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Phase 3 VALIANT Results

August 8, 2024

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Groundbreaking Phase 3 topline results in C3G and IC-MPGN

- ✓ Met primary endpoint, with **68% reduction in proteinuria** vs placebo (p<0.0001)
- ✓ Positive results **consistent across all subgroups**
- ✓ **Favorable safety**, consistent with established profile
- ✓ Plan to submit data for **regulatory approvals in US and EU**
- ✓ **~5,000** people with C3G/IC-MPGN in U.S.[1]

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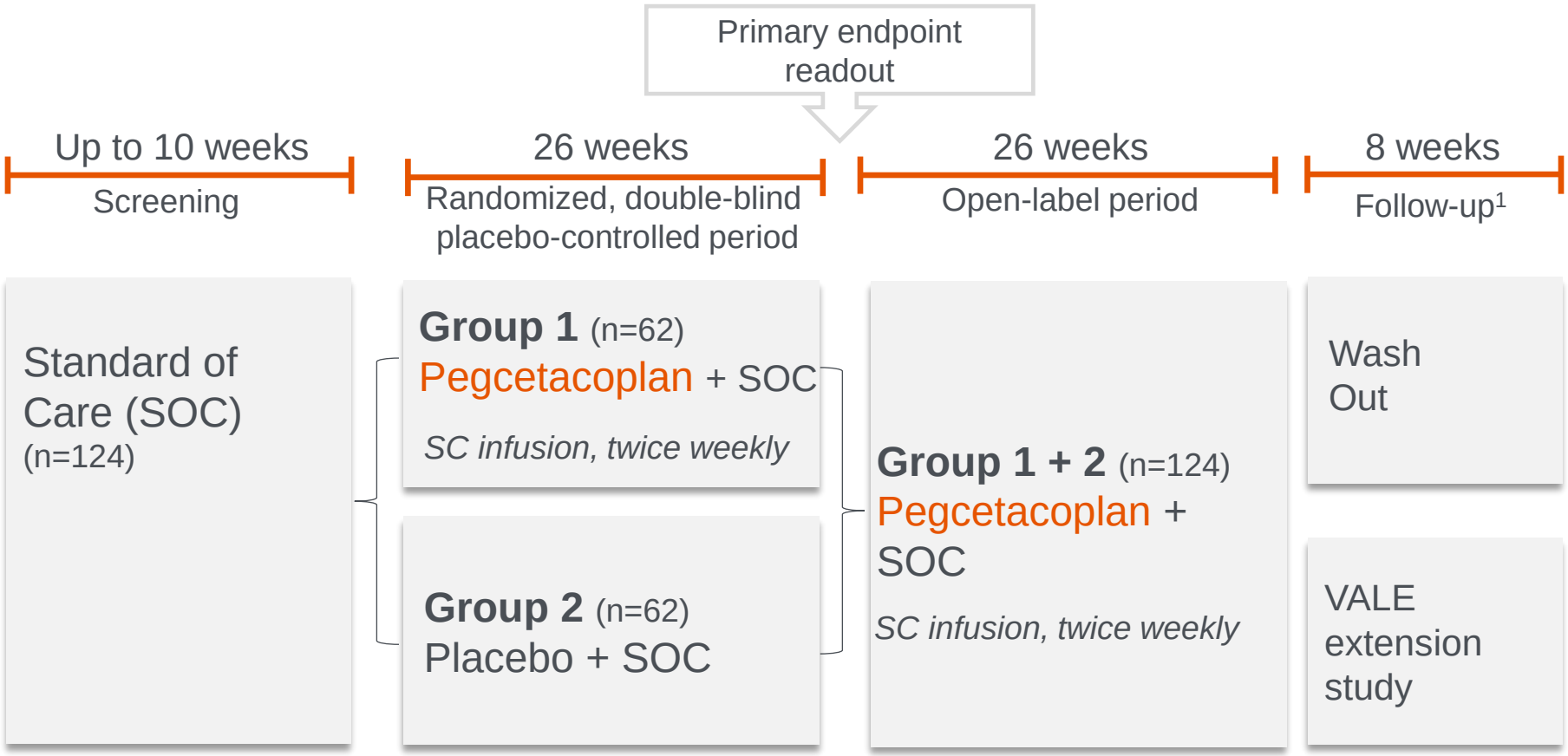
1. Based on moderate & severe patient population. C3G: ClearView Analysis using physician and literature consensus

