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): November 02, 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 November 2, 2023, Eledon Pharmaceuticals Inc. (the "Company" or "Eledon") issued a press release announcing updated data from the Company's ongoing Phase 1b open-label trial evaluating tegoprubart for the prevention of rejection in patients undergoing de novo kidney transplantation. Results were presented at the American Society of Nephrology Kidney Week 2023 Annual Meeting

taking place in Philadelphia, PA from November 2-5, 2023. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Also, on November 2, 2023 and as previously disclosed, the Company is hosting a conference call to discuss the updated Phase 1b clinical data. A copy of the 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release Issued on November 2, 2023
99.2	Kidney Transplantation Updated Phase 1b Clinical Data
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: November 2, 2023

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

Eledon Reports Updated Data from Ongoing Phase 1b Trial Evaluating Tegoprubart for Prevention of Rejection in Kidney Transplantation

Data from 11 participants demonstrates tegoprubart successfully prevented kidney transplant rejection and was generally safe and well-tolerated

Aggregate mean eGFR was above 70 mL/min/1.73m^2 at all reported time points after day 90 supporting tegoprubart's potential to protect organ function in patients undergoing kidney transplantation

Eledon will host a conference call today at 5:00 p.m. ET

IRVINE, Calif., Nov. 2, 2023 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today reported results from the Company's ongoing Phase 1b open-label trial evaluating tegoprubart for the prevention of rejection in patients undergoing de novo kidney transplantation. Results were presented at the American Society of Nephrology Kidney Week 2023 Annual Meeting taking place in Philadelphia, PA from November 2-5, 2023.

"We are excited to present updated safety and efficacy results from our ongoing Phase 1b trial which continue to support the potential of tegoprubart as a novel kidney transplant immunosuppressive therapy to prevent rejection and better preserve organ function without many of the side effects associated with tacrolimus, the current standard of care," said David-Alexandre C. Gros, M.D., Chief Executive Officer. "We remain committed to the transplant community who are in urgent need of better treatment options, and we look forward to continuing this study in parallel with our Phase 2 BESTOW study initiated earlier this year."

At the time of data submission, results from the 11 participants in the Phase 1b trial demonstrated that tegoprubart is generally safe and well-tolerated in patients undergoing kidney transplantation. There have been no cases of hyperglycemia, new onset diabetes, tremor, or cytomegalovirus infection commonly seen with tacrolimus. One participant experienced a mild T cell mediated rejection (Banff score 1a) on day 99. This patient was treated for the rejection and remains in the study. There were no cases of graft loss or death.

Aggregate mean estimated glomerular filtration rate (eGFR) – a measure of kidney function – was above 70 mL/min/1.73m^2 at all reported time points after day 90. Historical studies have reported average eGFRs generally in the low 50 mL/min/1.73m2 range during the first year after kidney transplant using standard of care. One participant has completed the study with an eGFR of 91 at one year (day 374) and is now enrolled in a Phase 2 open-label extension (OLE) study, which will evaluate the long-term safety, pharmacokinetics, and efficacy of tegoprubart in participants who have completed one year of treatment in either the ongoing Phase 1b or Phase 2 BESTOW study.

“In this phase 1B trial, patients treated with tegoprubart demonstrated robust improvements in eGFR with a strong safety profile,” said Dr. John S. Gill, MD, Professor of Medicine at the University of British Columbia, St. Paul’s Hospital, Vancouver, Canada, and Principal Investigator of the study. “These results further support the promise of CD40L costimulatory blockade in organ transplantation. I look forward to additional readouts from this study in 2024.”

The Phase 1b open-label study has enrolled 11 participants who underwent kidney transplantation in Canada, Australia, and the United Kingdom. Each participant received rabbit antithymocyte globulin (ATG) induction and a maintenance regimen consisting of tegoprubart, mycophenolate mofetil, and corticosteroids. The primary endpoint of the study is safety. Other endpoints include characterizing the pharmacokinetic profile of tegoprubart, the incidence of biopsy proven rejection, and eGFR.

