Eledon Pharmaceuticals

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

August 6, 2025

Forward-Looking Statements

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Photo: Gertrude "Trudy" Elion, inventor of azathioprine and recipient of Nobel Prize in Medicine in 1988.

Summary

- **This phase 1b clinical trial provides updated data on the first reported use of tegoprubart as the core immunosuppression therapy in *de novo* kidney transplantation**
- Phase 1b currently has 32 patients in 2 cohorts
  - Recruited patients are representative of a typical population undergoing kidney transplantation
- Tegoprubart demonstrated a **favorable safety profile and was well tolerated**
- **Kidney function**, as assessed by eGFR, **stabilized after the first month** and averaged **~68 mL/min/1.73 m²** at **month 12** for patients who remained on tegoprubart
- Average abbreviated iBox score at 12 months for patients that remained on tegoprubart was -4.11, suggesting that **tegoprubart may improve 5-year kidney graft survival**
- Six patients (18.8%) experienced a rejection episode of which four (75%) received low-dose rATG induction
  - The three patients who remained on tegoprubart post rejection and completed 12 months showed full recovery of real function with an average final mean eGFR of ~73 mL/min/1.73 m²

eGFR, estimated glomerular filtration rate; rATG, rabbit anti-thymocyte globulin

Phase 1b, 52-week, Open-label, Single Arm Study of Tegoprubart in *de novo* Kidney Transplantation (NCT05027906)

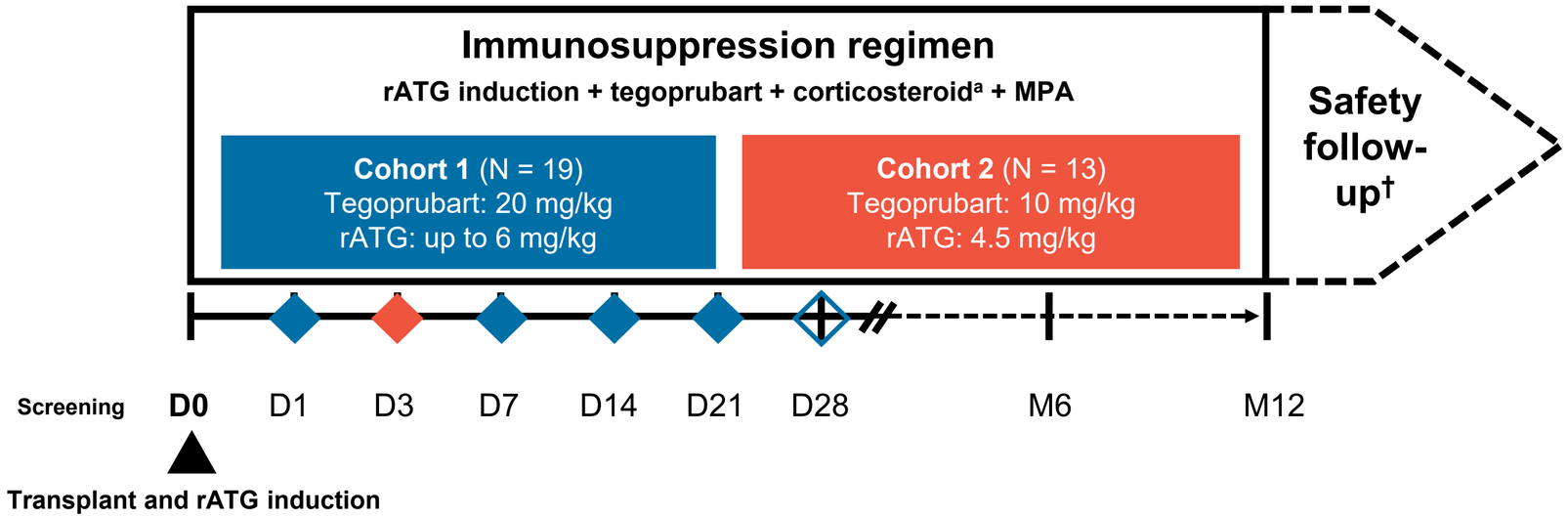
Inclusion criteria
- Male or female ≥ 18 years of age
- Recipient of first kidney transplant
- EBV positive
- DSA negative

Exclusion criteria
- Donor kidney with cold ischemia time > 30 h
- Kidney from living donor aged > 65 years **or** deceased donor who meets DCD/ECD criteria

Primary endpoints
- Safety and pharmacokinetics

Secondary endpoints
- Patient and graft survival
- Biopsy proven acute rejection
- Graft function (eGFR)
- Biomarkers of kidney injury and rejection risk
- Immune cell infiltrate of graft biopsy

Exploratory endpoints
- Abbreviated iBox score



†Patients who complete 12 months on treatment may elect to continue in an extension study

[a]Corticosteroid tapered to 5 mg by day 28.
D, day; DCD, donation after cardiac death; DSA, donor-specific antibodies; EBV, Epstein–Barr virus; ECD, extended criteria donor; eGFR, estimated glomerular filtration rate; M, month; MPA, mycophenolic acid; rATG, rabbit anti-thymocyte globulin

