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 31, 2022

Eledon Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-36620**	**20-1000967**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

19900 MacArthur Blvd. Suite 550 Irvine, California	**92612**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 949 238-8090

(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, $0.001 par value	ELDN	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 7.01 Regulation FD Disclosure.

On May 31, 2022, Eledon Pharmaceuticals Inc. (the "Company" or "Eledon") issued a press release announcing positive topline results from a Phase 2a trial of tegoprubart in patients with amyotrophic lateral sclerosis ("ALS"). A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Also on May 31, 2022 and as previously disclosed, the Company is hosting a conference call to discuss the foregoing Phase 2a topline data. A copy of the slide presentation that will be used during the Company's conference call is attached hereto as Exhibit 99.2 and incorporated by reference herein.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1 and Exhibit 99.2) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be, or be deemed, incorporated by reference in any filings under the Securities Act of 1933, as amended (the "Securities Act"), unless the Company specifically states that the information is to be considered "filed" under the Exchange Act or incorporates it by reference into a filing under the Securities Act or the Exchange Act.

Item 8.01 Other Events.

On May 31, 2022, the Company announced topline results from a Phase 2a trial of tegoprubart in patients with ALS.

The primary objectives of the study were to assess the safety and tolerability of multiple doses of tegoprubart in four sequential, ascending dose cohorts (1, 2, 4, and 8 mg/kg). Secondary outcome measures included pharmacokinetic assessment of multiple intravenous doses of tegoprubart on target engagement and on pro-inflammatory biomarkers associated with ALS. Each subject served as their own control, with changes being compared to baseline.

Tegoprubart successfully met the primary endpoints of safety and tolerability. Adverse events were equally distributed across dose levels. Tegoprubart was well-tolerated, and no drug-related serious adverse events were observed. Anti-drug antibodies ("ADAs") were present in less than 5 percent of samples. All ADAs were of low titer and did not impact tegoprubart drug levels.

Tegoprubart target engagement was demonstrated at the 4 and 8 mg / kg dosing levels using CD40L and CXCL13 biomarkers related to T cell and B cell function, respectively. A pro-inflammatory ALS signature was identified, consisting of 32 different inflammatory biomarkers in the tested population, including TNF-α, MCP1, EN-RAGE, C-Reactive Protein ("CRP"), and IL-6. IL-1 was not significantly detected in the study patient population. Dose dependent, significant reductions were observed in up to 23 of these biomarkers, including TNF-α, MCP1, EN-RAGE, and CRP. Other pro-inflammatory biomarkers significantly reduced included biomarkers also associated with IgA nephropathy and kidney transplant rejection, such as IgA, IgE, IgM, C3, CXCL9, and CXCL10. While the study was neither primarily designed nor powered to assess the effect of tegoprubart on ALS Functional Rating Scale ("ALSFRS"), both target engagement and level of pro-inflammatory biomarker reduction were associated with a trend in the slowing of disease progression as measured by ALSFRS slope when compared to a cohort from the ALS PRO-ACT database

The results of nonclinical studies and early clinical trials of the Company's product candidates may not be predictive of the results of later-stage clinical trials. Interim results of a clinical trial do not necessarily predict final results. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical and clinical trials have nonetheless failed to obtain marketing approval of their products. There is a risk that additional nonclinical and/or clinical safety studies will be required by the U.S. Food and Drug Administration or similar regulatory authorities outside the United States and/or that subsequent studies will not match results seen in prior studies. As a result, topline data should be viewed with caution until the final data are available.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release Issued on May 31, 2022
99.2	ALS Phase 2a Clinical Trial Update
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 thereunto duly authorized.

Eledon Pharmaceuticals, Inc.

Date: May 31, 2022

By: /s/ David-Alexandre C. Gros, M.D.
Name: David-Alexandre C. Gros, M.D.
Title: Chief Executive Officer

Eledon Announces Positive Topline Results from Phase 2a Trial of Tegoprubart Demonstrating Safety, Target Engagement, and Biomarker Response in Patients Living with Amyotrophic Lateral Sclerosis

- *Tegoprubart was well-tolerated, with no drug-related serious adverse events*
- *Dose dependent target engagement was demonstrated, and ALS associated pro-inflammatory biomarkers were both observed and significantly reduced in a dose dependent manner*
- *Target engagement and level of pro-inflammatory biomarker reduction were associated with a trend in the slowing of disease progression as measured by ALSFRS slope when compared to a cohort from the ALS PRO-ACT database*
- *Biomarkers significantly reduced included biomarkers also associated with IgA nephropathy and kidney allograft transplant rejection*
- *Eledon management will host a webcast and conference call regarding these clinical results at 8:00 a.m. ET today, May 31, 2022*

IRVINE, Calif., May 31, 2022 – Eledon Pharmaceuticals, Inc. (“Eledon”) (Nasdaq: ELDN), a patient-focused clinical stage biopharmaceutical company committed to the development of innovative and impactful treatments for organ and cell transplantation, autoimmune conditions, and neurodegenerative disease, today announced topline results from a Phase 2a clinical trial of tegoprubart (formerly AT-1501) in patients with amyotrophic lateral sclerosis (ALS).