In September, Eledon announced that the first participant had been dosed in the Company’s Phase 2 BESTOW trial evaluating tegoprubart for the prevention of organ rejection in patients receiving a kidney transplant. The multicenter, two-arm, active comparator clinical study is enrolling approximately 120 participants undergoing kidney transplantation in the United States and other countries to evaluate the safety, pharmacokinetics, and efficacy of tegoprubart compared to the calcineurin inhibitor tacrolimus. The BESTOW trial's primary endpoint is designed to test the potential superiority of tegoprubart vs. tacrolimus in post kidney transplant kidney function at 12 months as measured by eGFR. The Company expects to complete enrollment at the end of 2024.

Full details on the poster presentations are below:

Title: Tegoprubart for the prevention of rejection in kidney transplant: update of emerging data from an ongoing trial
Presenter: Steve Perrin, Ph.D., President and Chief Scientific Officer, Eledon Pharmaceuticals
Poster Number: TH-PO835
Session Title: Transplantation: Clinical - I [PO2102-1]
Session Date and Time: November 2, 2023 from 10:00 AM to 12:00 PM EDT

Following the presentation, a copy of the poster will be available on the Investor section of the Company’s website at https://ir.eledon.com/events-and-presentations/presentations.

Conference Call

Eledon will hold a conference call today, November 2, 2023 at 5:00 p.m. Eastern Time to discuss the updated trial results. The dial-in numbers are 1-888-886-7786 for domestic callers and 1-416-764-8658 for international callers. The conference ID is 66816567. A live webcast of the conference call will be available on the Investor Relations section of the Company's website at www.eledon.com. The webcast will be archived on the website following the completion of the call.

About Eledon Pharmaceuticals and tegoprubart

Eledon Pharmaceuticals, Inc. is a clinical stage biotechnology company that is developing immune-modulating therapies for the management and treatment of life-threatening conditions. The Company’s lead investigational product is tegoprubart, an anti-CD40L antibody with high affinity for CD40 Ligand, a well-validated biological target within the costimulatory CD40/CD40L cellular pathway. The central role of CD40L signaling in both adaptive and innate immune cell activation and function positions it as an

attractive target for non-lymphocyte depleting, immunomodulatory therapeutic intervention. The Company is building upon a deep historical knowledge of anti-CD40 Ligand biology to conduct preclinical and clinical studies in kidney allograft transplantation, xenotransplantation, and amyotrophic lateral sclerosis (ALS). Eledon is headquartered in Irvine, California. 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:

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

Media Contact:

Jenna Urban
Berry & Company Public Relations
(212) 253 8881
jurban@berrypr.com

Source: Eledon Pharmaceuticals

EXHIBIT 99.2

Eledon Pharmaceuticals

Phase 1b Trial Update: Evaluating Tegoprubart For The Prevention of Rejection In Patients Undergoing Kidney Transplantation

November 2, 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, 2022, 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, inventor of azathioprine and recipient of Nobel Prize in Medicine in 1988.

Tegoprubart:
Transplantation Focused Pipeline in a Product Opportunity

Indications	DEVELOPMENT STAGE				
	Pre-clinical	Phase 1 / Early Human Trials	Phase 2	Phase 3	
Kidney Transplantation					• Phase 2 BESTOW and ex-US Phase 1b enrolling • Sub-cutaneous formulation completed non-human primate study
Xenotransplantation					• Cardiac xenotransplantation performed at University of Maryland • eGenesis & academic collaborations
Liver Transplantation					• Academic collaboration
Amyotrophic Lateral Sclerosis (ALS)					• Seeking non-equity dilutive financing to advance program to Phase 3

Note: **As of September 22, 2023**. Development plans and timelines may change, including based on US and global regulatory interactions.

