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): January 09, 2023

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 January 9, 2023, Eledon Pharmaceuticals Inc. (the "Company" or "Eledon") issued a press release, which provided a business and pipeline update. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Also on January 9, 2023, the Company updated its investor presentation, which is used from time to time to conduct meetings with investors, stockholders and analysts. The investor presentation will also be available on the investor page of the Company's website at ir.eledon.com/investor-relations. A copy of the presentation is filed 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release Issued on January 9, 2023
99.2	Corporate Presentation by the Company for January 2023
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: January 9, 2023

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

Eledon Pharmaceuticals Provides Business and Pipeline Updates

Company plans to prioritize and focus resources on the advancement of tegoprubart in kidney transplantation

Continued enrollment in open-label Phase 1b kidney transplant trial with initial data release expected at the World Congress of Nephrology in March 2023

Phase 2 BESTOW trial planned to evaluate tegoprubart for the prevention of rejection in patients receiving a kidney transplant with site initiation anticipated in mid-2023

Deprioritize clinical development of tegoprubart in IgA Nephropathy (IgAN) and discontinue islet cell transplantation to focus on kidney transplant opportunity; high dose cohort safety data from IgAN trial expected at the World Congress of Nephrology in March 2023

Sufficient financial resources to fund operating activities into 2024

IRVINE, Calif., January 9, 2023 — Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN), today announced a business update aimed at maximizing shareholder value by prioritizing resources on its ongoing clinical development efforts in kidney transplantation.

Every year more than 24,000 people undergo a kidney transplant in the United States, and over 240,000 Americans are living with a functioning transplanted kidney. Eledon's investigational drug candidate, tegoprubart, seeks to address the challenges associated with current immunosuppressive transplantation regimens, such as those that administer calcineurin inhibitors (CNIs). The ability to prevent acute and chronic transplant rejection without the need for CNIs has the potential to transform the clinical management of transplantation by mitigating the nephrotoxicity and other side effects associated with CNIs, and potentially increasing the functional life of transplanted organs.

"We are excited with the progress we made last year advancing our kidney transplantation program and remain on track to achieve important milestones in 2023," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "We believe tegoprubart has the potential to reduce the nephrotoxicity and side effect burden associated with current calcineurin inhibitor-based standard of care immunosuppressive regimens that can lead to graft dysfunction, diabetes and other side effects. Given the significant market opportunity and unmet need, we made the strategic decision to prioritize and focus both our financial and organizational resources on our kidney transplantation programs."

"In order to allow us to focus on kidney transplantation, we are deprioritizing our IgAN program and have discontinued our islet cell transplant trial. As such, we do not expect to report out data in IgAN except for data relevant to our kidney transplant program, such as safety data. With respect to our amyotrophic lateral sclerosis program, we remain very enthusiastic about the positive Phase 2 biomarker data we

announced last year – including data relevant to our kidney transplant program – and we plan to continue to seek funding for a subsequent ALS trial."

Pipeline Update

Kidney Transplantation

- The Company received regulatory clearance to initiate a Phase 1b open-label trial in Canada, the United Kingdom and Australia, for up to twelve patients, evaluating tegoprubart as a replacement for tacrolimus as a component of an immunosuppressive regimen in patients undergoing kidney transplantation. Enrollment is currently ongoing, with three patients dosed in the second half of 2022.
- The Company received Investigational New Drug (IND) application clearance from the U.S. Food and Drug Administration (FDA) for BESTOW, a Phase 2 trial of tegoprubart for the prevention of transplant rejection in persons receiving a kidney allograft. BESTOW will be a multicenter, open-label, active control, trial to assess the safety and efficacy of tegoprubart compared with tacrolimus in the preservation of allograft function after kidney transplantation. The trial's primary endpoint is mean eGFR at one year post-transplantation. Secondary objectives include safety, incidence of new onset diabetes, biopsy-proven rejection, and graft survival. The trial will enroll approximately 120 participants (60/arm) undergoing kidney transplant and will run in parallel to the ongoing Phase 1b clinical trial of tegoprubart in kidney transplantation.
- BESTOW includes an open-label extension trial allowing for the collection of long-term efficacy and safety from both this Phase 2 as well as the ongoing Phase 1b trial.
- The Company announced a collaboration agreement with eGenesis for the use of tegoprubart in preclinical xenotransplantation studies. Anti-CD40L costimulatory blockade has been demonstrated as a key component of effective immunosuppressive regimens to suppress xenograft rejection in non-human primate models of organ transplantation.