Tegoprubart is an investigational humanized monoclonal antibody that inhibits CD40 Ligand (CD40L), a membrane protein linked to increased peripheral immune responses and neuroinflammation in ALS. The 12-week trial included 54 patients with ALS at 13 treatment sites in the United States and Canada. The primary objectives of the study were to assess the safety and tolerability of multiple doses of tegoprubart in four sequential, ascending dose cohorts (1, 2, 4, and 8 mg/kg). Secondary outcome measures included pharmacokinetic assessment of multiple intravenous doses of tegoprubart on target engagement and on pro-inflammatory biomarkers associated with ALS. Each subject served as their own control, with changes being compared to baseline.

Tegoprubart successfully met the primary endpoints of safety and tolerability. Adverse events were equally distributed across dose levels. Tegoprubart was well-tolerated, and no drug-related serious adverse events were observed. Anti-drug antibodies (ADAs) were present in less than 5 percent of samples. All ADAs were of low titer and did not impact tegoprubart drug levels.

Tegoprubart target engagement was demonstrated at the 4 and 8 mg / kg dosing levels using CD40L and CXCL13 biomarkers related to T cell and B cell function, respectively. A pro-inflammatory ALS signature was identified, consisting of 32 different inflammatory biomarkers in the tested population, including TNF-α, MCP1, EN-RAGE, C-Reactive Protein (CRP), and IL-6. IL-1 was not significantly detected in the study patient population. Dose dependent, significant reductions were observed in up to 23 of these biomarkers, including TNF-α, MCP1, EN-RAGE, and CRP. Other pro-inflammatory biomarkers significantly reduced included biomarkers also associated with IgA nephropathy and kidney transplant rejection, such as IgA, IgE, IgM, C3, CXCL9, and CXCL10. While the study was neither primarily designed nor powered to assess the effect of tegoprubart on ALS Functional Rating Scale (“ALSFRS”), both target engagement and level of pro-inflammatory biomarker reduction were associated with a trend in the slowing of disease progression as measured by ALSFRS slope when compared to a cohort from the ALS PRO-ACT database.

“Neuroinflammation is a driving force in the pathogenesis and progression of ALS. The ability to suppress inflammatory responses may translate into clinical benefit,” said Stanley H. Appel, MD, Co-Director of the Houston Methodist Neurological Institute and Chair of the Stanley H. Appel Department of Neurology at Houston Methodist. “These results reinforce the exciting potential of tegoprubart as a promising therapy for patients with ALS.”

“These positive Phase 2a topline trial results demonstrated target engagement and a reduction in key inflammatory biomarkers in patients living with ALS,” said Merit Cudkowicz, MD, Chief of the Neurology Department at Massachusetts General Hospital; Director of the Sean M. Healey & AMG Center for ALS; and Julieanne Dorn Professor of Neurology at Harvard Medical School. “A key goal for Phase 2 trials is confirming that a drug hits the intended targets. These encouraging data support advancing tegoprubart into larger clinical ALS studies.”

“There would be no tegoprubart without the resolve of so many ALS patients and their families who supported the early drug discovery efforts for tegoprubart, and who continue to champion the scientific advancement of ALS research,” said David-Alexandre C. Gros, MD, Chief Executive Officer of Eledon. “Our new data are helping elucidate the role of inflammation in ALS and tegoprubart. In addition to ALS, tegoprubart is in clinical-stage development for IgA nephropathy, renal transplantation, and islet cell transplantation. We look forward to presenting and reporting additional data from this and from our other clinical trials later this year.”

Conference Call and Webcast Details

Eledon management will host a webcast and conference call regarding these clinical results at 8:00 a.m. ET today, May 31, 2022. The live call may be accessed by dialing (877) 407-9039 for domestic callers and +1 (201) 689-8470 for international callers with conference ID code number: 13730346. A live webcast of the call will be available online in the investor relations section of Eledon's website at www.eledon.com or by registering here, and will be archived there for one year.

About ALS

ALS, commonly known as Lou Gehrig's disease, is a progressive neuromuscular disease, and there is a critical need for more effective therapies to improve outcomes for patients. Currently, there are two drugs approved by the U.S. Food and Drug Administration (FDA) for ALS; however, the average life expectancy remains only three to five years. In the United States, ALS affects approximately 30,000 persons, and approximately 5,000 new cases are diagnosed each year.

About the Phase 2a Study of Tegoprubart

This Phase 2a, multi-center, open label, multiple dose study of tegoprubart enrolled 54 adults with ALS at treatment sites in the United States and Canada. Four ascending doses of tegoprubart were administered as an IV infusion to sequentially enrolling cohorts of up to 18 subjects. Each participant received six bi-weekly (every other week) infusions of tegoprubart and served as their own control by comparing changes to baseline. Outcome measures included safety and tolerability, assessment of biomarkers of CD40L target engagement, and changes in pro-inflammatory chemokines and cytokines upregulated in ALS.

