participants withdrew for non-treatment related reasons

Two participants had serious adverse events that resolved within 24 hours and withdrew from the study

- Events were reviewed by Data Monitoring Committee and submitted to FDA and study is continuing as planned

Most common adverse event (AE) was injection site reactions (ISRs) which were mild, brief in duration and self limited

- No study discontinuations due to ISRs and all resolved

OLE Q1 2025 Updates

All patients in the OLE study are receiving 50 mg daily

Larimar's Safety Monitoring Team determined anaphylaxis to be an adverse drug reaction likely associated with nomlabofusp

To decrease the potential for allergic reactions, patients will be premedicated for the first month of dosing

Near-Term Milestones Support BLA Submission by End 2025

Larimar Selected to Participate in FDA START Pilot Program

Open-Label Extension Study

Introduction of lyophilized dosage form (formulation intended for commercialization) planned mid-2025

Topline 50 mg data from ongoing study expected September 2025

Adolescent PK Run-In Cohort

Completed dosing of adolescents

Study participants are eligible to screen for the OLE after assessment of safety and PK data

Data expected September 2025

Global Phase 3 Study

Feedback on protocol received from FDA and EMA

On track to initiate mid- 2025

BLA Submission

Continued interaction with FDA under START pilot program, including seeking feedback on adequacy of safety data set to support BLA submission

BLA seeking accelerated approval expected by year-end 2025

Clinical-Stage Novel Protein Replacement Therapy Platform

First potential disease modifying therapy for FA	Nomlabofusp is designed to directly address frataxin deficiency in patients with Friedreich's ataxia (FA) by delivering a recombinant fusion protein to mitochondria. Granted Orphan Drug (US & EU), Rare Pediatric Disease (US), Fast Track (US), PRIME (EU) and ILAP (UK-MHRA) designations. Selected by FDA to participate in its START pilot program
Seeking FDA accelerated approval pathway	FDA stated as part of a START pilot program meeting that it is open to considering skin FXN concentration as a reasonably likely surrogate endpoint (RLSE) in support of an accelerated approval. The acceptability of FXN concentrations as an RLSE to support approval will be a matter of review in a future marketing application
Positive initial data from long-term OLE study	Daily nomlabofusp 25 mg was generally well-tolerated and increased and maintained tissue FXN concentrations over time with early trends in improvements across multiple clinical outcomes with some participants having received daily dosing for up to 1 year. Continuing to enroll with active patients currently receiving 50 mg dose
Adolescent PK run-in Study	Completed dosing in adolescent cohort of PK run-in study which was initiated in early 2025 Participants will be eligible to screen for entry into the OLE study after assessment of safety and PK data
Near-term catalysts	Topline 50 mg data from OLE study planned for Sept 2025 Data in adolescent cohort of PK run-in study planned for Sept 2025 On track to initiate global Phase 3 study in mid-2025 Biologics License Application (BLA) submission to seek accelerated approval targeted by year-end 2025

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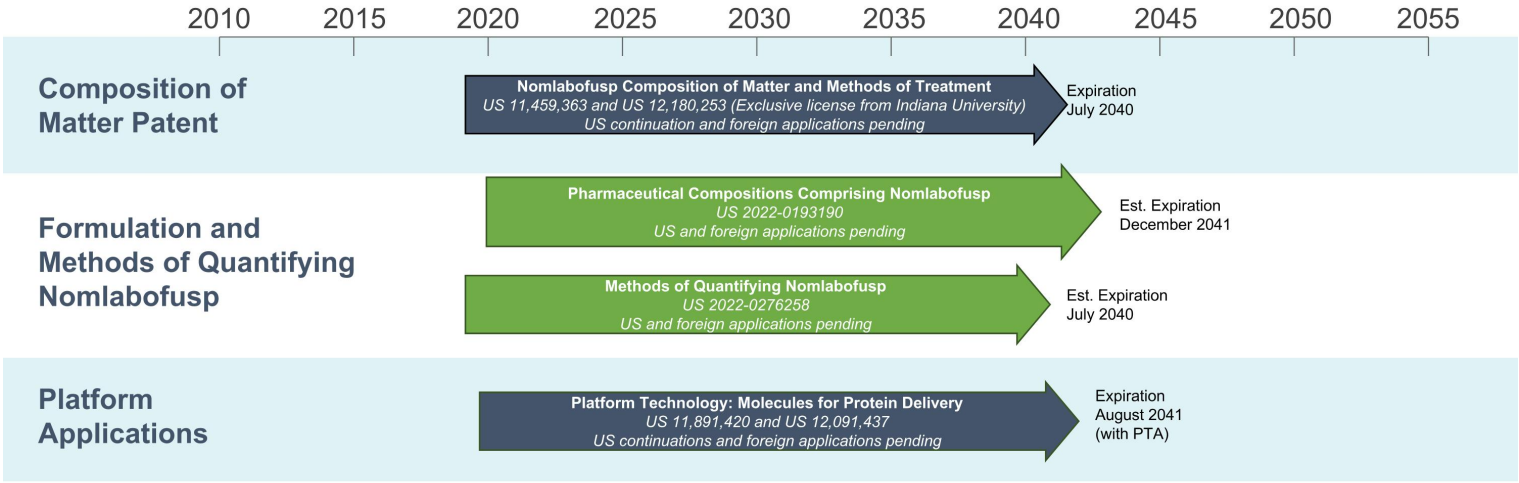
$157.5 million in cash and investments as of March 31, 2025, with projected cash runway into Q2 2026