Phase 3 VALIANT study design



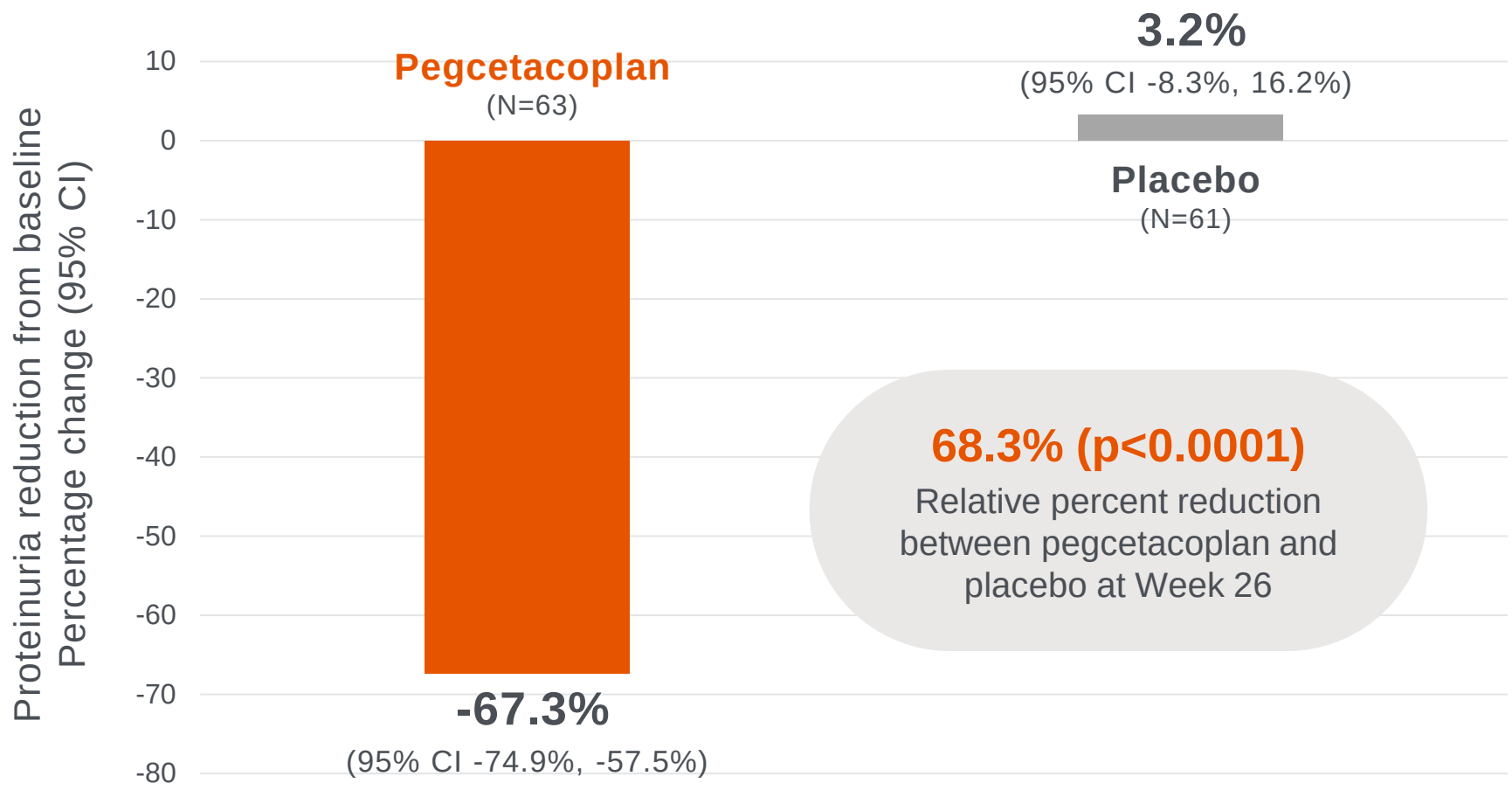
[1]Subjects entering VALE, the planned long-term extension study, will not complete the follow-up period.