About Eledon Pharmaceuticals and tegoprubart (formerly AT-1501)

Eledon Pharmaceuticals is a clinical stage biotechnology company using its expertise in targeting the CD40 Ligand (CD40L, also called CD154) pathway to develop potential treatments for persons requiring an organ or cell-based transplant, living with autoimmune disease, or living with ALS. The company's lead compound in development is tegoprubart, an anti-CD40L antibody with high affinity for CD40 Ligand, a well-validated biological target with broad therapeutic potential. Eledon is headquartered in Irvine, Calif. For more information, please visit the company's website at www.eledon.com.

Follow Eledon Pharmaceuticals on social media: LinkedIn; Twitter

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Any statements about the company's pre-clinical and clinical trial results, data releases, future expectations, plans and prospects, including statements about planned clinical trials, the tolerability, safety profile, development and potential of product candidates, expected

timing for initiation of future clinical trials, and the expected timing for receipt of data from clinical trials, as well as other statements containing the words "believes," "anticipates," "plans," "expects," "estimates," "intends," "predicts," "projects," "targets," "looks forward," "could," "may," and similar expressions, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are inherently uncertain and are subject to numerous risks and uncertainties, including: risks relating to the safety and efficacy of our drug candidates; risks relating to clinical development timelines, including interactions with regulators and clinical sites, as well as patient enrollment; risks relating to costs of clinical trials and the sufficiency of the company's capital resources to fund planned clinical trials; and risks associated with the impact of the ongoing coronavirus pandemic. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors. These risks and uncertainties, as well as other risks and uncertainties that could cause the company's actual results to differ significantly from the forward-looking statements contained herein, are discussed in our quarterly 10-Q, annual 10-K, and other filings with the U.S. Securities and Exchange Commission, which can be found at www.sec.gov.

In addition, the results of nonclinical studies and early clinical trials of the company’s product candidates may not be predictive of the results of later-stage clinical trials. Interim results of a clinical trial do not necessarily predict final results. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical and clinical trials have nonetheless failed to obtain marketing approval of their products. There is a risk that additional nonclinical and/or clinical safety studies will be required by the FDA or similar regulatory authorities outside the United States and/or that subsequent studies will not match results seen in prior studies. As a result, topline data should be viewed with caution until the final data are available.

Any forward-looking statements contained in this press release speak only as of the date hereof and not of any future date, and the company expressly disclaims any intent to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Media Contact:
Linda Johnson
Jeff Winton & Associates
(215) 584-6720
linda@jeffwintonassociates.com

Investor Contact:
Stephen Jasper
Gilmartin Group
(858) 525 2047
stephen@gilmartinir.com

Source: Eledon Pharmaceuticals

Exhibit 99.2

Eledon Pharmaceuticals

ALS Phase 2a Clinical Trial Update

May 31, 2022

Forward-Looking Statements

This presentation contains forward‐looking statements that involves substantial risks and uncertainties. Any statements about the company's future expectations, plans and prospects, including statements about its strategy, future operations, development of its product candidates, and other statements containing the words "believes," "anticipates," "plans," "expects," "estimates," "intends," "predicts," "projects," "targets," "could," "may," and similar expressions, constitute forward‐looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, although not all forward‐looking statements include such identifying words. Forward‐looking statements include, but are not limited to statements regarding: expectations regarding the timing for the commencement and completion of product development or clinical trials; the rate and degree of market acceptance and clinical utility of the company's products; the company's commercialization, marketing and manufacturing capabilities and strategy; the company's intellectual property position and strategy; the company's ability to identify additional products or product candidates with significant commercial potential; the company's estimates regarding expenses, future revenue, capital requirements and needs for additional financing; developments relating to the company's competitors and industry; and the impact of government laws and regulations.

Actual results may differ materially from those indicated by such forward‐looking statements as a result of various important factors, including: the ability to develop commercially viable product formulations; the sufficiency of the company's cash resources; the ability to obtain necessary regulatory and ethics approvals to commence additional clinical trials; whether data from early clinical trials will be indicative of the data that will be obtained from future clinical trials; whether the results of clinical trials will warrant submission for regulatory approval of any investigational product; whether any such submission will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies and, if we are able to obtain such approval for an investigational product, whether it will be successfully distributed and marketed. These risks and uncertainties, as well as other risks and uncertainties that could cause the company's actual results to differ significantly from the forward‐looking statements contained herein, are discussed in our annual report on Form 10‐K for the year ended December 31, 2021, and other filings with the SEC which can be found at www.sec.gov. Any forward‐looking statements contained in this presentation speak only as of the date hereof and not of any future date, and the company expressly disclaims any intent to update any forward‐looking statements, whether as a result of new information, future events or otherwise.