Larimar Therapeutics

Appendix

Larimar Technology is Supported by a Strong IP Portfolio

Granted nomlabofusp (CTI-1601) composition of matter patent extends into 2040



Additional nomlabofusp IP protection

- US and foreign pending applications and patents cover key biomarkers, analytical tools and methods of treatment for additional disease indications for nomlabofusp
- Nomlabofusp should be eligible for **12 years of market exclusivity** upon approval in the US (independent of patents) and at least **10 years of market exclusivity** upon approval in EU (independent of patents)

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Granted Pending

Nomlabofusp is a Competitively Differentiated Treatment Approach*

$7.3B Acquisition supports the **robust market potential** for FA treatments

REATA PHARMACEUTICALS
Biogen

Nomlabofusp is a potential **first-and-only protein replacement therapy** designed to address the underlying cause of FA

Approach	Product	Company	Mechanism of Action	Clinical Status
Protein replacement	**Nomlabofusp (CTI-1601)**	**Larimar**	**Frataxin Protein Replacement**	**Phase II**
Mitochondrial Oxidative Stress Modifier	Omaveloxolone (SKYCLARYS™)	Biogen	Nrf2 Activator	Approved (US and EU)
	Vatiquinone	PTC Therapeutics	15-Lipoxygenase Inhibitor	Phase III
Gene Expression Regulator	DT-216P2 (new formulation)	Design Therapeutics	GeneTAC	Pre-clinical
Gene Therapy	LX2006	Lexeo Therapeutics	Frataxin Gene Replacement	Phase I/II

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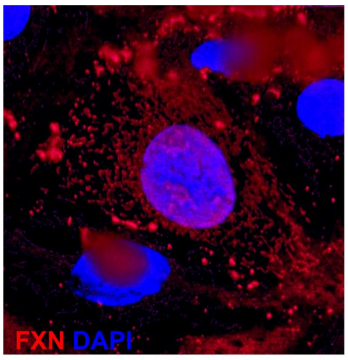
*Competitive landscape focuses on clinical-stage, industry-sponsored programs from public companies

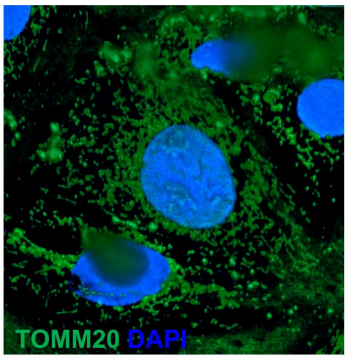
Mitochondrial Localization and Preclinical Data

Nomlabofusp Transduction of Cells In Vitro Leads to hFXN Located in Mitochondria

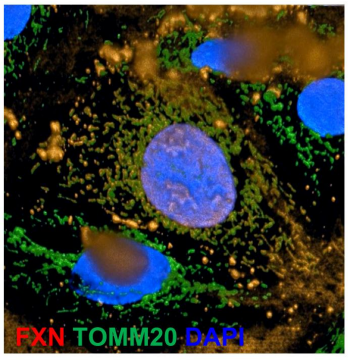
FXN staining



TOMM20 (mitochondria) staining



FXN co-localizes with TOMM20



- Rat cardiomyocytes (H9C2) were transduced with nomlabofusp
- Cells were fixed and analyzed by immunofluorescence microscopy to detect the presence of human frataxin (hFXN) and TOMM20 (a mitochondrial outer membrane protein)
- Nuclei were stained with DAPI

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Nomlabofusp Extends Survival in FXN-deficient KO Mice

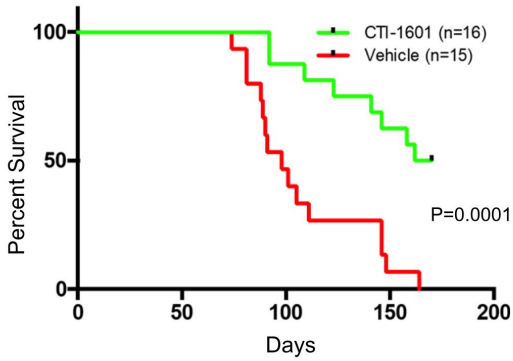
Initial proof-of-concept for FXN replacement therapy in cardiac mouse model of FA

Median survival of MCK-Cre FXN-KO mice

- 166 days (nomlabofusp) vs. 98 days (Vehicle)
- Nomlabofusp administered 10 mg/kg SC every other day

Survival beyond vehicle mean (107.5 days)

- 87.5% (nomlabofusp) vs. 33% (Vehicle)
- Demonstrates that nomlabofusp is capable of delivering sufficient amounts of FXN to mitochondria



Nomlabofusp (CTI-1601) rescues a severe disease phenotype in a well-characterized cardiac mouse model of FA

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Nomlabofusp Prevents Development of Ataxic Gait in Neurologic KO Mouse Model

In-Vivo Efficacy Data in Pvalb-Cre FXN-KO Mouse Model

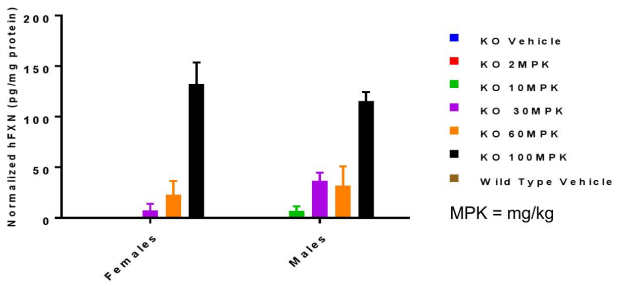
Single dose level: 10 mg/kg nomlabofusp or vehicle given intraperitoneally three times per week