IgAN

- The Company received IND application clearance from the FDA to evaluate tegoprubart for the treatment of IgAN. This global clinical trial is a 96-week open-label clinical trial that may include up to 42 total participants, equally split between an initial high dose and a potential subsequent low dose cohort. Ten patients have been dosed to date in the high dose cohort.

Amyotrophic Lateral Sclerosis (ALS)

- In mid-2022, the Company announced positive topline results from a Phase 2a trial of tegoprubart in patients with ALS. Tegoprubart successfully met the primary endpoints of safety and tolerability, with no drug-related serious adverse events. Tegoprubart treatment was associated with dose dependent target engagement and a reduction in pro-inflammatory biomarkers in circulation.
- The Company continues to work closely with key stakeholders on potential next steps, as well as evaluating a range of approaches to fund a potential future trial.

Anticipated 2023 Milestones

- 1Q 2023: initial three and six-month open-label data from the Phase 1b trial of tegoprubart in kidney transplantation.
- 1Q 2023: initial open-label safety data from the Phase 2a trial of tegoprubart in IgAN.
- Mid-2023: initiate Phase 2 BESTOW trial of tegoprubart in kidney transplantation.
- 2H 2023: complete enrollment in Phase 1b trial of tegoprubart in kidney transplantation.

About Eledon Pharmaceuticals and tegoprubart

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 future expectations, plans and prospects, including statements about planned clinical trials, the development of product candidates, expected timing for initiation of future clinical trials, expected timing for receipt of data from clinical trials, the company's capital resources and ability to finance planned 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 sides, 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. 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.

Investor Contact:
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Gilmartin Group
(858) 525 2047
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Source: Eledon Pharmaceuticals

Exhibit 99.2

Eledon Pharmaceuticals

Targeted Immunology CD40/CD40L Therapeutics

Transplantation | Autoimmunity | ALS

January 2023

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.

Photo: Gertrude "Trudy" Elion.

Single Company Focus: Leveraging Validated Biology to Develop Best-in-Class Immune-Modulating Therapeutics

Optimized & Differentiated Lead Asset

- CD40/CD40L **pathway validated by extensive historical proof-of-concept data**
- Tegoprubart was engineered to increase potency, half-life and manufacturability vs. other anti-CD40 approaches
- Targeting areas of high unmet need including organ transplantation and ALS

Strong Financial Profile

- **$65.9M in cash** and cash equivalents (as of September 30, 2022)
- Expected **sufficient to fund operations into 2024**
- ~29.9 M fully diluted shares outstanding

Near-Term Milestones

- Multiple interim **clinical data** readouts expected beginning **in Q1'23** in **Kidney Transplantation & IgA Nephropathy** (safety)
- **Initiation of Phase 2 BESTOW trial** of tegoprubart in **kidney transplantation** expected in **mid-2023**

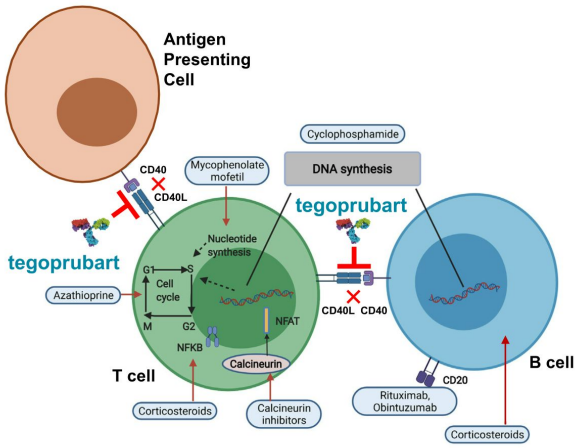
Tegoprubart: Tegoprubart: Pipeline in a Product Opportunity With Transplantation as the Primary Focus

Product Candidate	Indication	Development Stage				Notes
		Pre-clinical	Phase 1	Phase 2	Phase 3	
Tegoprubart	Kidney Transplantation					• Phase 1b enrolling with interim data readout expected Q1 2023 • Phase 2 expected to launch mid-2023
	Liver Transplantation					• Academic collaboration
	Xenotransplantation					• eGenesis collaboration
	Amyotrophic Lateral Sclerosis (ALS)					• Phase 2 top-line reported May 2022
	IgA Nephropathy					• Program deprioritized • Interim safety data readout Q1 2023
AT-2001	Autoimmune Indications					

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

Mechanism Overview of CD40L Inflammatory Signaling

CD40/CD40L Pathway and Tegoprubart Site of Action



- 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 away 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

Source: Adapted from Kant, 2022.