Tegoprubart: Pipeline in a Product Opportunity

Product Candidate	Indication	Development Stage				Anticipated Milestones
		Pre-clinical	Phase 1	Phase 2	Phase 3	
Tegoprubart (AT-1501)	Amyotrophic Lateral Sclerosis (ALS)					✓ Phase 2 top-line data in 2Q2022
	Kidney Transplantation					Enroll first Phase 1b patient Interim data readout late 2022
	Islet Cell Transplantation for Type 1 Diabetes					Enroll first Phase 2 patient Interim data readout late 2022
	IgA Nephropathy					On-going enrollment Interim data readout late 2022
AT-2001	Autoimmune Indications					Pre-clinical animal studies

Note: Development plans and timelines may change, including based on US and global regulatory interactions.

Eledon Pharmaceuticals

ALS Overview & Market Opportunity

Characterized by **gradual, progressive muscle weakness**

Affects **~30,000 Americans**

~5,000 new cases diagnosed annually in the US and **~600,000** cases globally

Average age of **55** at time of diagnosis

Only **10%** of ALS cases are **hereditary**

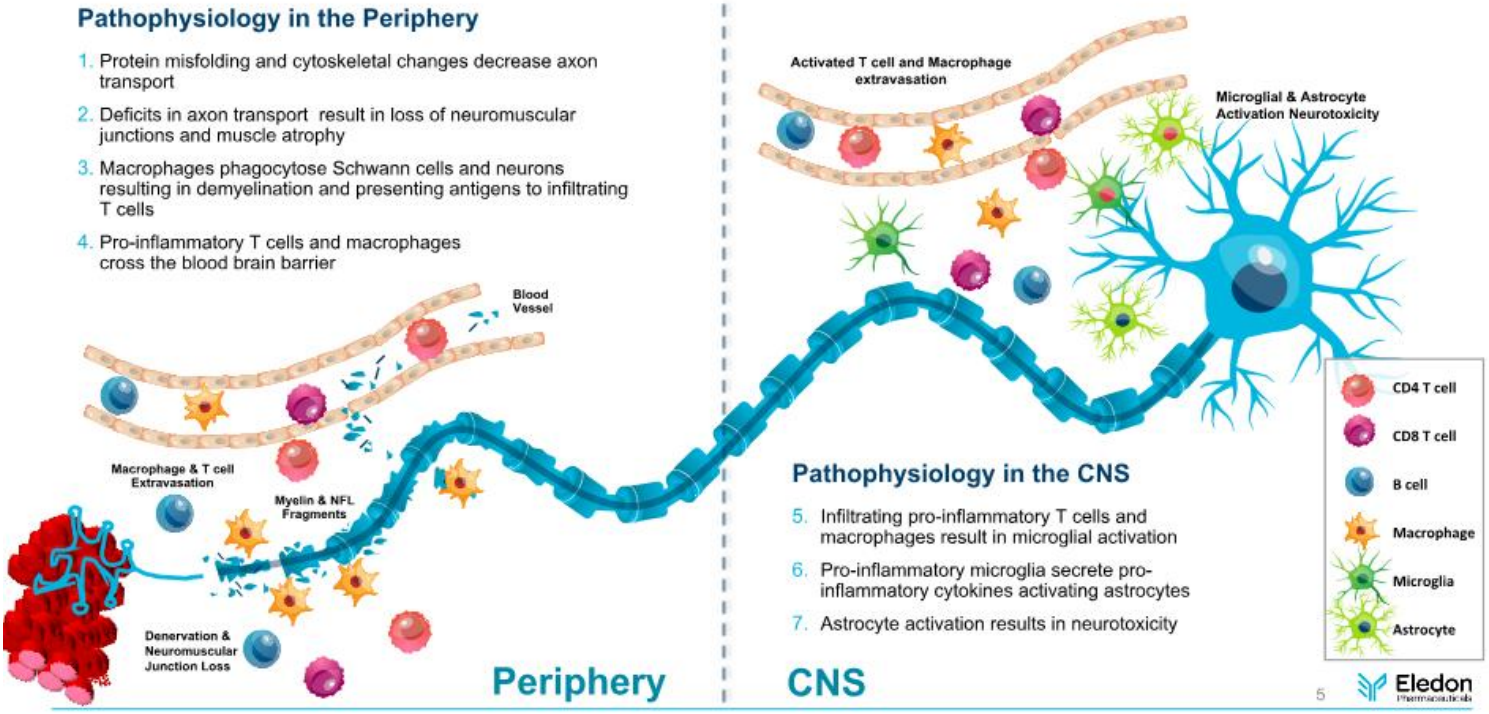
- People with ALS ultimately lose the ability to ambulate, move their arms, talk, swallow, and breath independently
- On average, death occurs between 3 to 5 years from diagnosis, most often from respiratory failure or cachexia

Very high 5-year ALS morbidity and mortality despite two FDA approved treatments

Pathophysiology of Amyotrophic Lateral Sclerosis

Pathophysiology in the Periphery

1. Protein misfolding and cytoskeletal changes decrease axon transport
2. Deficits in axon transport result in loss of neuromuscular junctions and muscle atrophy
3. Macrophages phagocytose Schwann cells and neurons resulting in demyelination and presenting antigens to infiltrating T cells
4. Pro-inflammatory T cells and macrophages cross the blood brain barrier