- hFXN replacement with nomlabofusp **prevents development of ataxic gait**
- Nomlabofusp-treated mice **survive longer** than untreated mice
- Human frataxin **present in brain, dorsal root ganglia and spinal cord** demonstrating central nervous system penetration

Nomlabofusp Delivers hFXN to Mitochondria and Restores SDH Activity in KO Mice

Study Design – Cardiac and skeletal muscle FXN knockout mice (MCK-CRE) were treated at varying SQ doses of nomlabofusp every other day for two weeks at Jackson Laboratories (Bar Harbor, ME). After dosing, animals were sacrificed, and heart and skeletal muscle were evaluated for hFXN concentration in mitochondrial extracts and SDH activity was assessed.

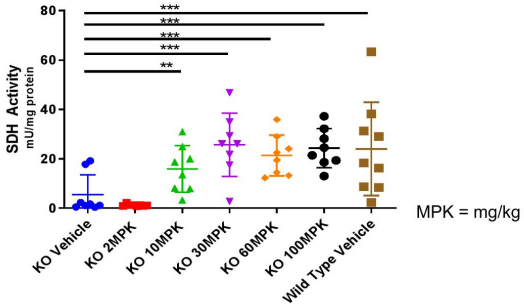
Mitochondrial FXN (Heart)



Mitochondria hFXN concentration increases dose-dependently

Given subcutaneously, nomlabofusp functionally replaces hFXN in mitochondria of KO mice

SDH Activity (Muscle)



Succinate dehydrogenase (SDH) activity, which is indicative of mitochondrial function, increases in a dose-dependent manner after administration of nomlabofusp; activity plateaus at 30 mg/kg and is equivalent to activity in wild type

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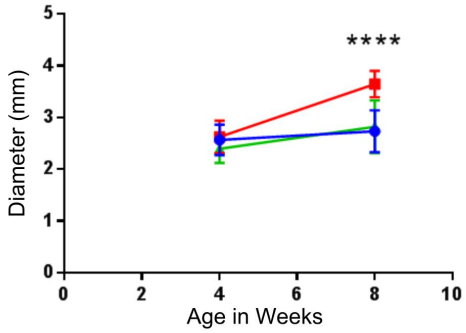
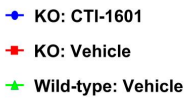
Nomlabofusp Prevents Left Ventricle Dilation in KO Mice

Study Design – Cardiac and skeletal muscle FXN knockout mice (MCK-CRE) were treated at 10 mg/kg every other day at Jackson Laboratories (Bar Harbor, ME). Echocardiograms were performed pre-dose and post dose.

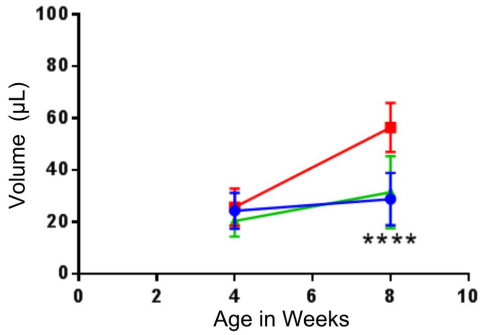
Left Ventricle Internal Diameter (Systole)



Left ventricular (LV) volume increases in systole in untreated mice by 8 weeks (after 4 weeks of dosing with vehicle), but remains similar to wildtype when treated with nomlabofusp (10 mg/kg every other day)



Left Ventricle Volume (Systole)



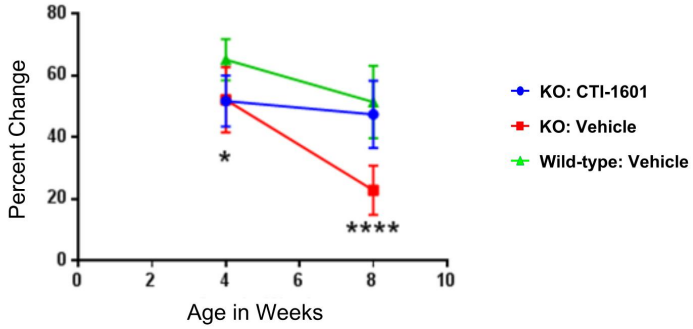
Nomlabofusp-treated mice have similar LV volume as wild type; echocardiogram shows significant differences between vehicle and nomlabofusp treated (10 mg/kg every other day) KO mice

Larimar Therapeutics

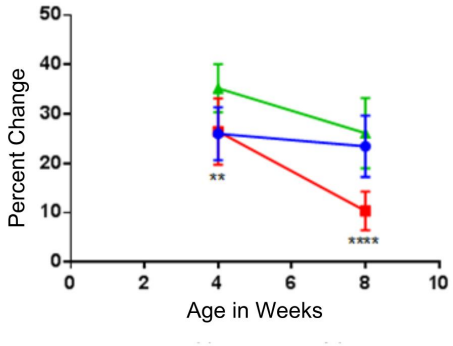
Nomlabofusp Preserves Left Ventricle Function in KO Mice

Study Design – Cardiac and skeletal muscle FXN knockout mice (MCK-CRE) were treated at 10 mg/kg every other day at Jackson Laboratories (Bar Harbor, ME). Echocardiograms were performed pre-dose and post dose.