Eledon Pharmaceuticals

Kidney Transplantation Immunosuppression Market Represents a Multi-Billion Dollar Commercial Opportunity

Large Patient Population

255,000+ (US) **188,000+** (EU)

People living with a functioning kidney transplant

90,000+ Americans on transplant waiting list

5,000 Americans per year die waiting for a kidney transplant

~15% of U.S. adults on waitlist are waiting for **repeat transplants**

Kidney Transplants Annually

25,000+ (US) **21,000+** (EU)

Average age transplant U.S. **50 years old**

Average organ only functions **10-15 years**

Many patients require **repeat transplants**

Heavy Economic Burden

End Stage Renal Disease & Transplant

$50+ Billion annual U.S. **Medicare** expenditure including **Kidney Transplantation** costs of **$420,000+ / transplant**

Medicare covers cost of immunosuppressive transplant drugs, regardless of patient age, if patient does not have other insurance

Global organ transplant immunosuppressant market size estimated **$5.3+ billion**

Astellas reported **tacrolimus** global revenues **~$1.5B** in **FY2022**
(Prograf, first FDA approval 1994)

Early graft failure of transplanted kidneys

$150,000+ average incremental U.S., medical costs / patient year after graft failure

Patients returning to dialysis:
▼ quality of life
< 50% 5-year survival rate

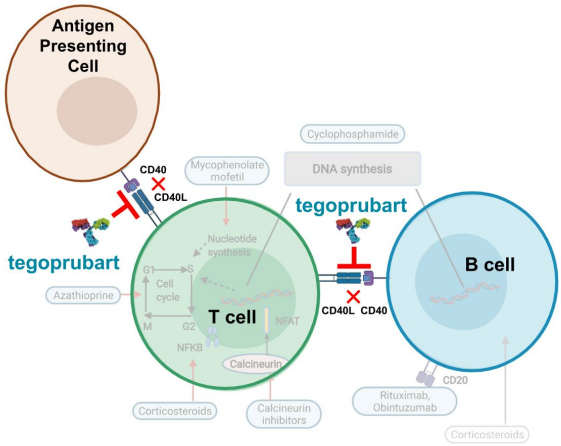
Re-transplants deplete an already inadequate **donor organ pool**

Sources: NIDDK; USRDS; DHHS OPTN; Milliman 2020; Statista 2021; Astellas; Novartis; Precision Reports 2023.

Eledon Pharmaceuticals

Mechanism Overview of CD40L Inflammatory Signaling

CD40/CD40L Pathway and Tegoprubart Site of Action

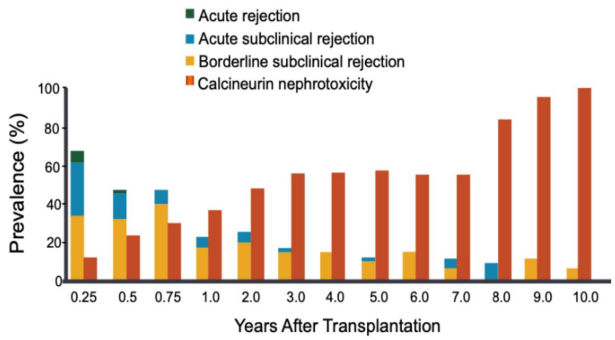


- Interaction of CD40 with CD40L on immune cells **mediates activation of the co-stimulatory immune pathway**, controlling "cross talk" between the adaptive and innate immune systems
- Maximal activation of inflammatory system is a 3-step process requiring co-stimulatory signaling
  - **Step 1:** Major 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

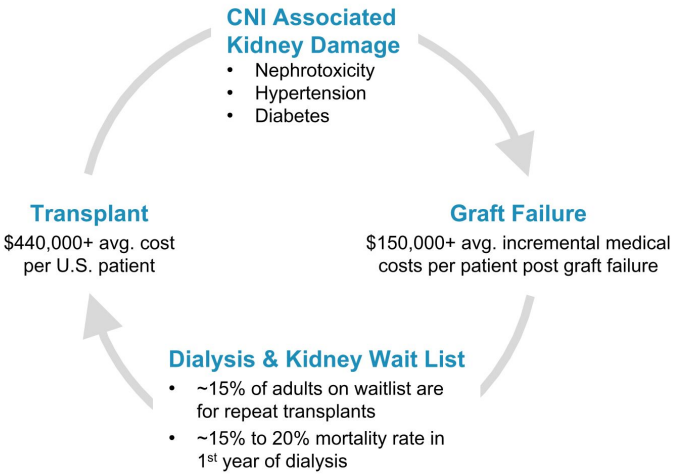
Source: Adapted from Kant, 2022.