Pathophysiology in the CNS

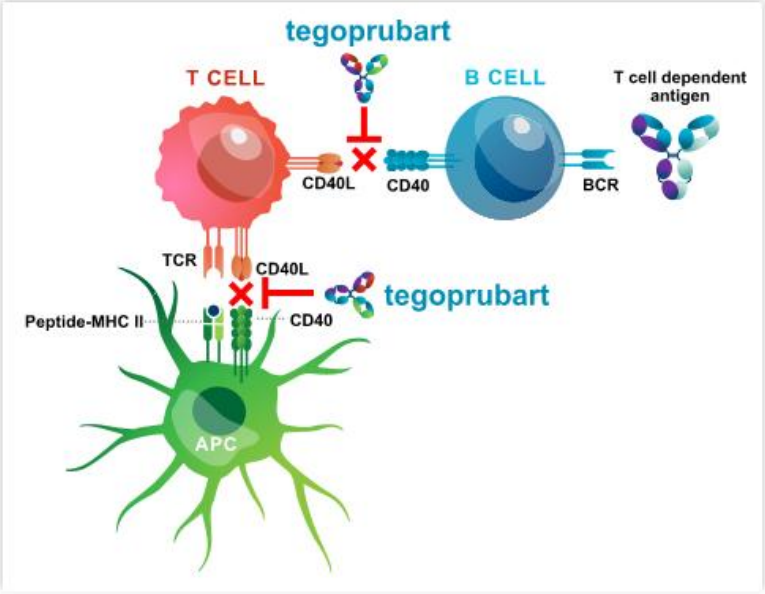
5. Infiltrating pro-inflammatory T cells and macrophages result in microglial activation
6. Pro-inflammatory microglia secrete pro-inflammatory cytokines activating astrocytes
7. Astrocyte activation results in neurotoxicity

Periphery **CNS**

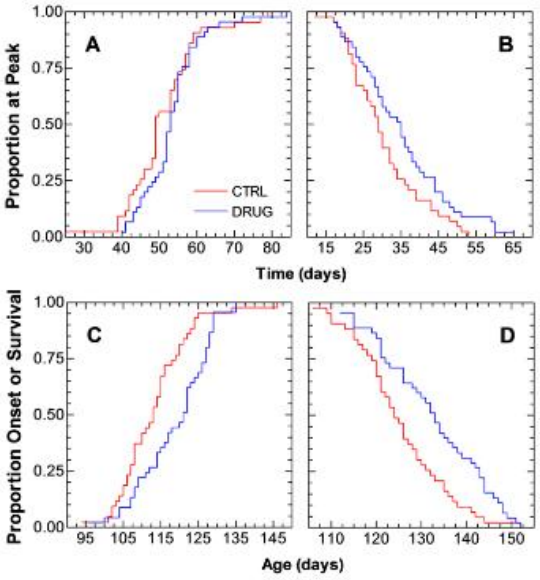
Eledon Pharmaceuticals

Mechanism Overview of CD40L Inflammatory Signaling

- Interaction of CD40 with CD40L on immune cells **mediates activation of the co-stimulatory immune pathway**, controlling "cross talk" between the adaptive and innate immune systems
- Maximal activation of inflammatory system is a 3-step process requiring co-stimulatory signaling
  - **Step 1:** Major histocompatibility complexes (MHC) and CD3/TCR engagement
  - **Step 2:** CD40 and CD40L binding resulting in cell division and clonal expansion
  - **Step 3:** Pro-inflammatory response by polarized T cells expressing inflammatory chemokines and cytokines
- Blocking CD40L shifts polarization from pro-inflammatory signaling to T cell anergy, apoptosis, and polarization to a Treg environment
  - Blocking CD40L thus **does not generally result in lymphopenia** often seen with immunosuppressive agents



Blocking CD40L Ameliorates Disease in SOD1 Mice



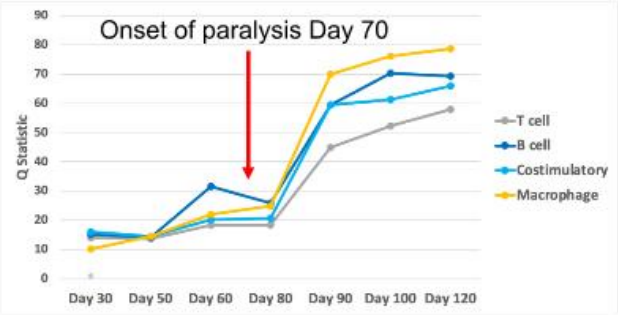
Blocking CD40L improves body-weight maintenance, delays disease onset and extends survival in SOD1 mice

A. Kaplan-Meier time-to-event analysis for time required to attain peak body weight. Time to peak was not significantly ($p = 0.35$) changed by anti-CD40L treatment
B. Body-weight maintenance was significantly ($p = 0.0413$) improved by anti-CD40L treatment
C. Time-to-event analysis for disease onset (neurological severity score of 2) was significantly ($p = 0.0038$) delayed by anti-CD40L treatment
D. Time-to-event analysis for age at which mice died was significantly ($p = 0.0043$) prolonged by anti-CD40L treatment

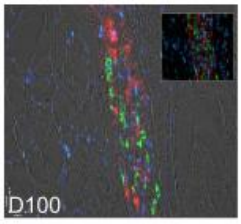
Source: Lincecum, 2010.