Left Ventricle Ejection Function



Left Ventricle Fractional Shortening



Left ventricular (LV) function drops significantly in vehicle treated mice by Week 8

Nomlabofusp-treated (10 mg/kg every other day) mice have similar LV function as wildtype; echocardiogram shows significant differences between vehicle and nomlabofusp treated KO mice

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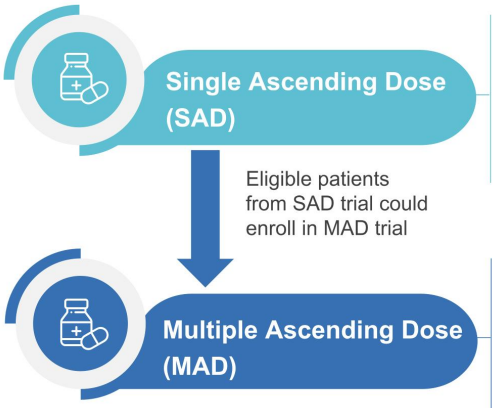
Phase 1 Clinical Data

CTI-1601: Phase 1 Clinical Program in Patients with FA

Program consisted of double-blind, placebo controlled single- and multiple-ascending dose trials

Phase 1 Development Plan

- Two double-blind, placebo-controlled dosing trials in patients with FA
- Patient dosing began December 2019
- Safety Review Committee assessed all blinded data between each cohort to ensure patient safety



Number of subjects: 28
Dose levels: 25 mg, 50 mg, 75 mg and 100 mg (subcutaneous administration)
Treatment Duration: 1 day
1º Endpoint: Safety and tolerability
2º Endpoints: PK; PD; FXN levels; multiple exploratory
Status: Complete

Number of Subjects: 27
Dose Range: 25 mg, 50 mg, 100 mg (subcutaneous administration)
Treatment Regimen: Multiple increasing doses administered subcutaneously over 13 days
1º Endpoint: Safety and tolerability
2º Endpoints: PK; PD; FXN levels (buccal cells, platelets, optional skin biopsies); multiple exploratory
Status: Complete

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Completed Phase 1 Multiple Ascending Dose Study

Treatment Schedules for Each Cohort- nomlabofusp (CTI-1601) or placebo

Cohort 1 (25 mg; n = 8)

13-day Treatment Period

1	2	3	4	5	6	7	8	9	10	11	12	13	14

= Administration of nomlabofusp or placebo

= No Administration

Cohort 2 (50 mg; n = 9)

13-day Treatment Period

1	2	3	4	5	6	7	8	9	10	11	12	13	14

= Administration of nomlabofusp or placebo

= No Administration

Cohort 3 (100 mg n = 10)

13-day Treatment Period

1	2	3	4	5	6	7	8	9	10	11	12	13	14

= Administration of nomlabofusp or placebo

= No Administration

FXN Level Sampling Days Presented for Each Cohort

Cohort 1 Sampling Days	
Buccal Cells	Baseline, Day 4, Day 13
Skin	Baseline, Day 13
Platelets	Baseline, Day 4, Day 13

Cohort 2 Sampling Days	
Buccal Cells	Baseline, Day 7, Day 13
Skin	Baseline, Day 13
Platelets	Baseline, Day 7, Day 13

Cohort 3 Sampling Days	
Buccal Cells	Baseline, Day 7, Day 13
Skin	Baseline, Day 13
Platelets	Baseline, Day 7, Day 13

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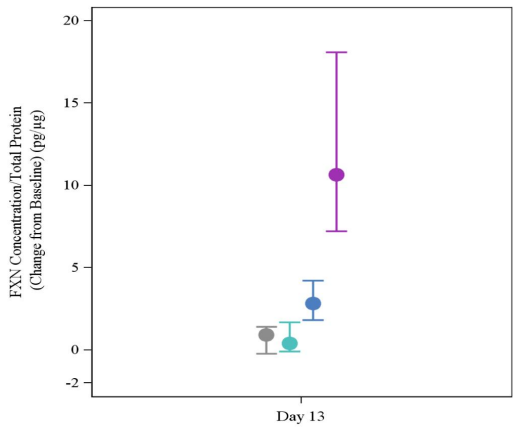
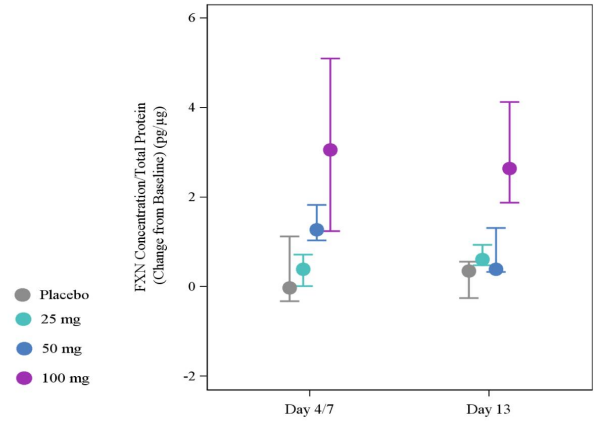
Dose Dependent Increases in FXN Levels Observed in Skin and Buccal Cells in Phase 1

FXN* Change from Baseline By Dose Group (Skin Cells)



FXN* Change from Baseline By Dose Group (Buccal Cells)



Placebo: Participants randomized to placebo in each cohort
25 mg: Dosed daily for 4 days, every third day thereafter
50 mg: Dosed daily for 7 days, every other day thereafter
100 mg: Dosed daily for 13 days