Tegoprubart: Potential Best-in-Class Anti-CD40/CD40L Antibody

Targeting CD40 Ligand vs. CD40 Receptor		IgG1 vs. fusion protein or pegylated FAB
CD40L and CD40	**CD40L only**	
Targeting both anti-CD40L and anti-CD40 inhibits B cell polarization and class switching, as well as inhibits the pro-inflammatory polarization of $CD4^+$ Helper T cells	✓ Blocking anti-CD40L also inhibits CD11 costimulatory receptors on antigen presenting cells, thus blocking the pro-inflammatory polarization of $CD8^+$ Cytotoxic T cells	✓ Up to over 2x times longer half-life
	✓ Blocking CD40L also polarizes $CD4^+$ lymphocytes to $FoxP3^+$ Regulatory T cells (Tregs), thus creating a potentially more tolerogenic environment	✓ Manufacturing advantages
	✓ CD40L is more selectively expressed, providing the potential for additional safety and PK/PD/dosing advantages	✓ Less anti-drug antibodies

Note: Potential advantages versus selected other CD40/CD40L clinical programs; not based on head-to-head studies. Differences versus any individual competitive program may vary.

Tegoprubart Experience

Tegoprubart Phase 1a/1b Single Ascending Dose Trial Completed in Healthy Subjects and ALS Patients

Healthy Volunteers or ALS Patients Receiving Either tegoprubart (mg/kg, IV) or Placebo

Subjects	Healthy	Healthy	ALS	Healthy	Healthy	Healthy	Tego-prubart	Placebo
Dose (mg/kg)	0.5	1	**1**	2	4	8	NA	NA
n=	6	3	**3**	3	3	6	24	8
Number of Subjects (%) Experiencing TEAEs by Maximum Toxicity Grade								
Grade 1 (% Subjects Experiencing Events)	3 (50.0%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	1 (33.3%)	1 (16.7%)	11 (45.8%)	5 (62.5%)
Grade 2 (% Subjects Experiencing Events)	–	–	1 (33.3%)	–	–	1 (16.7%)	2 (8.3%)	–
Grade 3	–	–	–	–	–	–	–	–
Grade 4	–	–	–	–	–	–	–	–
Grade 5	–	–	–	–	–	–	–	–

Phase 2a ALS: Trial Design, Safety & Tolerability

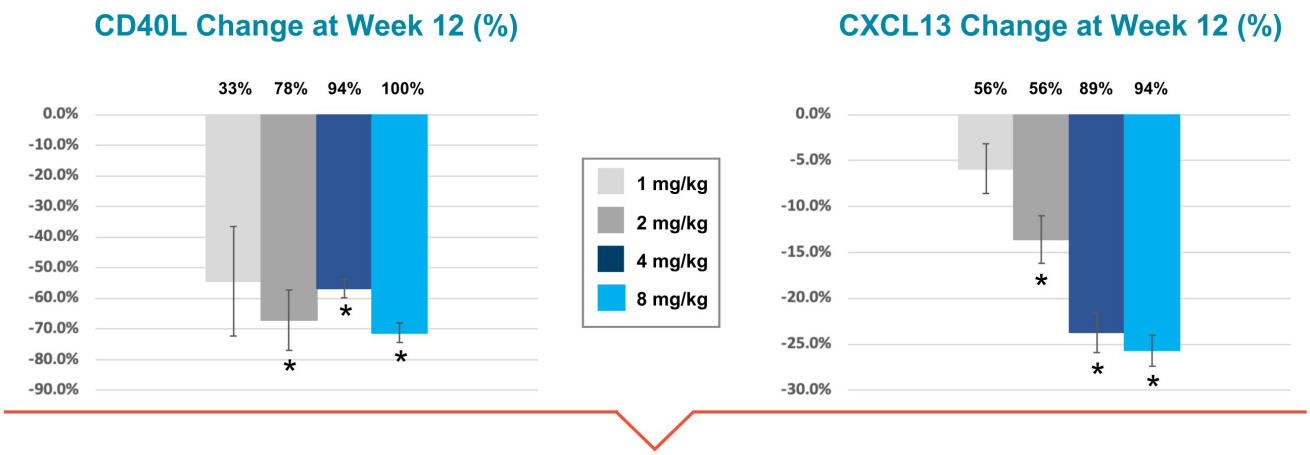
Trial design:

- 12-week, open label, multiple ascending dose level study
- Four sequential dose cohorts of 9 participants (1 and 2 mg/kg) and 18 participants (4 and 8 mg/kg) each
- Each participant serves as own control by comparing biomarker changes over time from initial baseline assessment