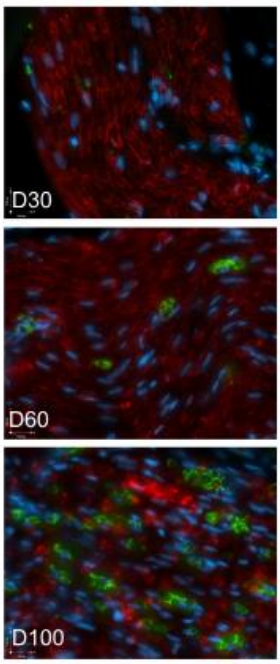
Inflammatory Pathways are Activated in the Periphery in ALS Animal Models

Activation of Inflammatory Pathway in ALS Rodent Skeletal Model



- Macrophages accumulate on peripheral nerves in skeletal muscle
- Staining shows Myelin (Red), Macrophages (Green), and Nuclei (Blue)



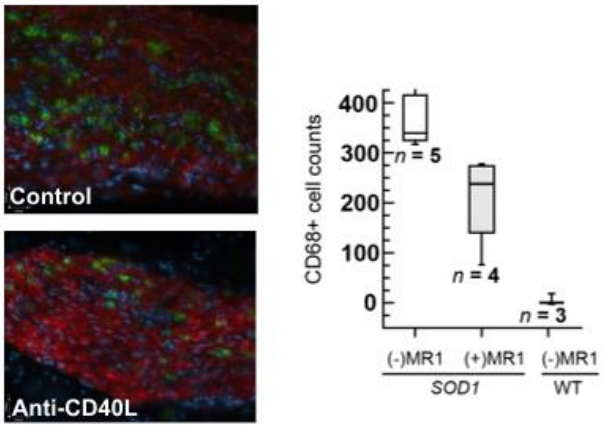


Source: Lincecum, 2010.

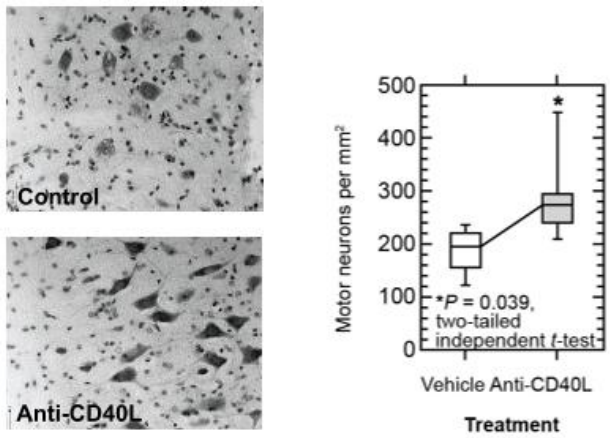
Eledon

Blocking CD40L Reduces Neuroinflammation and Improves Motor Neuron Survival in SOD1 Mice

Anti-CD40L (MR1) treatment reduces macrophage infiltrate and "attack" of denervated peripheral nerves in skeletal muscle



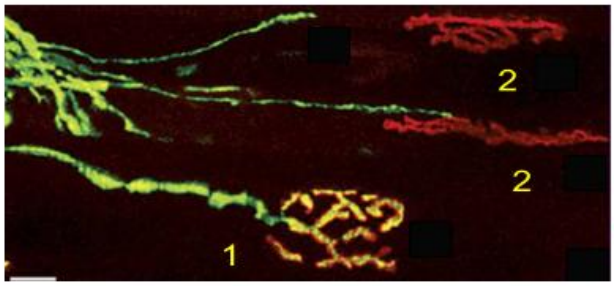
Anti-CD40L treatment reduces neuroinflammation in the spinal cord resulting in improved motor neuron survival



Source: Lincecum, 2010.

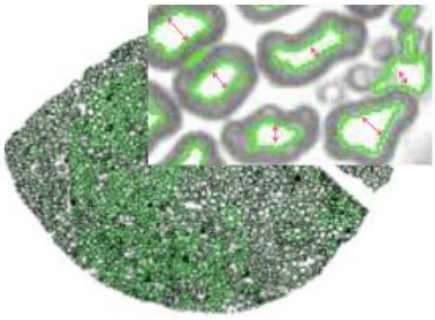
Eledon Pharmaceuticals

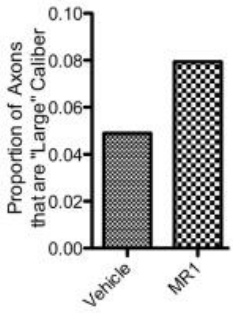
Blocking CD40L Improves Neuromuscular Junction Occupancy and Demyelination in SOD1 Mice



Staining: Myelin (green), alpha bungarotoxin acetylcholine receptors (red)

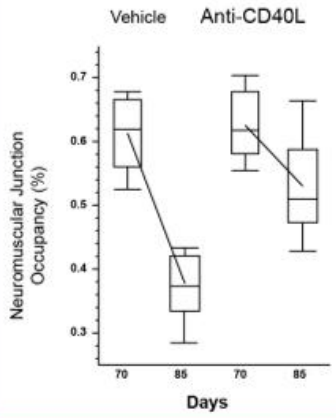
1: Innervated neuromuscular junction
2: Denervated neuromuscular junction





Anti-CD40L treatment (MR1) increases survival of large caliber axons

Anti-CD40L treatment reduces macrophage infiltrate resulting in increased neuromuscular junction occupancy



Source: Lincecum, 2010; ALS Therapy Development Institute, unpublished data.