*FXN levels measured via detection of peptide derived from mature FXN; FXN concentrations are normalized to total cellular protein content in each sample; Data represent median and 25th and 75th percentiles; FXN levels from Day 4, & Day 13 measurements are shown for data derived from the 25 mg cohort; FXN levels from Day 7 & Day 13 measurements are shown for data derived from the 50 & 100 mg cohorts;

MAD Trial Patient Demographics

Parameter	Statistic	All placebo (n=7)	25 mg CTI-1601 (n=6)	50 mg CTI-1601 (n=7)	100 mg CTI-1601 (n=7)	All CTI-1601 (n=20)	Overall (n=27)
Sex							
Male	n (%)	5 (71.4)	3 (50.0)	4 (57.1)	3 (42.9)	10 (50.0)	15 (55.6)
Female	n (%)	2 (28.6)	3 (50.0)	3 (42.9)	4 (57.1)	10 (50.0)	12 (44.4)
Age (years)							
	Mean	25.7	39.7	34.7	28.0	33.9	31.7
	SD	6.37	16.59	9.03	8.96	12.13	11.40
	Median	23	37	36	24	34	28
	Min, Max	20,36	21,65	19,47	20,44	19,65	19,65
Race							
White	n (%)	6 (85.7)	6 (100.0)	6 (85.7)	6 (85.7)	18 (90.0)	24 (88.9)
Asian	n (%)	0	0	1 (14.3)	1 (14.3)	2 (10.0)	2 (7.4)
American Indian	n (%)	1 (14.3)	0	0	0	0	1 (3.7)
Ethnicity							
Hispanic/Latino	n (%)	2 (28.6)	0	0	0	0	2 (7.4)
Not Hispanic/Latino	n (%)	5 (71.4)	6 (100.0)	7 (100.0)	7 (100.0)	20 (100.0)	25 (92.6)

SD: Standard deviation

MAD Trial Patient Disease Characteristics

Parameter	Statistic	All placebo (n=7)	25 mg CTI-1601 (n=6)	50 mg CTI-1601 (n=7)	100 mg CTI-1601 (n=7)	All CTI-1601 (n=20)	Overall (n=27)
Age at Symptom Onset							
	Mean	14.1	24.0	19.3	11.9	18.1	17.1
	SD	5.34	14.48	6.21	6.72	10.37	9.39
	Median	15.0	18.0	19.0	10.0	18.0	16.0
	Min, Max	8,23	12,44	8,28	5,22	5,44	5,44
Age at Diagnosis							
	Mean	18.3	31.5	26.4	15.9	24.3	22.7
	SD	7.87	19.88	4.28	8.21	13.24	12.23
	Median	20.0	25.5	28.0	13.0	27.0	21.0
	Min, Max	9,32	14,64	17,30	5,27	5,64	5,64
Assistive Device							
Walker	n (%)	0	2 (33.3)	3 (42.9)	0	5 (25.0)	5 (18.5)
Wheelchair	n (%)	4 (57.1)	3 (50.0)	1 (14.3)	6 (85.7)	10 (50.0)	14 (51.9)
Other	n (%)	1 (14.3)	0	1(14.3)	0	1 (5.0)	2 (7.4)
None	n (%)	2 (28.6)	1 (16.7)	2 (28.6)	1 (14.3)	4 (20.0)	6 (22.2)

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SD: Standard deviation

PK analyses support evaluating once-daily and every-other-day dosing regimens for CTI-1601

Summary of MAD Trial PK Analyses

- CTI-1601 was quickly absorbed after subcutaneous administration
- Dose-proportional increases in exposure observed with increasing doses of CTI-1601
- Mean half life of CTI-1601 in plasma was approximately 11 hours
- CTI-1601 appeared to be at or close to steady state exposure after 13 days of dosing 100 mg once daily

Additional
Phase 2 Dose Exploration Data

Nomlabofusp: Predictable Long-Term Pharmacokinetics

1. Rapid absorption after subcutaneous administration
2. Nomlabofusp reached steady state in plasma by Day 30 with no further accumulation
3. Pharmacokinetic profile consistent with Phase 1 and Phase 2 studies

Absolute Increases in Skin FXN Levels

Dose response in tissue FXN concentrations and increases from baseline after dosing

Day 14 Skin FXN Levels			
Dose	Visit	Absolute Values (pg/µg)	
		Median	Mean
25 mg	Baseline	3.70	3.38
	Day 14	5.53	6.40
	Change from Baseline	**2.81**	**3.02**
50 mg	Baseline	2.12	2.08
	Day 14	7.40	7.32
	Change from Baseline	**5.57**	**5.24**

Day 28 Skin FXN Levels			
Dose	Visit	Absolute Values (pg/µg)	
		Median	Mean
25 mg	Baseline	3.70	3.38
	Day 28	4.39	4.80
	Change from Baseline	**2.28**	**1.41**
50 mg	Baseline	2.12	2.08
	Day 28	5.23	5.24
	Change from Baseline	**3.14**	**3.17**

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Only participants with quantifiable levels at baseline and day 14 and day 28 are included in the tables.