Methods

- **Data from the two cohorts with a total of 32 patients**
- **Safety**: AEs of special interest summarized, as well as TEAEs by system organ class reported by > 10% of patients
- **Rejection rate**: BPAR evaluated based on an independent central pathologist's assessment of all biopsies
- **Kidney function (eGFR) post transplantation**: eGFR was calculated based on CKD-EPI [1] and reported as mean
- **iBox**: abbreviated iBox score was calculated according to published methodology[2]
- **All data as of the cutoff date: July 9, 2025**

AE, adverse event; BPAR, biopsy-proven acute rejection; eGFR, estimated glomerular filtration rate; TEAE, treatment-emergent adverse event

1. Inker LA et al. N Engl J Med 2021;385:1737–49. 2. Klein A et al. Am J Transplant 2023;23:1496–506

Patient Baseline Characteristics (n = 32 patients)

Baseline characteristics	Recipient
Age, years, mean (SD)	52.9 (14.8)
Male, n (%)	21 (66)
Race, n (%)	
Asian	7 (22)
Black or African American	1 (3)
White	22 (69)
Other[a]	2 (6)
BMI, kg/m^2, mean (SD)	26.7 (3.6)
Number of HLA mismatches, n (%)	
0	0
1 - 2	4 (13)
3 - 4	10 (31)
5 - 6	18 (56)
Living donor, n (%)	24 (75)

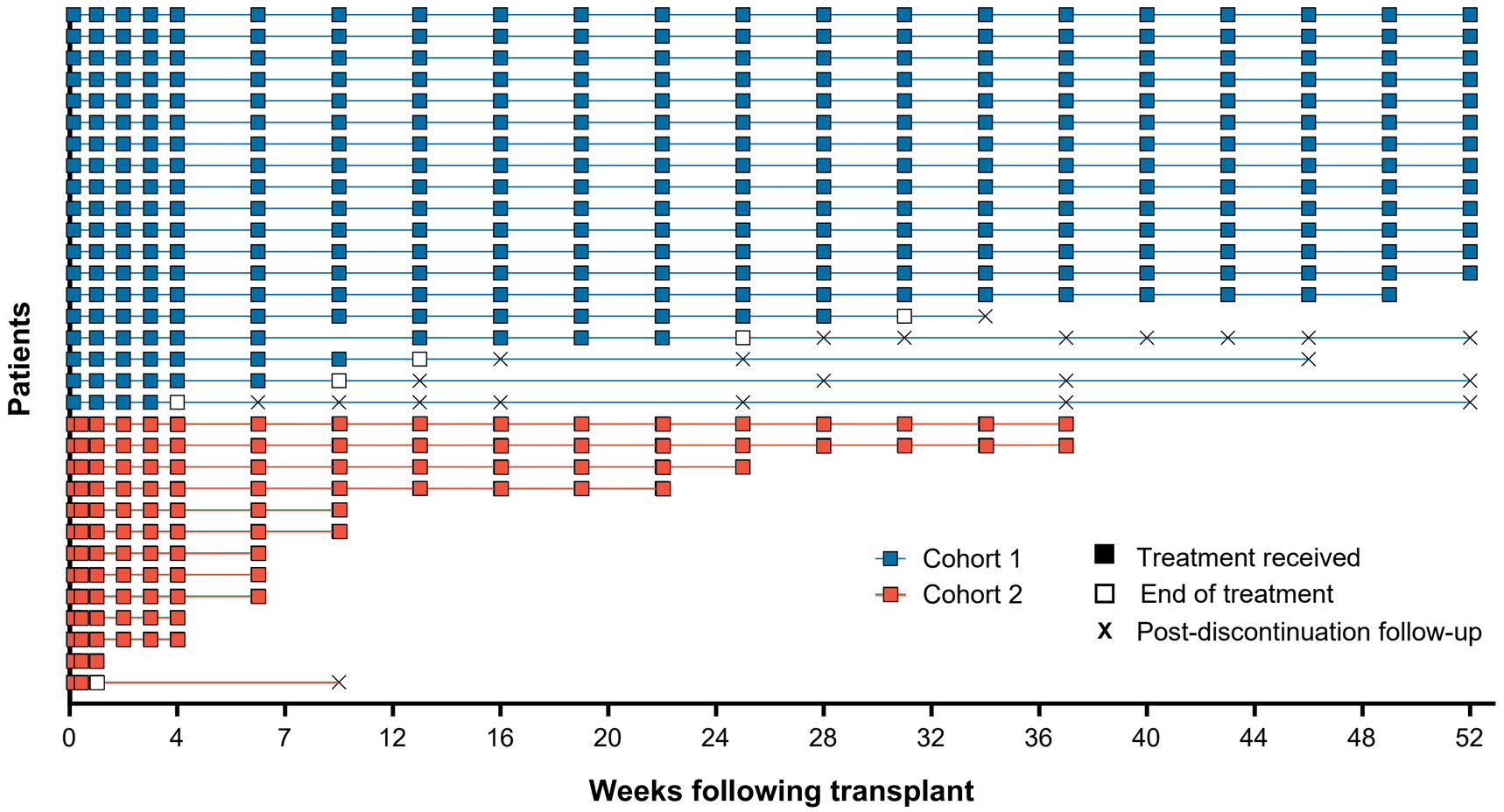
Baseline characteristics cont.	Recipient
Duration of ESRD, years, mean (SD)	4.2 (6.0)
Time on dialysis, months, mean (SD)	35.2 (40.8)
Pre-emptive transplantation, n (%)	7 (22)
Etiology of ESRD, n (%)	
Glomerulonephritis	13 (41)
Hypertension	11 (34)
Diabetes	7 (22)
Cystic disease	5 (16)
Other[b]	6 (19)
Cold ischemia time, hours, mean (SD)	4.9 (3.6)
Living donor	3.6 (2.1)
Deceased donor	8.8 (4.2)
CMV risk classification, n (%)	
High	4 (13)
Intermediate	22 (69)
Low	6 (19)