Safety & Tolerability:

- 35.2% of participants 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 participants experienced adverse events leading to withdrawal
    - 1 participant withdrew because of worsening depression in the 1 mg/kg cohort
    - 1 participant withdrew because of malaise in the 2 mg/kg cohort
- Anti-Drug Antibodies detected in ~4.2% of samples
  - ADAs were of low titer and did not effect tegoprubart levels

Phase 2a ALS: Tegoprubart Demonstrates Dose Dependent T and B Cell Target Engagement



- **Tegoprubart exposure decreased inflammatory biomarker levels in a dose dependent manner**
- **20 biomarkers detected were statistically significantly reduced at one or both of the higher dose levels, including: IgA, IgE, IgM, C3, CXCL9 & CXCL10**
- **Target engagement at 12 weeks increased with dose**

Note: Percentage of subjects with ≥10% reduction from baseline in a target biomarker shown above. Positive Target Engagement defined as participants with ≥10% decrease in CXCL13

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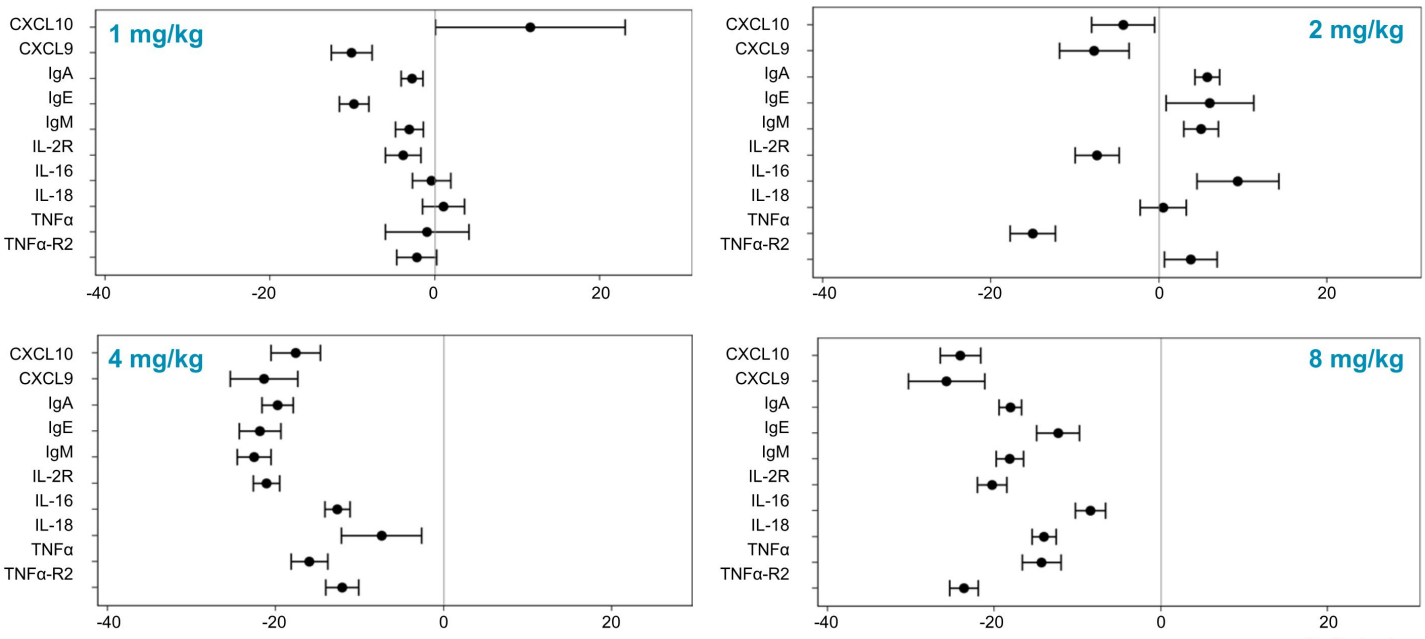
Phase 2a ALS: Tegoprubart Demonstrates Dose Dependent Reduction in Pro-Inflammatory Biomarkers



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Kidney Transplantation Opportunity & Clinical Development Plan