Absolute Increases in Buccal FXN Levels

Dose response in tissue FXN concentrations and increases from baseline after dosing

Day 14 Buccal FXN Levels			
Dose	Visit	Absolute Values (pg/µg)	
		Median	Mean
25 mg	Baseline	1.78	1.80
	Day 14	2.24	2.22
	Change from Baseline	**0.56**	**0.42**
50 mg	Baseline	1.61	1.69
	Day 14	2.44	2.38
	Change from Baseline	**0.72**	**0.69**

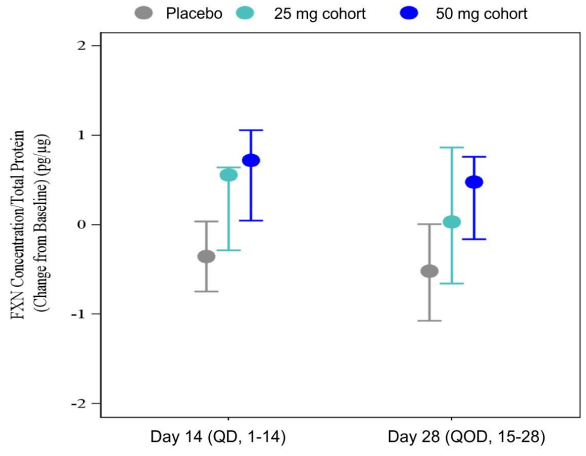
Day 28 Buccal FXN Levels			
Dose	Visit	Absolute Values (pg/µg)	
		Median	Mean
25 mg	Baseline	1.70	1.65
	Day 28	1.73	1.76
	Change from Baseline	**0.03**	**0.11**
50 mg	Baseline	1.76	1.77
	Day 28	2.15	2.15
	Change from Baseline	**0.48**	**0.38**

Only participants with quantifiable levels at baseline and day 14 and day 28 are included in the tables.

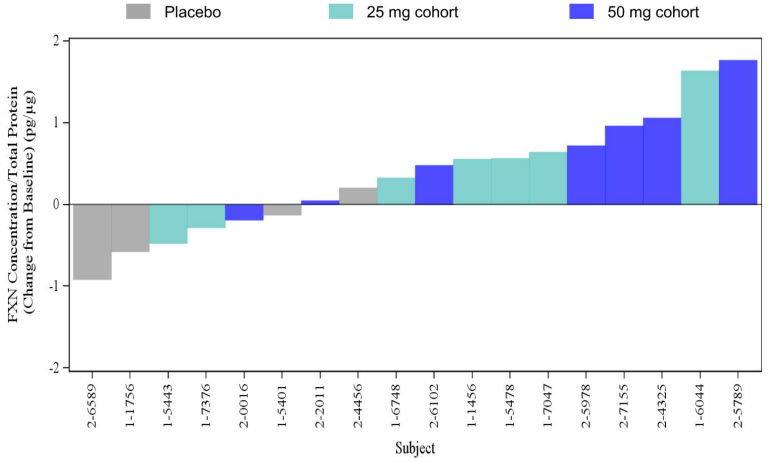
Dose-Dependent Increase in FXN Levels in Buccal Cells

Participants dosed daily for 14 days, then every other day until day 28

Buccal Cells
FXN Levels* Change from Baseline**

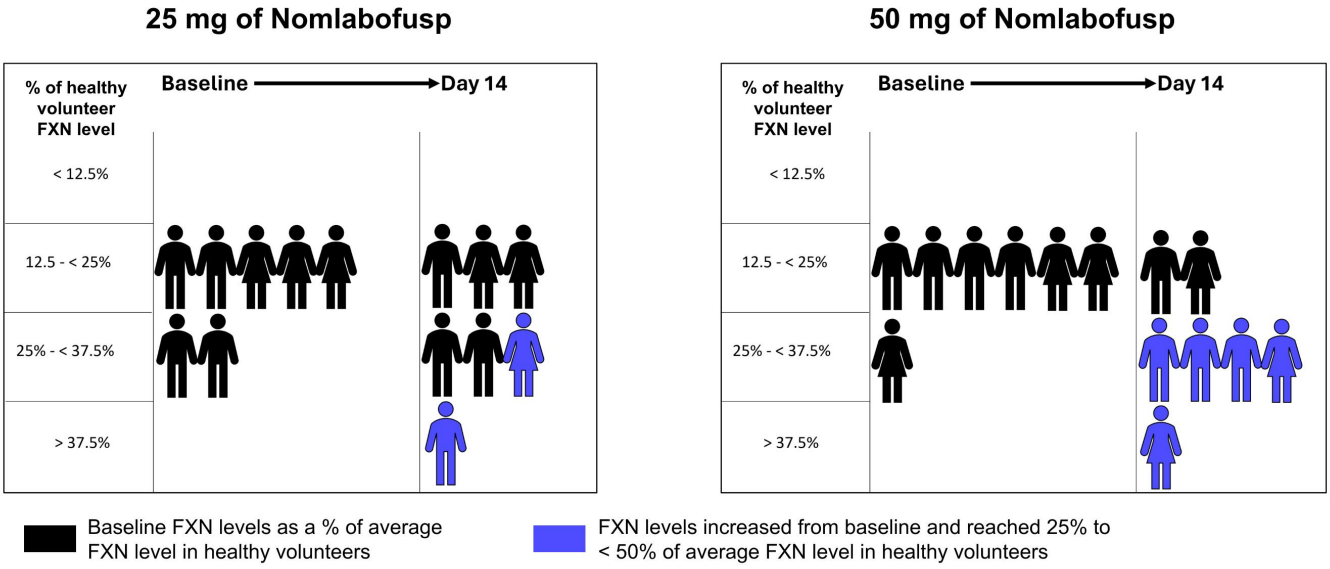


FXN Levels* in Buccal Cells
Change from Baseline at Day 14



*FXN levels measured via detection of peptide derived from mature FXN; FXN concentrations are normalized to total cellular protein content in each sample. Data represent median and 25th and 75th percentiles. Only participants with quantifiable levels at both baseline and Day 14 are included in the figures.
**Median baseline FXN level in patients were 2.1 pg/µg for the placebo, 1.8 pg/µg for the 25 mg cohort and 1.6 pg/µg for the 50 mg cohort.