Recruited patients are representative of a typical population undergoing kidney transplantation

- **Median recipient age:** 53 years (vs. CPI median of 51 y.o.)
- **Median donor age:** 47 years (vs. CPI median of 44 y.o.)
- **High degree of HLA mismatch:**
  - 56% of patients ≥ 5
  - No perfect matches

[a]American Indian or Alaska Native, or multiple. [b]Unknown/undetermined, kidney atrophy or vesicoureteral reflux
BMI, body mass index; CMV, cytomegalovirus; ESRD, end-stage renal disease; HLA, human leukocyte antigen; SD, standard deviation

Patient Disposition



Mean treatment exposure of 233 days

- **32 patients across 2 cohorts**
  - Cohort 1: 19 patients
  - Cohort 2: 13 patients
- **13 patients (41%) completed study**
- **13 patients (41%) ongoing**
- **6 patients discontinued:**
  - Rejection episode: 2
  - Patient decision: 2
  - Polyomavirus viremia: 1
  - Post-hemorrhage acute kidney injury: 1

Overall Treatment Emergent Adverse Events (n = 32)

AESIs	n (%)
Opportunistic infections	13 (41)
BKV viremia	8 (25)
BKV nephropathy	1 (3)
CMV viremia	6 (19)
EBV infection	0
Other opportunistic infections	7 (22)
Tremor[a]	3 (9)
Malignancy[b]	2 (6)
Any thrombotic event[c]	2 (6)
Bleeding	1 (3)
New-onset diabetes	0
Patients with an AESI	**17 (53)**
Patients with a SAESI	5 (16)
Patients with a TEAE	**29 (91)**
Patients with a TESAE	13 (41)

Other TEAEs		n (%)
Metabolism	Hypophosphatemia	13 (41)
	Hyperglycemia	5 (16)
Blood and lymphatic	Leukopenia	14 (44)
	Neutropenia	7 (22)
	Anemia	4 (13)
Gastrointestinal	Constipation	9 (28)
	Diarrhea	8 (25)
	Nausea	6 (19)
	Vomiting	5 (16)
Renal	Increased blood creatinine	5 (16)
	Acute kidney injury	4 (13)
Vascular	Hypotension	4 (13)
	Hypertension	4 (13)
General	Procedural or back pain	8 (25)
	Pyrexia	7 (22)
	Peripheral edema	6 (19)
	Insomnia	6 (19)
	Fatigue	4 (13)

No cases of death, graft loss or new-onset diabetes

- **1 case of DGF, resolved in 3 days**
- **1 case of DSA (class II)**

- Viral infections were controlled with antivirals and/or with MPA dose reductions
- Two of the cases of **tremor started after tegoprubart discontinuation and conversion to tacrolimus**; one case of tremor occurred transiently in a patient with pre-existing carpal tunnel syndrome
- Thrombotic and bleeding events were deemed by investigators to be not related to tegoprubart

[a]Tremors were deemed by investigators to not be related to tegoprubart. [b]Basal cell carcinoma and squamous cell carcinoma. [c]Bilateral PE/DVT (R iliac vein) deemed by investigators to not be related to tegoprubart and patients remained on drug.
AESI, adverse event of special interest; BKV, BK virus; CMV, cytomegalovirus; DGF, delayed graft function; DSA, donor-specific antibodies; EBV, Epstein–Barr virus; MPA, mycophenolic acid; SAESI, serious adverse event of special interest; TEAE, treatment-emergent adverse event; TESAE, treatment emergent serious adverse event.

Treatment Emergent Adverse Events by Cohort

	Cohort 1	Cohort 2
AESIs	n (%)	n (%)
Opportunistic infections	10 (53)	3 (23)
BKV viremia	6 (32)	2 (15)
BKV nephropathy	1 (3)	0
CMV viremia	5 (26)	1 (8)
EBV infection	0	0
Other opportunistic infections	7 (37)	0
Tremor[a]	2 (11)	1 (8)
Malignancy[b]	1 (5)	1 (8)
Any thrombotic event[c]	0	2 (16)
Bleeding	0	1 (8)
New-onset diabetes	0	0
Patients with an AESI	**12 (63)**	**5 (39)**
Patients with a SAESI	2 (11)	3 (23)
Patients with a TEAE	**19 (100)**	**10 (77)**
Patients with a TESAE	9 (47)	4 (31)