Removing CNIs May Stop the Cycle of Transplantation and Subsequent CNI Related Graft Failure

CNI side effects are a leading cause of kidney graft failure over time….



….and can lead to a cycle of transplantation and graft failure



Source: Nankivell 2003; ATC 2018; NIDDK; USRDS; DHHS OPTN; Milliman 2020; Statista 2021; Astellas; Novartis; Precision Reports 2023; UCSF.

Eledon Pharmaceuticals

Distribution of eGFRs Using Standard of Care Post Transplant: Median ~51 mL/min/1.73m2 in First Year

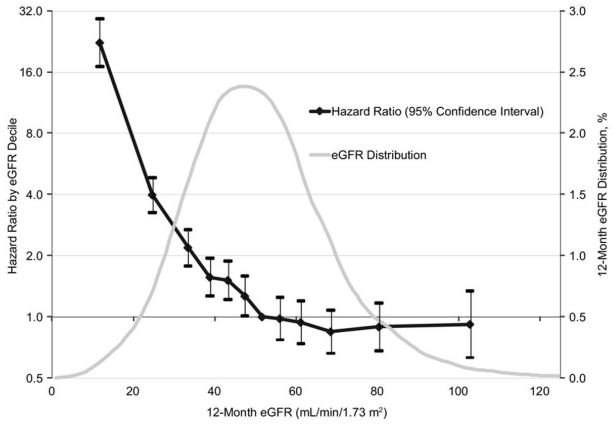
Time Posttransplant	No. of Centers	No. of Patients	No. of eGFR Values	eGFR Value (mL/min/1.73 m^2) at Listed Percentiles 5th	25th	50th	75th	95th	Percentage in Listed eGFR (in mL/min/1.73 m^2) Categories ≥90	60-89	45-59	30-44	15-29	<15
Discharge	11	23,053	18,393	11	31	45	60	86	4	21	26	26	15	9
1 mo	8	22,597	12,715	21	38	50	62	85	4	25	32	27	10	2
3 mo	9	21,894	12,887	26	40	51	63	86	4	27	33	28	8	1
6 mo	9	21,212	13,272	26	40	51	62	84	3	26	35	28	7	1
1 y	12	19,989	13,671	25	39	50	61	83	3	24	34	29	9	1
2 y	10	17,449	11,298	23	38	49	62	83	3	25	32	28	11	1
3 y	11	15,103	10,221	22	37	49	61	83	3	24	31	29	12	2
4 y	10	12,806	8,520	21	37	48	61	84	3	23	31	28	12	2
5 y	10	10,620	7,269	21	36	48	61	83	3	23	29	30	13	2

Abbreviations: CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate.

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

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.

Eledon Pharmaceuticals

Phase 1b and Phase 2 Kidney Transplantation Studies are Running in Parallel

Phase 1b

Up to 12 participants undergoing kidney transplantation

Canada, UK and Australia

52-week, open label, single arm study

ATG induction therapy plus

CNI-free maintenance therapy with tegoprubart

(as a replacement for tacrolimus) as part of a maintenance immunosuppressive regimen including mycophenolate and a corticosteroid taper

Primary endpoints:
- Safety & tolerability

Secondary endpoints:
- Graft function (eGFR)
- Participant and graft survival
- Biopsy proven acute rejection (BPAR)
- Immune cell infiltrate of graft biopsy
- Biomarker measures of kidney injury and rejection risk

Phase 2 "BESTOW"

~120 participants (60/arm) undergoing kidney transplantation

U.S. and other countries

52-week, head-to-head, superiority study

ATG induction therapy plus

CNI-free maintenance therapy with tegoprubart or tacrolimus

as part of a maintenance immunosuppressive regimen including mycophenolate and a corticosteroid taper

Primary endpoints:
- Graft function (eGFR)
- Safety & tolerability

Secondary endpoints:
- Participant and graft survival
- Biopsy proven acute rejection (BPAR)
- Immune cell infiltrate of graft biopsy
- Rate of new onset diabetes mellitus (NODAT)
- Biomarker measures of kidney injury and rejection risk