Buccal Cell FXN Levels Achieve Higher % of Healthy Volunteers* Following 14 days of Daily Nomlabofusp



Only participants with quantifiable levels at baseline and day 14 are included in the figures.
*% of healthy volunteer FXN level is calculated by dividing each participant's FXN level by the average FXN level (8.24 pg/µg) from Larimar's noninterventional healthy volunteer study (N=60).

Additional Phase 1 and 2 Data Presented at the International Congress for Ataxia Research, November 2024

Nomlabofusp Clinical Studies Included a Broad, Representative Population of Adults with FA

Broad population of adults with FA included in Phase 1 and 2 Studies

Age of onset between 5 - 60 years with a median age of onset of 15 yrs

81% of participants had FXN levels at baseline less than 30% of healthy controls and 37% of participants had less than 20%

Over 50% of participants were non-ambulatory at baseline

**18 subjects participated in more than 1 study*
***Quantifiable buccal cell FXN levels relative to the median of healthy controls*
****Ambulatory status is based on the gait score (E7=5 vs. <5) of the upright stability subscore of the mFARS*
*****Data presented at the International Congress for Ataxia Research, November 2024*

Demographics and Baseline Disease Characteristics from Nomlabofusp Phase 1 and 2 Interventional Studies****

	N*	Median	Mean	Min	Max
Age	61	28.0	31.9	19	69
Age of Onset	61	15.0	15.9	5	60
Age of Diagnosis	61	19.0	21.0	5	64
Shorter GAA (GAA_1)	60	550.0	555.8	99	1000
Longer GAA (GAA_2)	60	900.0	890.2	265	1300
Frataxin, % of Control**	57	24.4	23.9	8.7	61.9
mFARS Score	61	52.0	49.5	13.2	74.5
Upright Stability Score	61	32.0	26.9	7.0	35.0
Dominant hand 9-hole peg test	61	71.0	84.8	26.0	229.2
T25-FW Test Score	51	9.9	13.4	4.3	48.5
Left Ventricular Mass (g)	61	163.4	168.0	73.7	398.8
LVEF %	61	63.0	63.5	52	76
Ambulatory Status***					
No	36				
Yes	25				

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Pooled Data from Completed Phase 1 & 2 Studies Confirms Disease & FXN Relationships are Consistent with Literature

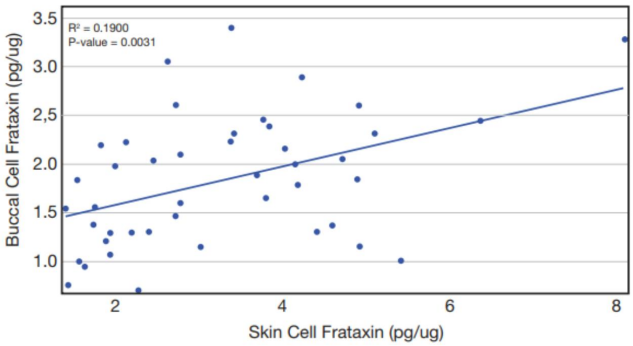
Disease Characteristics by Quartiles Based on Buccal Cell FXN Levels at Baseline

Quartile	FXN Concentration* (pg/mcg)	Age at Symptom Onset**	Age at Diagnosis **	GAA_1**	GAA_2**
Q1 (N=14)	< 1.31	10.5	14.5	616.5	899.5
Q2 (N=14)	1.31 - <1.95	13.5	23.0	486.0	866.0
Q3 (N=14)	1.95 - <2.30	16.0	19.0	555.0	871.5
Q4 (N=15)	≥ 2.30	19.0	27.0	400.0	933.0

**Quantifiable buccal cell frataxin levels*
***Median values*
Median buccal cell FXN concentration in healthy controls = 8.1 ng/mcg

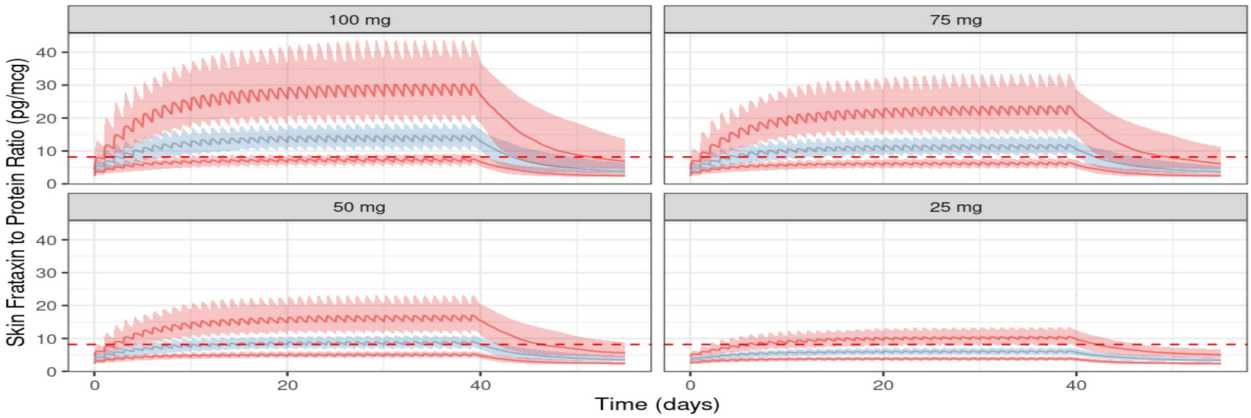
Buccal cell FXN levels correlated with age of onset and inversely correlated with the number of GAA repeats and rate of disease progression