Eledon Pharmaceuticals

Inflammatory Biomarkers & CD40L Levels are Elevated in Serum of Patients with ALS

Serum Biomarker Levels: ALS Patients vs. Controls

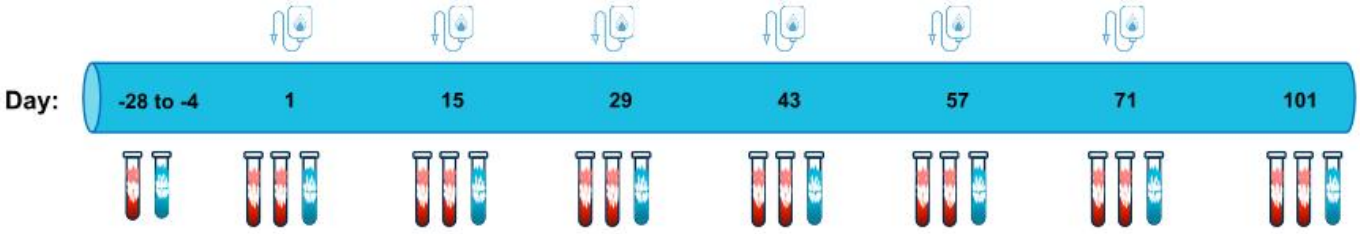
Serum	Ctrl (n = 94)	ALS (n = 60)	*p* value
Nf-L (pg/ml)	30.20 ± 23.41	512.4 ± 417.4	**< 0.0001**
VCAM-1 (ng/ml)	647 ± 181	891 ± 366	**< 0.0001**
ICAM-1 (ng/ml)	485 ± 120	750 ± 297	**< 0.0001**
VEGF (pg/ml)	199.1 ± 232.5	150.0 ± 77.23	0.523
Eotaxin (pg/ml)	242.4 ± 143.3	284.5 ± 104.6	0.134
MCP-1 (pg/ml)	256.9 ± 96.94	373.8 ± 169.1	**< 0.0001**
IP-10 (pg/ml)	384.7 ± 289.5	640.2 ± 320.4	**< 0.0001**
IL-17a (pg/ml)	0.68 ± 0.53	1.38 ± 1.48	**< 0.0001**
TNF-α (pg/ml)	1.76 ± 0.72	4.99 ± 7.85	**< 0.0001**
IL-2 (pg/ml)	N.A	0.40 ± 0.41	
IL-10 (pg/ml)	0.29 ± 0.34	0.51 ± 0.19	**< 0.0001**
IL-8 (pg/ml)	106.1 ± 186.5	172.3 ± 354.9	0.395
IL-6 (pg/ml)	0.58 ± 0.58	2.0 ± 2.6	**< 0.0001**
IL-1β (pg/ml)	N.A	0.47 ± 0.73	
IFN-γ (pg/ml)	5.31 ± 5.22	2.96 ± 2.25	**< 0.0001**

- **Levels of inflammatory biomarkers have been found to be elevated in ALS patients and correlated with disease progression**
- **CD40-CD40L signaling** between antigen presenting cells and T-cells is **upregulated in** the blood of **56% of patients with ALS**
  - **sCD40L levels** have also demonstrated **correlation with rate of disease progression**

Source: Brodovitch, 2021; Ots, 2022.

Eledon Pharmaceuticals

Phase 2a ALS: Study Design



- 12-week, open label, multiple ascending dose level study
- Four sequential dose cohorts of 9 patients (1 and 2 mg/Kg) and 18 patients (4 and 8 mg/Kg) each
- Each subject serves as own control by comparing changes from baseline assessment

Phase 2a ALS: Demographics

- 54 subjects recruited
- Average age - 59 years old
  - 72% male
  - 96% Caucasian
- Average baseline ALSFRS-R of 39.5
  - 7 subjects had ALSFRS–R < 35 or ALS Bulbar domain scores ≤ 4 at first infusion

- **Demographics and stage of disease confirm overall recruitment of target population**
- **Recruited population generally in line with demographics of ALS in the United States**
- **Some patients enrolled who at 1st infusion would not have met screening entry criteria**

Phase 2 ALS: Planned Data Generation

Safety & Tolerability

Biomarkers of CD40L target engagement

Pro-inflammatory Biomarkers

Exploratory Endpoints

- Key sub-analyses:
  1. Compare subjects who did or not achieve target engagement as defined by a change in CXCL-13
  2. Compare subjects who had target engagement but differed in changes in pro-inflammatory biomarkers (i.e., High vs. Low Responders)