Kidney Transplantation Overview

Unmet Need

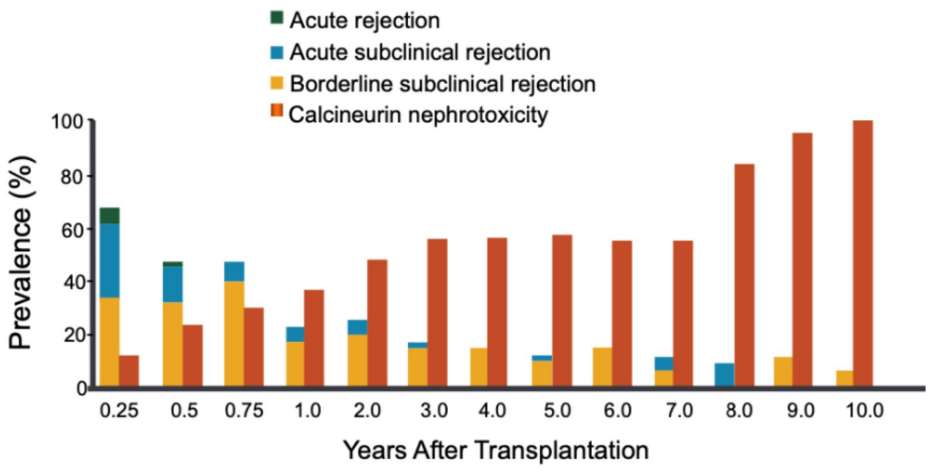
- In the 1990s, Calcineurin inhibitors (CNIs) revolutionized the field of transplantation, allowing transplant medicine to grow across transplant types, and providing meaningful treatment to thousands of people
- CNIs provide excellent 1 year patient and graft outcomes, but:
  - They are less effective against long term antibody mediated rejection
  - They are nephrotoxic and slowly harm the graft over time
  - They are associated with significant adverse effects including post-transplant new onset diabetes, tremors, and hair loss
- On average, transplanted kidneys from deceased donors function about 10 years

Market Size

- 24,000+ U.S. kidney transplants per year
- 240,000+ Americans living with a kidney graft
- ~90,000 Americans face a 3-5 year wait for a kidney
  - ~5,000 Americans per year on the transplant waiting list die without getting a transplant
- Pre-transplant dialysis costs over $100,000 per year
  - Hemodialysis has a 15-20% first-year mortality rate with a 5-year survival rate of under 50% (vs. ~80% 5-year survival post kidney transplant)
- Annual medical cost to treat transplant patients who experience renal graft failure increase 450%

Source: Donate Life America; NIDDK & Shapiro 2017; USRDS 2019; DHHS OPTN; Ghisdal 2012; Kidney.org; UCSF.

CNI Nephrotoxicity Over Time is a Leading Cause of Long-Term Kidney Transplant Graft Failure



At 6 months post transplant:

- ~24% of CNI treated patients demonstrate kidney impairment
- Up to 1/3 of CNI treated patients experience New Onset Diabetes After Transplant (NODAT) or impaired fasting glucose levels, which may also negatively impact kidney grafts over time

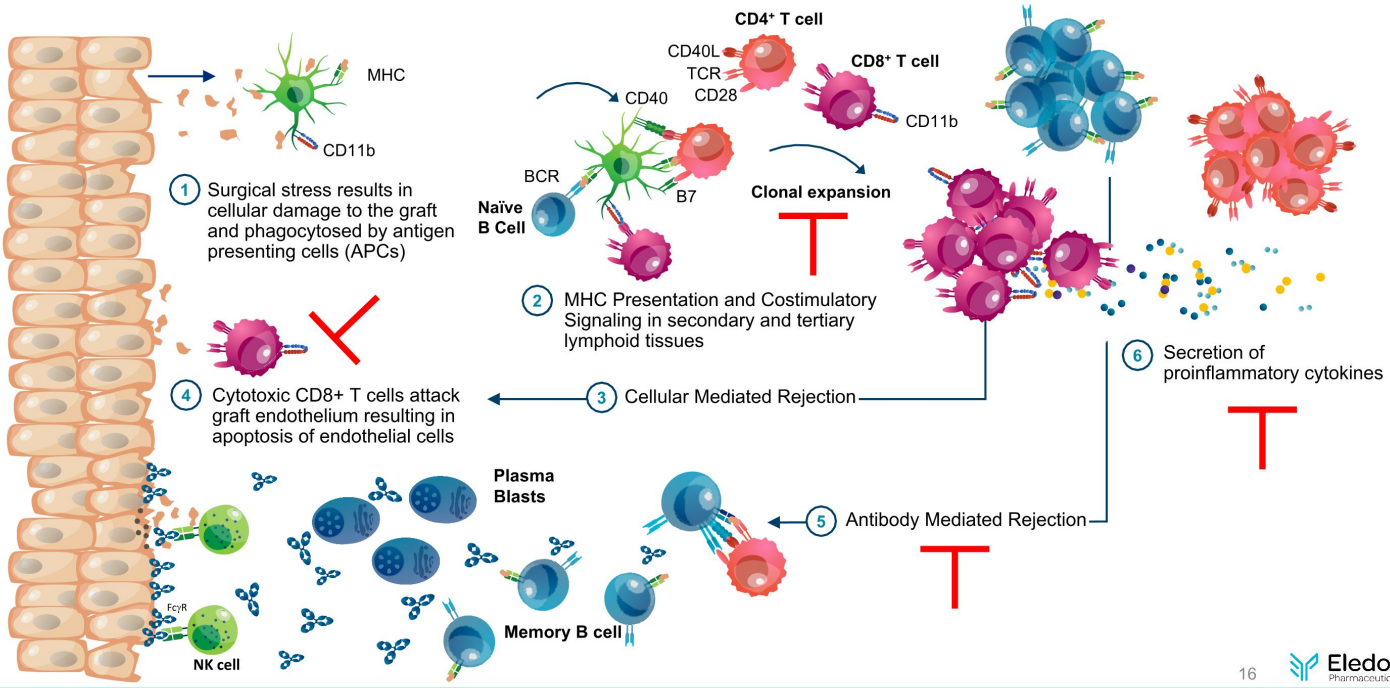
Source: Nankivell 2003; ATC 2018; Vincenti 2007.