Baseline Buccal and Skin Cell FXN Levels



Buccal cell FXN levels correlated with skin cell FXN levels

Modeling/Simulation Predicts* 50mg Daily Can Achieve Skin FXN Levels ≥50% of Healthy Controls in Most Patients



Dashed red line – 50% the average skin FXN/protein ratio (8.17 pg/ug) in a non-interventional study in healthy controls (HC)
Blue line – median of simulated values across trials
Red lines – 10th and 90th percentiles
Shaded regions – 95% confidence intervals of the corresponding percentiles (10th, 50th, and 90th).

Data presented at the International Congress for Ataxia Research, November 2024

50 mg nomlabofusp daily was predicted to lead to:
A median increase of 5.64 (2.3 – 13.5) pg/µg in FXN levels from baseline

Increase in skin FXN levels in 59% of simulated patients with FA to levels ≥50% of average skin FXN levels in HC

**PK/PD model was developed with data collected from 3 completed studies in adults with FA. A population of virtual FA patients (n = 100, 100 trials) receiving subcutaneous daily doses of 25, 50, 75, or 100 mg nomlabofusp for 40 days was simulated*

Additional
OLE Study Information

Nomlabofusp: Predictable Pharmacokinetics

1. Quick absorption after subcutaneous administration
2. Dose-proportional increases in exposure observed
3. Pharmacokinetic profile consistent with Phase 1 studies

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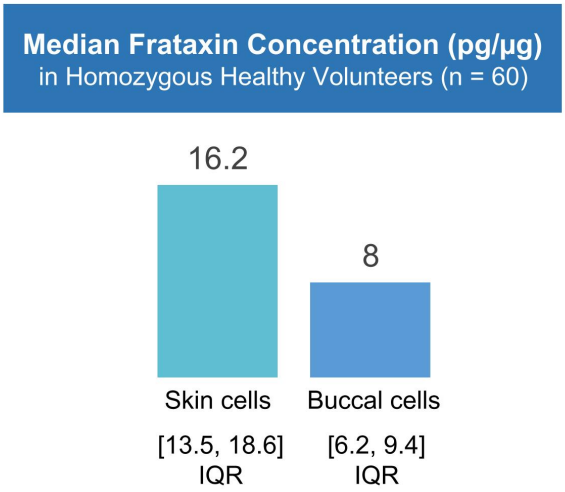
Non-Interventional Study Data

CLIN-1601-002: Top-line Non-interventional Study Results

Non-interventional study measured FXN in homozygous healthy volunteers



Most patients with FA only produce ~20-40%[1] of normal frataxin levels depending on the tissue, sampling technique, and assay considered

Lower FXN levels seen with typical onset[2] (5 to 15 years of age)

Higher FXN levels seen with late onset[2] (after 25 years of age)

Heterozygous carriers who show no signs of disease have buccal cell FXN levels of ~50% of unaffected healthy persons[1]

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FXN concentrations were measured in skin and buccal cells from 60 homozygous healthy volunteers utilizing the same sampling technique and assay as clinical trials of nomlabofusp; FXN levels measured via detection of peptide derived from mature FXN; FXN concentrations normalized to total cellular protein content in each sample. 1. E.C. Deutsch et al. Molecular Genetics and Metabolism 101 (2010) 238–245. 2. Friedreich's Ataxia Research Alliance

FDA START Pilot Program

Nomlabofusp Selected by FDA for START Pilot Program

Highlights FDA commitment to augment formal meetings with more rapid, ad-hoc communications to accelerate program development of rare diseases

START Pilot Program Support for Clinical Trials Advancing Rare Disease Therapeutics	**CDER Selection Based On**
A new milestone-driven program launched by the FDA in September 2023 Designed to **accelerate development of novel therapies** intended to address unmet medical needs in **rare diseases** **7 novel drugs selected** • 3 products by CDER (nomlabofusp) for rare neurodegenerative conditions • 4 products by CBER for cell and gene therapy	Demonstrated development **program readiness** (e.g., sponsors who demonstrate the ability to move the program towards a marketing application) Potential to address serious and unmet medical need in a **rare neurodegenerative condition** **Alignment of CMC** development timelines with clinical development plans Proposed plan where **enhanced communication can improve efficiency of product development**

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FDA: Food and Drug Administration; CDER: Center for Drug Evaluation and Research; CBER: Center for Biologics Evaluation and Research; CMC: Chemistry, Manufacturing, and Controls

FARA

Strong Relationship with FARA – Joined FARA's TRACK-FA Neuroimaging Consortium as an Industry Partner

TRACK-FA collects natural history data to establish disease specific neuroimaging biomarkers for potential use in clinical trials. Larimar will have access to all study data for use in regulatory filings, as appropriate

FARA provides industry with several key items

- Assistance with patient recruitment and education
- Access to Global Patient Registry with demographic and clinical information on more than 1,000 FA patients
- Sponsored a Patient-Focused Drug Development Meeting in 2017 resulting in a publication titled "The Voice of the Patient"

FARA Friedreich's Ataxia Research Alliance

National, non-profit organization dedicated to the pursuit of scientific research leading to treatments and a cure for FA