Eledon Pharmaceuticals

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

November 2, 2023

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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.

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

Large Patient Population

255,000+ **188,000+**

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+ **21,000+**

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.

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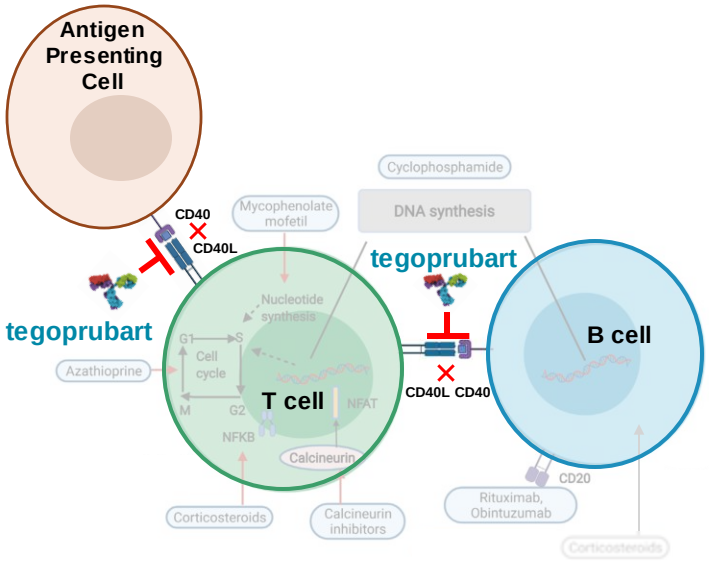
Mechanism Overview of CD40L Inflammatory Signaling

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.

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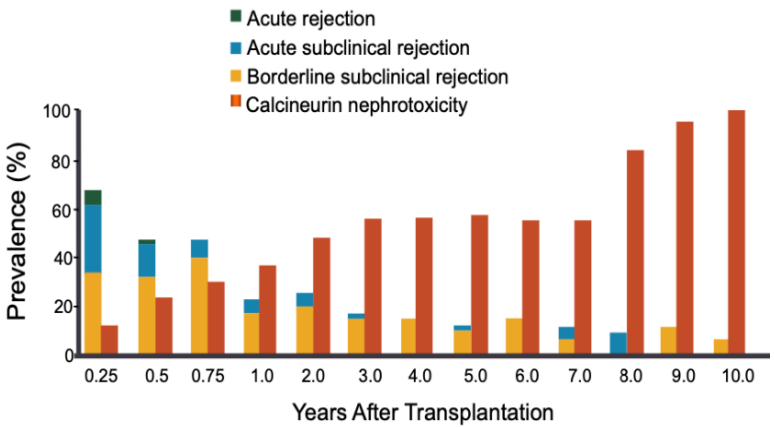
Removing CNIs May Stop the Cycle of Transplantation and Subsequent CNI Related Graft Failure

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



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

CNI Associated Kidney Damage
- Nephrotoxicity
- Hypertension
- Diabetes

Graft Failure
$150,000+ avg. incremental medical costs per patient post graft failure

Dialysis & Kidney Wait List
- ~15% of adults on waitlist are for repeat transplants
- ~15% to 20% mortality rate in 1st year of dialysis

Transplant
$440,000+ avg. cost per U.S. patient

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

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

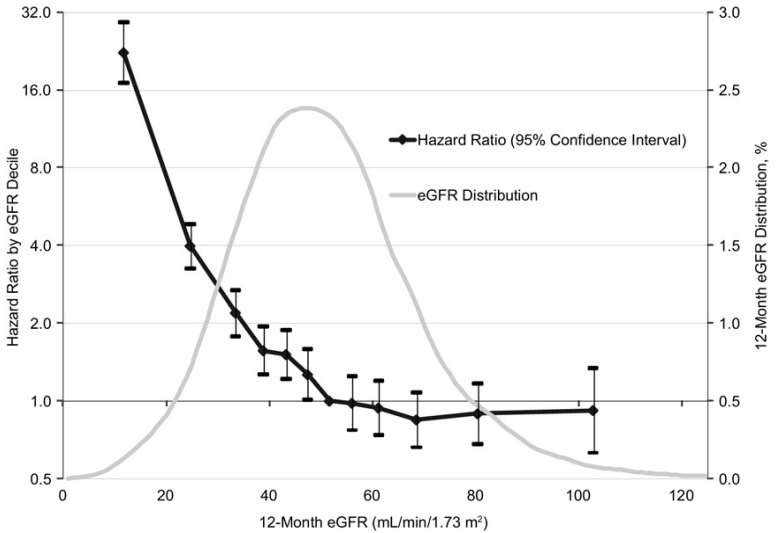
Time Posttransplant	No. of Centers	No. of Patients	No. of eGFR Values	eGFR Value (mL/min/1.73 m^2) at Listed Percentiles 5th	25th	50th	75th	95th	Percentage in Listed eGFR (in mL/min/1.73 m^2) Categories ≥90	60-89	45-59	30-44	15-29	<15
Discharge	11	23,053	18,393	11	31	45	60	86	4	21	26	26	15	9
1 mo	8	22,597	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.

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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

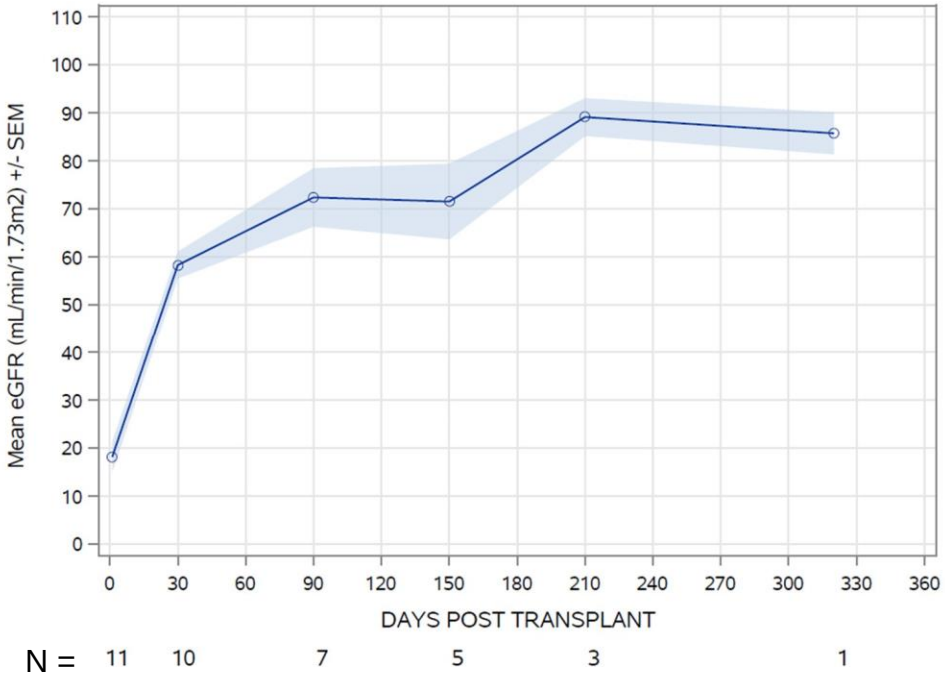
System Organ Class	Preferred Term	N (%)
Gastrointestinal	Diarrhea	5 (45%)
	Constipation	4 (36%)
	Nausea	3 (27%)
	Vomiting	2 (18%)
Infections	Polyomavirus viremia	4 (36%)
	Urinary tract Infection	2 (18%)
Procedural Complication	Complications of Transplant Surgery	3 (27%)
	Procedural pain	2 (18%)
Blood 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

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