Incidence of CNI Related Nephrotoxicity Increases with Time Post Transplant Across Organ Types

Organ Transplant	Duration of CNI Exposure (Years)	CNI Nephrotoxicity (defined as decreased kidney function / histology)
Kidney-Pancreas	1 5 10	30% 55% 100%
Liver	4 5	16% 18%
Bone Marrow	8	67%
Heart	5 10	9% 9% ESRD
Lung	5	14%
Intestine	5	21%

Source: Kemper, 2014.

Anti-CD40L in the Prevention of Transplant Rejection



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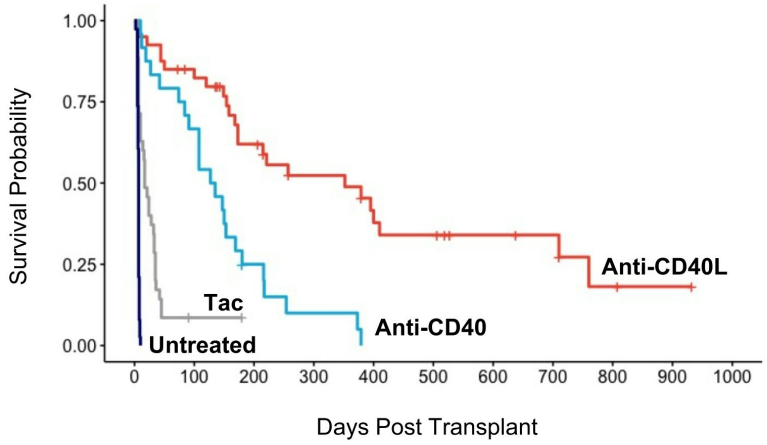
Inhibition of CD40L Improved Survival vs. CD40 Inhibition in Non-Human Primate (NHP) Kidney Transplantation Monotherapy Studies

NHP Survival Post Kidney Transplant



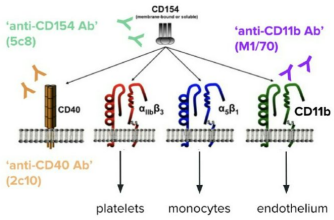
In aggregated data from published studies, **NHPs receiving anti-CD40L** (e.g., 5c8, AI794, IDEC-131) immunomodulation monotherapy post kidney transplantation **had longer average survival** than those receiving anti-CD40 monotherapy (e.g., 4D11, cH5D12, Chi220, ASKP1240, tacrolimus monotherapy or untreated controls

Sources: Perrin, 2022. Song, 2014; Song, 2016; Duan, 2017.
Note: **Meta-analysis not based on head-to-head studies.** Differences between any individual programs may vary. Tac = tacrolimus.

Recent NHP Experience has Demonstrated Advantage of Blocking CD40L vs. CD40R in Xenotransplantation

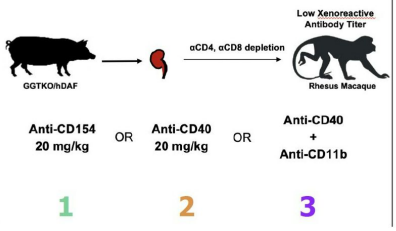
Combined CD11b/CD40 Blockade is Superior to CD40 Blockade Alone in Prolonging Survival in Pig-to-Nonhuman Primate Renal Xenotransplantation

How does combination CD11b/CD40 blockade affect graft survival in a pig-to-NHP model of renal xenotransplantation?