		Cohort 1	Cohort 2
Other TEAEs		n (%)	n (%)
Metabolism	Hypophosphatemia	9 (47)	4 (31)
	Hyperglycemia	3 (16)	2 (15)
Blood and lymphatic	Leukopenia	10 (53)	4 (31)
	Neutropenia	6 (32)	1 (8)
	Anemia	3 (16)	1 (8)
Gastrointestinal	Constipation	6 (32)	3 (23)
	Diarrhea	6 (32)	2 (15)
	Nausea	4 (21)	2 (15)
	Vomiting	3 (16)	2 (15)
Renal	Increased blood creatinine	4 (21)	1 (8)
	Acute kidney injury	3 (16)	1 (8)
Vascular	Hypotension	3 (16)	1 (8)
	Hypertension	4 (21)	0
General	Procedural or back pain	8 (42)	0
	Pyrexia	4 (21)	3 (23)
	Peripheral edema	4 (21)	2 (15)
	Insomnia	4 (21)	2 (15)
	Fatigue	4 (21)	0

[a]Tremors were deemed by investigators to not be related to tegoprubart. [b]Basal cell carcinoma and squamous cell carcinoma. [c]Bilateral PE/DVT (R iliac vein) deemed by investigators to not be related to tegoprubart and patients remained on drug.
AESI, adverse event of special interest; BKV, BK virus; CMV, cytomegalovirus; DGF, delayed graft function; DSA, donor-specific antibodies; EBV, Epstein–Barr virus; MPA, mycophenolic acid; SAESI, serious adverse event of special interest; TEAE, treatment-emergent adverse event; TESAE, treatment emergent serious adverse event.

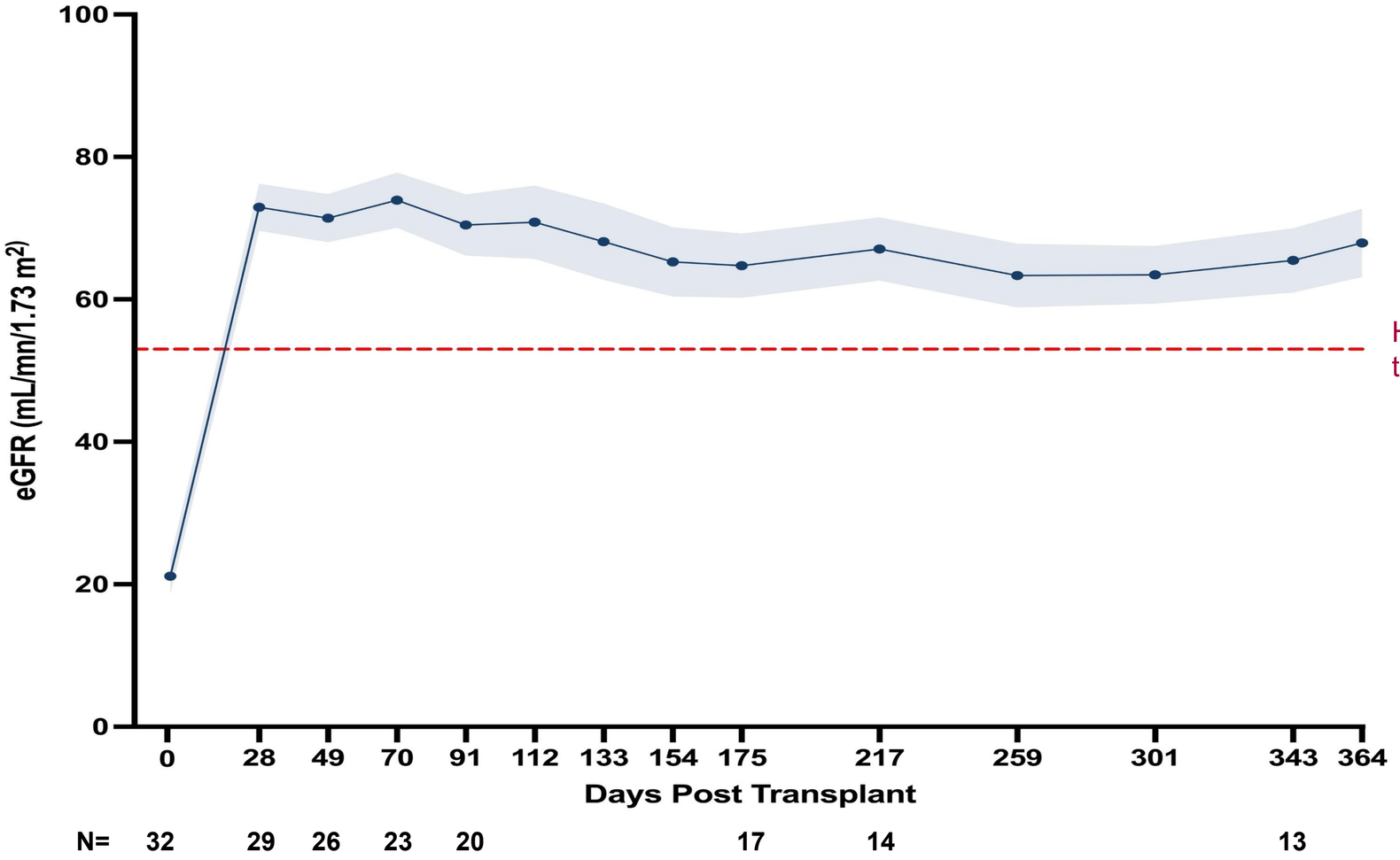
Overview of Rejection Episodes

Patients with rejection (n = 6, 19%)				
Banff Grade	**Donor Type**	**HLA Mismatch**	**rATG at Induction (mg/kg)**	**Disposition**
IB	Living	6	**3.6**	Remained on tegoprubart
IIA	Deceased	5	**2.5**	Remained on tegoprubart
IIA	Deceased	5	**2.8**	Remained on tegoprubart
IIB	Deceased	3	5.7	Switched to tacrolimus
IIB	Living	5	**3.1**	Switched to tacrolimus
IIB	Deceased	5	6.0	Switched to tacrolimus