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

Phase 1b Kidney Transplantation: Demographics & Disposition

Participant	Age/Gender	Ethnicity	Donor	Underlying Disease	Days Post TxP (DS: Discontinued Study)	Status
1	60/F	White	Living	Polycystic Kidney Disease	217 (DS)	Discontinued study on day 217 due to alopecia and fatigue
2	77/F	White	Deceased	Diabetes	380	
3	62/M	White	Living	Cystic Disease	54 (DS)	Discontinued study on day 54 due to Polyomavirus viremia
4	68/M	White	Living	Diabetes	217	
5	23/F	Asian	Living	Glomerulonephritis	181	
6	44/M	White	Deceased	Polycystic Kidney Disease	154	
7	65/M	White	Living	Type 1 Diabetes	146	
8	57/F	White	Living	Diabetes	83	
9	35/M	Other	Living	Glomerulonephritis	75	
10	56/F	White	Living	Polycystic Kidney Disease	60	
11	59/M	White	Living	Diabetes	43	

Source: ASN, November 2, 2023.

Phase 1b Kidney Transplantation: Treatment Emergent Adverse Events

System Organ Class	Preferred Term	N (%)
Gastrointestinal	Diarrhea	5 (45%)
	Constipation	4 (36%)
	Nausea	3 (27%)
	Vomiting	2 (18%)
Infections	Polyomavirus viremia	4 (36%)
	Urinary tract Infection	2 (18%)
Procedural Complication	Complications of Transplant Surgery	3 (27%)
	Procedural pain	2 (18%)
Blood and Lymphatic System	Leukopenia	2 (18%)
	Neutropenia	2 (18%)
Cardiac	Tachycardia	2 (18%)
General	Oedema peripheral	2 (18%)
	Pyrexia	2 (18%)
Metabolism	Hypoglycemia	2 (18%)
	Hypophosphatemia	2 (18%)
Musculoskeletal and Connective Tissue	Back pain	2 (18%)
Skin and Subcutaneous tissue	Alopecia	2 (18%)
Vascular	Hypertension	2 (18%)
	Hypotension	2 (18%)

* Occurring in 2 or more study subjects as of October 13, 2023. Of all the reported TEAEs, 7 events experienced by 3 subjects are reported as serious. These SAEs include neutropenia, acute kidney injury, T-cell rejection, Polyomavirus viremia, anterior abdominal wall collection, and hyperkalemia

- 1 participant experienced a T cell mediated rejection (Banff score 1a). The patient was treated and remains in the study
- 1 patient experienced a surgical related acute tubular necrosis on day 0 (prior to administration of study drug) which impacted their kidney function. The patient continues to be in the study
- **No cases of hyperglycemia, new onset diabetes, tremor, or cytomegalovirus infection**

Source: ASN, November 2, 2023.

Phase 1b Kidney Transplantation: Mean eGFR Over Time

- **Aggregate mean eGFR was above 70 mL/min/1.73m2 at all reported time points after day 90**
- One participant completed the 12-month study with an eGFR of 91 on day 374, and is now enrolled in a Phase 2 open-label extension study

Note: Estimated glomerular filtration rate (eGFR) as of October 19, 2023, calculated using the chronic kidney disease epidemiology collaboration (CKD-EPI) creatinine equation. N is the number of participants at that time contributing data to mean eGFR calculation.

Source: ASN, November 2, 2023.

Phase 1b Kidney Transplantation: Summary Conclusions

- Data from 11 participants demonstrates tegoprubart successfully prevented kidney transplant rejection and was generally safe and well-tolerated
- Aggregate mean eGFR was above 70 mL/min/1.73m2 at all reported time points after day 90, supporting tegoprubart's potential to better protect organ function than with regimens using calcineurin inhibitors, the current standard of care
- Eledon next plans to report updated data from the Phase 1b trial mid-2024

Source: ASN, November 2, 2023.

Q&A

Eledon Pharmaceuticals

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