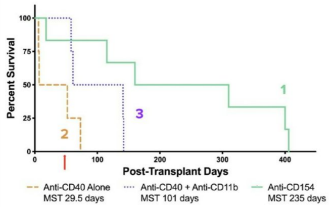


Pig-to-NHP renal xenotransplantation performed to one of three groups:

(1) anti-CD154; (2) anti-CD40 alone; (3) anti-CD40 plus anti-CD11b



- Treatment with anti-CD11b mitigates early xenograft rejection seen with anti-CD40 therapy
- CD11b acts as an additional ligand of CD154 through which rejection signals can bypass CD40 blockade



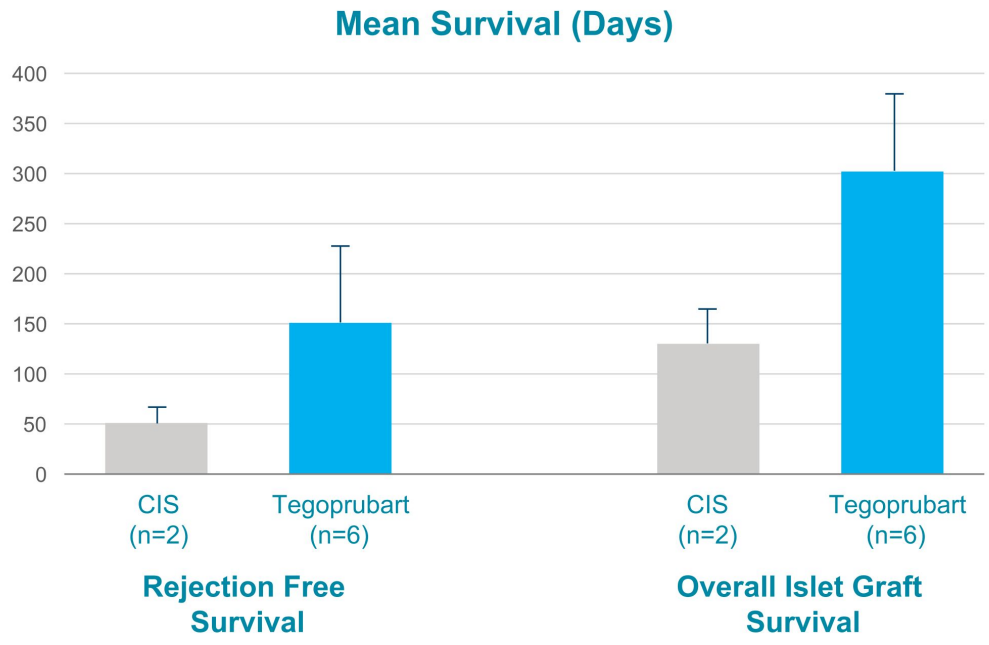
Emory University, University of Minnesota; Faber, Lovasik, Matar, Breeden, Kim, Adams

Abstract number 2

Source: Adams @ ACT 2021

Eledon Pharmaceuticals

Tegoprubart Prolonged Graft Survival vs. CNI Containing Regimen (CIS) in a Non-Human Primate Islet Cell Transplant Model…



Source: Kenyon, 2021.

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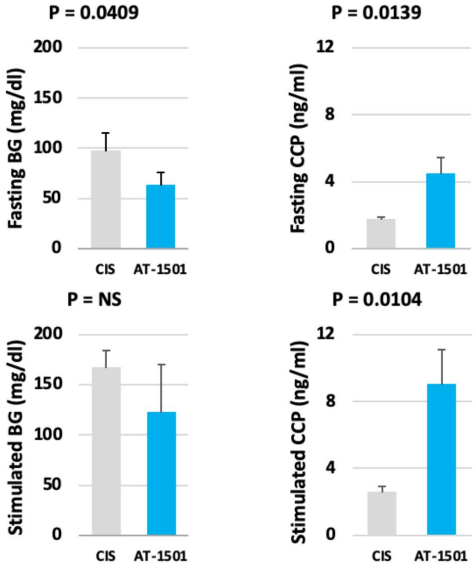
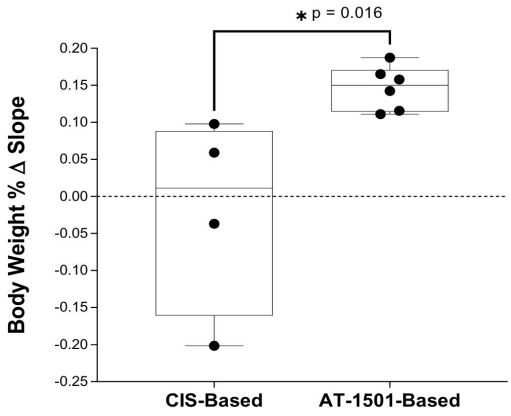
… And Tegoprubart was Associated With Better Metabolic Control as Well as Healthier Animals Overall as Demonstrated by Body Weight