The three patients with rejection episodes who remained on tegoprubart maintained good kidney function at 1 year

- **4 out of 6 patients** with a rejection episode received **low doses of rATG induction**

Overall eGFR Post Transplantation



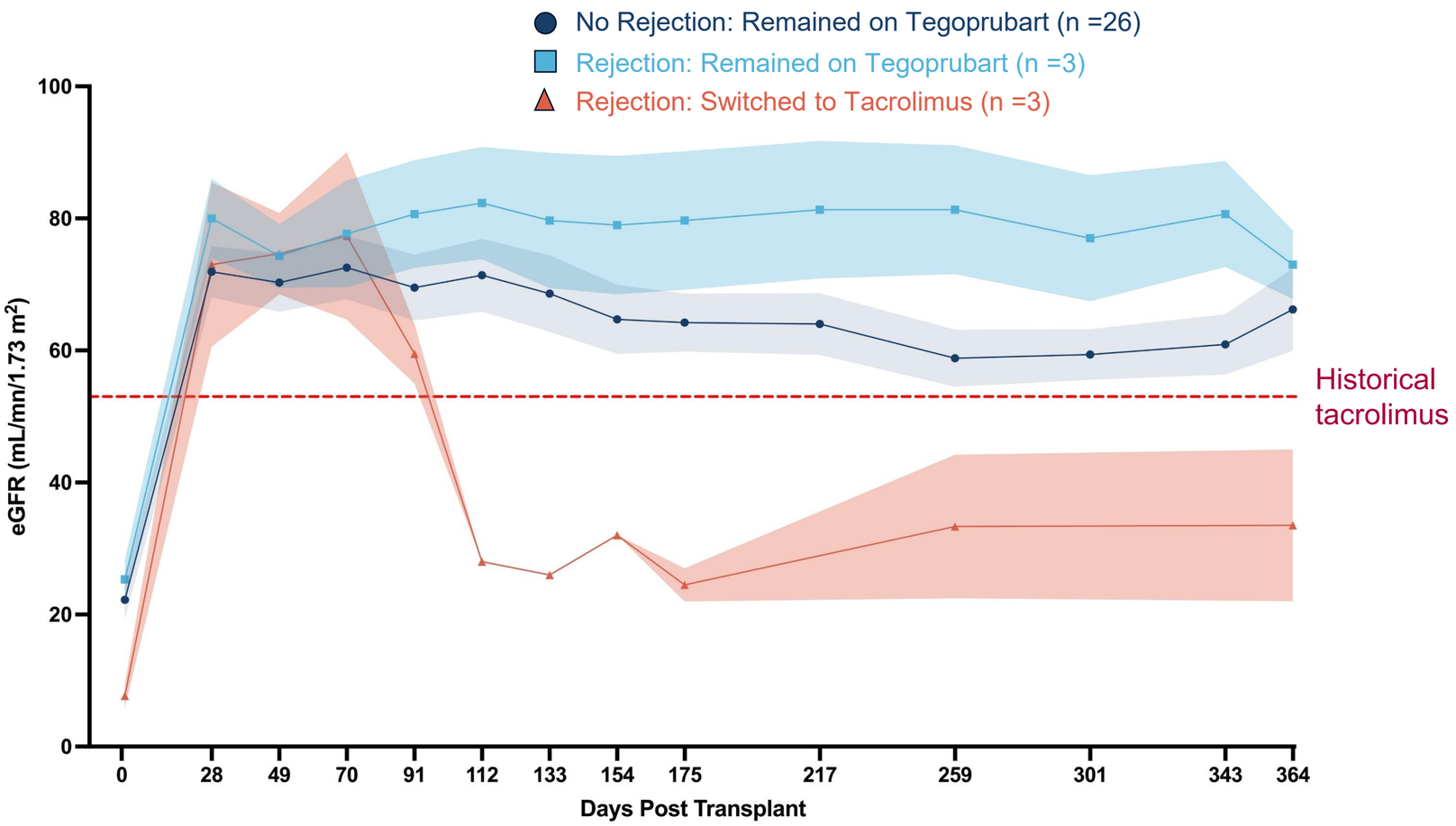
Functional eGFR levels were restored within 1 month after transplantation, which was maintained up to 1 year

On Treatment Mean (n=12) (SEM) 12-month eGFR:

68 (4.8) mL/min/1.73 m²

eGFR, estimated glomerular filtration rate; SEM, standard error of the mean. Kosinski et al. *Clin Transl Sci*. 2023 Nov; 00:1–11.