Phase 2a ALS: Safety & Tolerability

- All adverse events were reviewed by an independent data safety monitoring board that recommended continued dosing

- 35.2% of patients had 1 or more drug-related adverse events (AEs)
  - No drug-related serious or severe AEs
  - Occurrence of drug-related adverse events was balanced across dose cohorts
  - No thrombosis or signs of platelet activation
  - 2 subjects experienced adverse events leading to withdrawal
    - 1 subject withdrew because of worsening depression in the 1 mg/Kg cohort
    - 1 subject withdrew because of malaise in the 2 mg/Kg cohort

- Anti-Drug Antibodies detected in ~4.2% of samples
  - ADAs of low titer and did not effect tegoprubart levels

Phase 2a ALS: Key Observed Biomarker Decreases at Week 12

CD40L Target Engagement

Biomarker	Significance at 2mg/Kg	Significance at 4mg/Kg	Significance at 8mg/Kg
CXCL13	X	*p<0.01*	*p<0.0001*
CD40L	*p<0.0001*	*p<0.0001*	*p<0.0001*

Pro-Inflammatory

Biomarker	Significance at 1 or 2mg/Kg	Significance at 4mg/Kg	Significance at 8mg/Kg
TNF-α	X	*p<0.0001*	*p<0.0001*
MCP1	X	X	*p=0.0002*
IL-6	X	X	X
EN-RAGE	X	*p=0.05*	*p=0.02*
CRP	X	*p=0.03*	*p=0.003*

- Up to 23 of 32 inflammatory biomarkers detected were significantly reduced at 4 and 8 mg/Kg dose levels, including: IgA, IgE, IgM, C3, CXCL9 & CXCL10
- IL-1 was not significantly detected in the 54 subject cohort

Eledon Pharmaceuticals

Phase 2a ALS: Monthly Change in ALSFRS-R by Cohort, Baseline Criteria, Target Engagement, and Level of Response

Monthly Change in ALSFRS-R (% Improvement vs. PRO-ACT)

Group	All Subjects	Baseline Criteria	Positive Target Engagement	High Responders
PRO-ACT *(Comparator)*	-0.83	-0.83	-0.83	-0.83
All	-1.02 **22.9%** n=54	-0.75 **(9.6%)** n=47	-0.67 **(19.3%)** N=40	-0.60 **(27.7%)** n=37
Low Dose (1/2 mgs)	-0.89 **7.2%** n=18	-0.89 **7.2%** n=18	-0.68 **(18.1%)** n=11	-0.71 **(14.5%)** n=10
High Dose (4/8 mgs)	-1.08 **30.1%** n=36	-0.66 **(20.5%)** n=29	-0.66 **(20.5%)** n=29	-0.57 **(31.3%)** n=27

- **All Subjects** includes 54 subjects enrolled in the study
- **Baseline Criteria** excludes 7 subjects with an ALSFRS-R < 35 at time of first infusion and/or a total aggregate score ≤ 4 out of 12 in the bulbar domains of ALSFRS-R
- **Positive Target Engagement** defined as subjects with at least a 10% decrease in CXCL13
- **Low Dose Subjects without Target Engagement had a mean change of –1.14 or 37.3% vs. PRO-ACT**
- **High Responders** defined as subjects with a minimum 10% reduction in 75% or more of inflammatory biomarkers

Phase 2 ALS: Data Summary

Safety & Tolerability

- 35.2% of patients had 1 or more drug-related adverse events (AEs)
- No drug-related serious or severe AEs
- Occurrence of drug-related adverse events was balanced across dose cohorts

Biomarkers of CD40L target engagement

- At 4 and 8 mg / kg dose levels, target engagement was demonstrated using CD40L and CXCL13 biomarkers related to T cell and B cell function, respectively

Pro-inflammatory Biomarkers

- Dose dependent, significant reductions were observed in up to 23 of 32 biomarkers, including TNF-α, MCP1, EN-RAGE, and C-Reactive Protein

Exploratory Endpoints

- Target engagement and level of reduction in pro-inflammatory biomarkers were associated with a trend in the slowing of disease progression as measured by ALSFRS slope when compared to a cohort from the ALS PRO-ACT database

2022 Execution Priorities

- ✓ Complete ALS Phase 2 study and release data
- Continue IgA Nephropathy clinical trial enrollment
- Begin Kidney Transplantation clinical trial enrollment
- Begin Islet Cell Transplantation for Type 1 Diabetes clinical trial enrollment
- Advance tegoprubart subcutaneous formulation

Interim clinical data readouts in up to 3 other open label studies expected by year-end

Note: Development plans and timelines subject to change based on several factors, including US and global regulatory agency interactions.

Q&A


Eledon Pharmaceuticals
19900 MacArthur Blvd., Suite 550
Irvine, California 92612 USA
info@eledon.com
+1 949-238-8090
21
Eledon