Tegoprubart (AT-1501) vs. CNI Regimens (CIS) in NHP Islet Cell Transplantation Model





Source: Kenyon @ IPITA 2021.

Eledon Pharmaceuticals

Phase 1b Kidney Transplantation Study Design

DESIGN

- 52-week, open label, single dose level study
- Up to 12 participants undergoing kidney transplantation at multiple sites in Canada, the United Kingdom and Australia
- Kidney transplant using standard induction therapy plus maintenance therapy with tegoprubart as a replacement for CNIs (tacrolimus)

PLANNED DATA GENERATION

- **Safety & tolerability**
- **PK/PD**
- **Graft survival & function**
- **Biopsy proven acute rejection**
- **Immune cell infiltrate of graft biopsy**
- **Biomarker measures of kidney injury and rejection risk**

This study will run in parallel to the Phase 2 clinical trial of tegoprubart in kidney transplantation

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

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Phase 2 BESTOW Kidney Transplantation Study Design

DESIGN

- 52-week, head-to-head, superiority trial, open label, 2-arm, active comparator safety, PK, and efficacy study
- Approximately 120 participants (60/arm) undergoing kidney transplantation at multiple sites in the United States and other countries
- Participants will receive tegoprubart or the active comparator, tacrolimus, as part of an immunosuppressive regimen including corticosteroids and mycophenolate mofetil (MMF) or mycophenolate sodium (MPS)

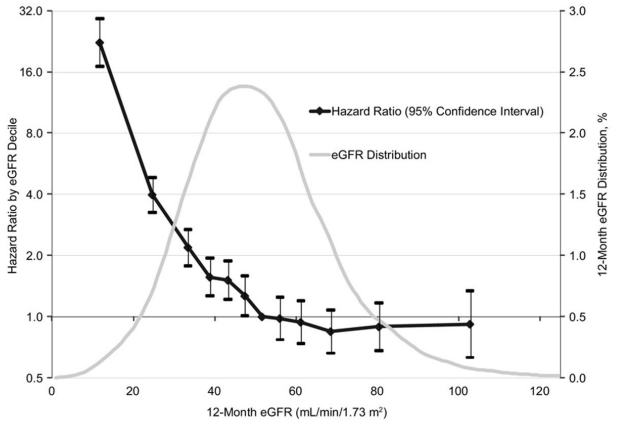
PLANNED DATA GENERATION

- **Safety & tolerability**
- **Graft function (eGFR)**
- **Rates of graft functional impairment**
- **Biopsy proven acute rejection (BPAR)**
- **Rate of new onset diabetes mellitus (NODAT)**
- **Rate of participant and graft survival**
- **PK and immunogenicity**

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

Kidney Allograft Function is an Early Predictor of Future Graft Failure

eGFR at 12 months is associated with subsequent death-censored graft failure



- Graft function measured using eGFR at 12 months post transplant is associated independently with subsequent graft failure
- Of multiple covariates, **12-month eGFR is the strongest predictor of graft failure**

Source: Am J Kidney Dis. 2011 Mar; 57(3):466-75.

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Single Company Focus: Leveraging Validated Biology to Develop Best-in-Class Immune-Modulating Therapeutics

Optimized & Differentiated Lead Asset

- CD40/CD40L **pathway validated by extensive historical proof-of-concept data**
- Tegoprubart was engineered to increase potency, half-life and manufacturability vs. other anti-CD40 approaches
- Targeting areas of high unmet need including organ transplantation and ALS

Strong Financial Profile

- **$65.9M in cash** and cash equivalents (as of September 30, 2022)
- Expected **sufficient to fund operations into 2024**
- ~29.9 M fully diluted shares outstanding

Near-Term Milestones

- Multiple interim **clinical data** readouts expected beginning **in Q1'23** in **Kidney Transplantation & IgA Nephropathy** (safety)
- **Initiation of Phase 2 BESTOW trial** of tegoprubart in **kidney transplantation** expected in **mid-2023**

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