eGFR in Patients According to Transplant Rejection Status



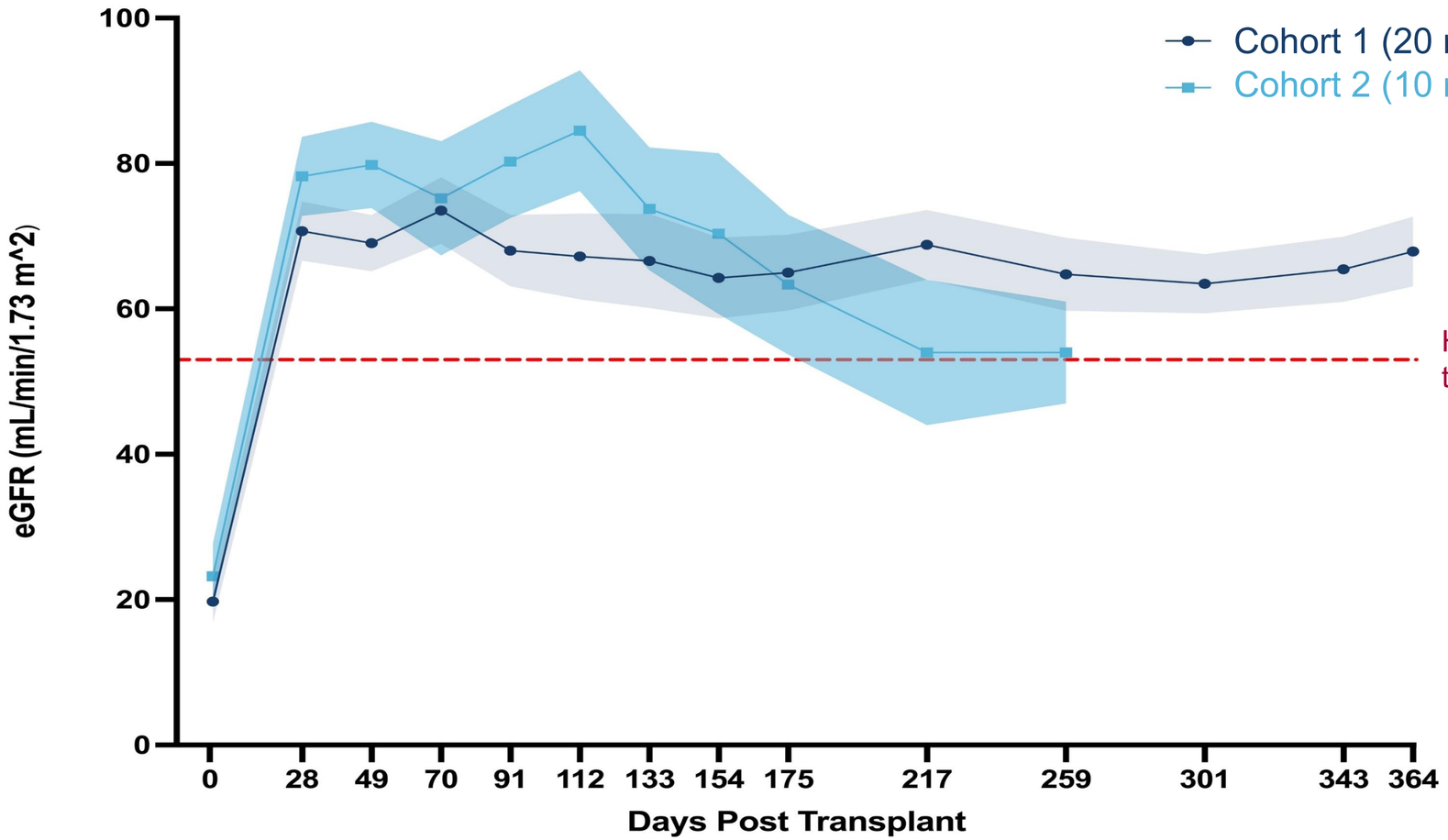
The transplanted kidneys with treatment continued to function effectively at 1-year post transplantation despite rejection

Mean 12-month eGFR:

- **Rejection (remained on tegoprubart):** 73 mL/min/1.73 m²
- **Rejection (switched to tacrolimus):** 34 mL/min/1.73 m²
- **No rejection (remained on tegoprubart):** 66 mL/min/1.73 m²
- **Intent to Treat Mean (n=15):** 63 mL/min/1.73 m²

eGFR, estimated glomerular filtration rate; SEM, standard error of the mean. Kosinski et al. *Clin Transl Sci.* 2023 Nov; 00:1–11.

eGFR by Cohort



Although still early data, 10 mg/kg appears to successfully protect transplanted kidneys

eGFR, estimated glomerular filtration rate; SEM, standard error of the mean. Kosinski et al. *Clin Transl Sci*. 2023 Nov; 00:1–11.

Composite Biomarker Panel (iBox)

- **iBox is a predictive model of 5-year kidney graft survival** developed **to estimate the risk of long-term graft loss following kidney transplantation** using kidney function and recipient immunological response, either with a 12-month biopsy (i.e., ‘full iBox’) or without histopathologic assessment (i.e., ‘abbreviated iBox’).
- **Abbreviated iBox** (without biopsy) includes:
  - eGFR
  - anti-HLA DSA
  - proteinuria
  - time since transplantation
- iBox is superior to BPAR as a surrogate for long-term graft loss and excludes BPAR, whose effectiveness as a predictor of long-term graft survival is close to random chance.

C-statistics (SE) at 1-year post transplantation

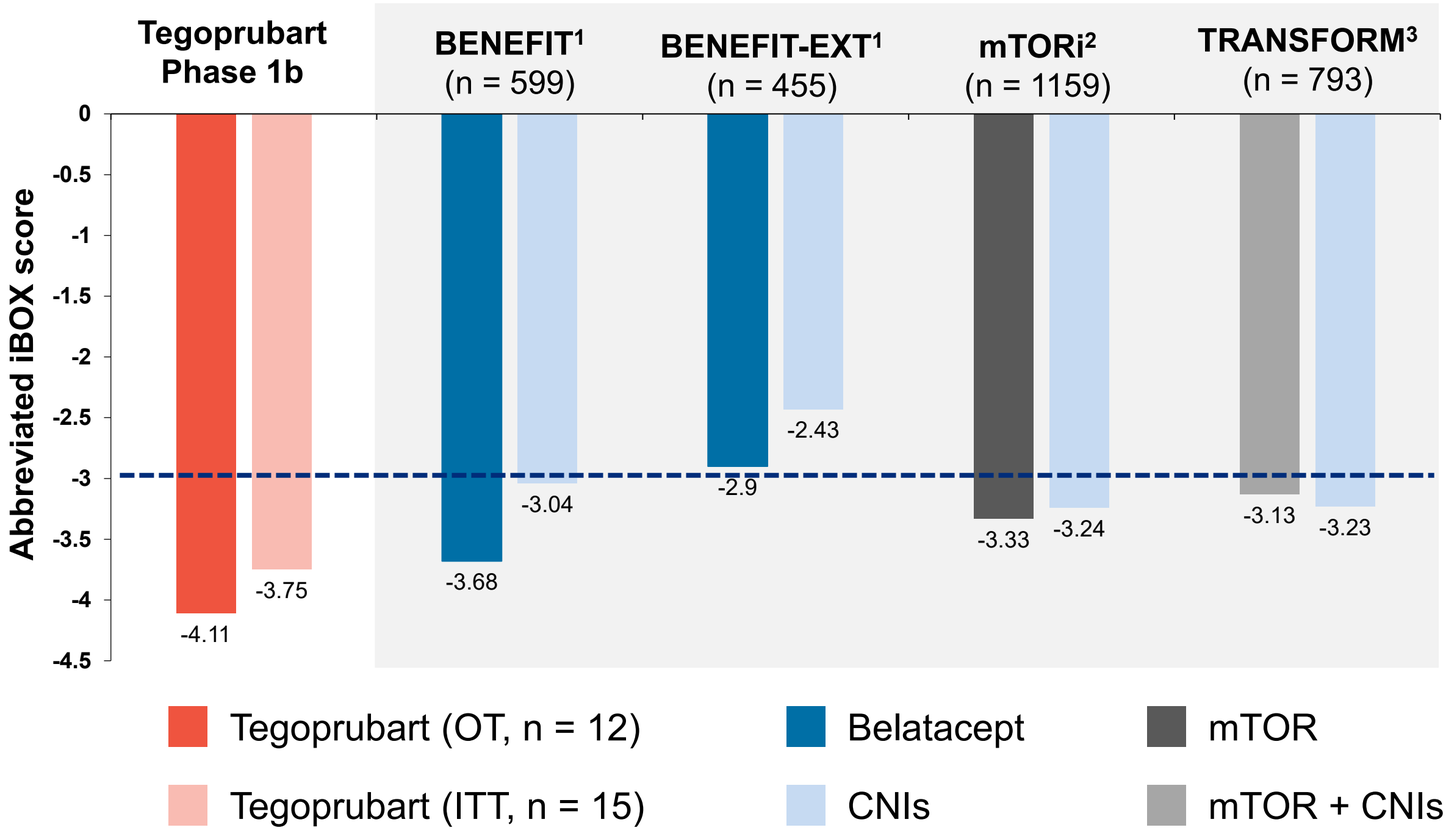
	Full iBox	Abbreviated iBox	BPAR
Combined validation (n = 1,534)	**0.81 (0.03)**	**0.80 (0.03)**	**0.57 (0.03)**

C-statistics ≥ 0.80 indicates a strong predictive model

A difference in abbreviated iBox score of −0.40 at 12 months is considered a minimum clinically important difference and is predictive of a 4–5% difference in 5-year graft survival

BPAR, biopsy-proven acute rejection; DSA, donor-specific antibodies; eGFR, estimated glomerular filtration rate; HLA, human leukocyte antigen; SE, standard error
Source: Klein A et al. Am J Transplant 2024;24:1784–93

Comparative Abbreviated iBox Scores at 12 Months



–2.98 CNI historical mean

Tegoprubart iBox scores of –3.75 (ITT) and –4.11 (OT) may indicate 5-year allograft survival rate of > 96%[a]

[a]Based on BENEFIT trial calculations[1]

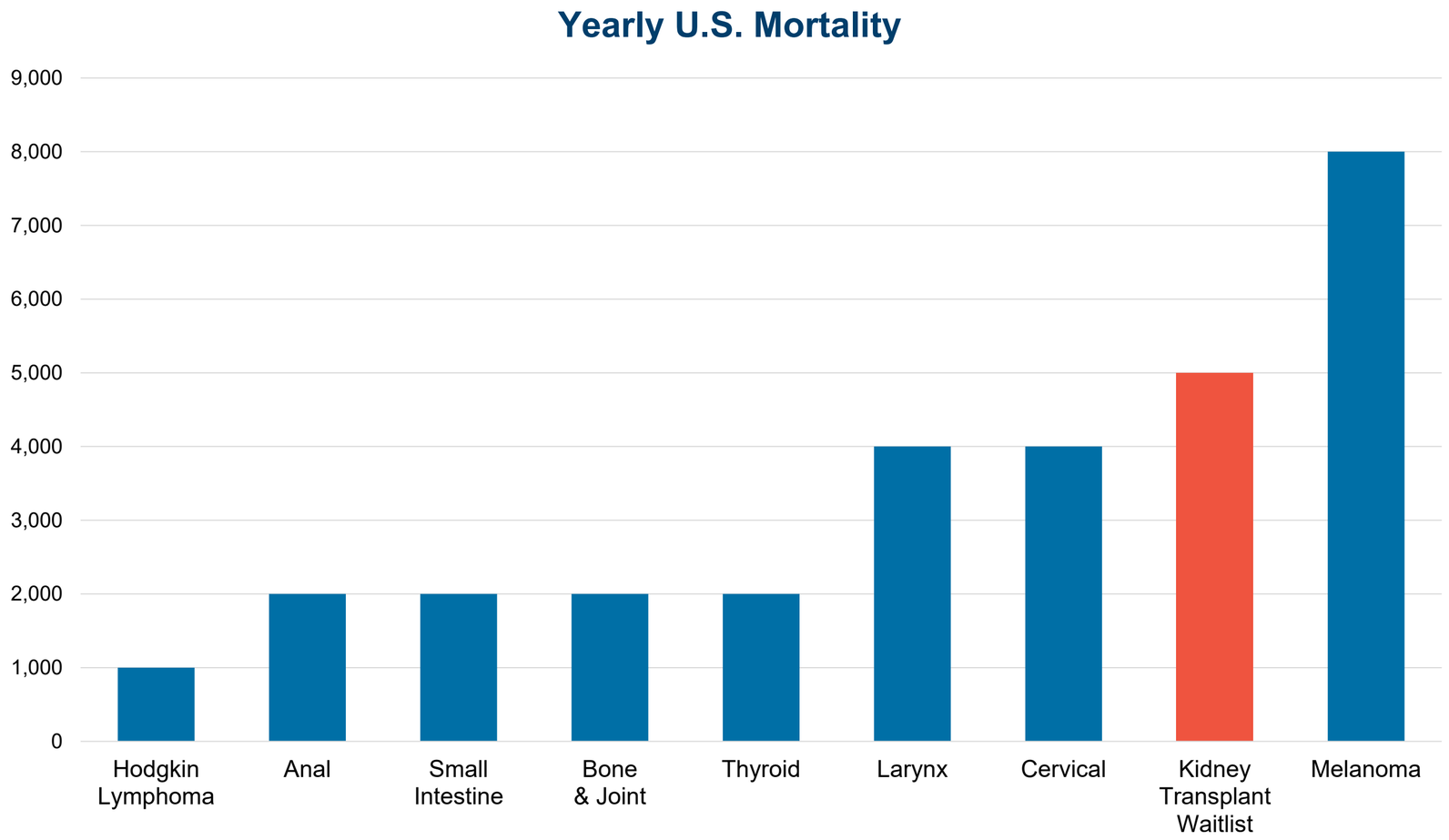
CNI, calcineurin inhibitor; ITT, intent to treat; mTOR, mammalian target of rapamycin; mTOR, mTORi, mammalian target of rapamycin inhibitor; OT, on treatment

1. Klein A *et al. Am J Transplant* 2023;23:1496–506. 2. European Medicines Agency (EMA) Scientific Opinion-Qualification. Briefing Dossier. https://www.ema.europa.eu/en/documents/scientific-guideline/qualification-opinion-applicant-revised-briefing-book-ibox-scoring-system-composite-biomarker-panel_en.pdf (Accessed 24 Jul 2025) 3. Aubert O *et al. BMJ Open* 2021;11:e052138

Conclusion

- Tegoprubart continues to perform in a manner consistent with prior data
- To date in the Phase 1b de novo trial, tegoprubart **was well tolerated** with a **favorable safety profile**
- **Kidney function**, as assessed by eGFR, **stabilized after the first month** and averaged **~68 mL/min/1.73 m^2** at **month 12** for patients who remained on tegoprubart
- Average abbreviated iBox score at 12 months for patients that remained on tegoprubart of -4.11, suggesting that **tegoprubart may improve 5-year graft survival**
- We look forward to completing the Phase 2 BESTOW trial and to reporting data expected later this year

Yearly Morbidity: Cancers vs. Lack of Transplanted Kidneys, and Potential Impact of a Novel Immunosuppressant



- ~5,000 Americans die yearly waiting on the waitlist for a kidney
- Increasing 5-year survival kidney transplant function by ~5% could equate to up to ~1,500 kidneys being made available annually in the United States, thus potentially reducing the numbers of Americans dying without access to a transplanted kidney by up to ~30%

Note: Numbers are approximate & rounded to nearest thousand.
Source: https://seer.cancer.gov/statfacts/html/common.html;