Population: Patients 12 years+ with **C3G or primary IC-MPGN** pre- and post-transplant and evidence of active renal disease.

Primary endpoint: Log-transformed ratio of urine protein-to-creatinine ratio (uPCR) at Week 26 vs. baseline.

Secondary endpoints: Change in kidney function measured by eGFR. Reduction in C3 staining.

Pegcetacoplan treatment achieves 68% (p<0.0001) relative reduction in proteinuria vs placebo at Week 26



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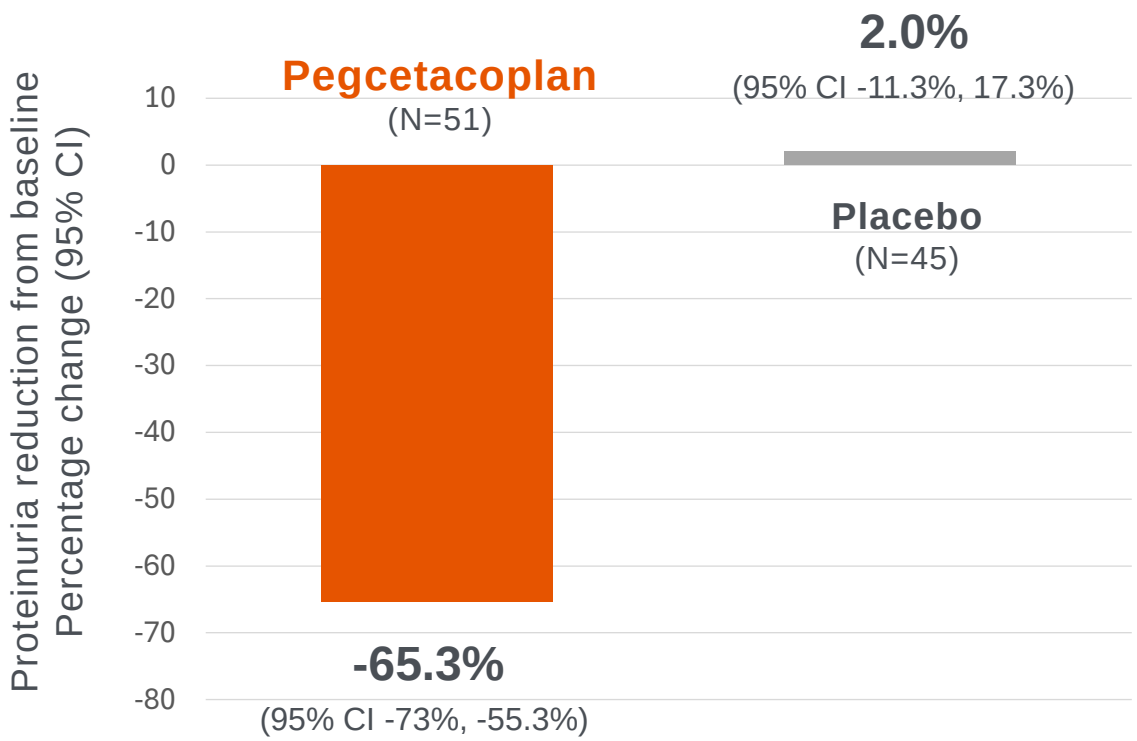
Positive effects consistent across subgroups: C3G and IC-MPGN

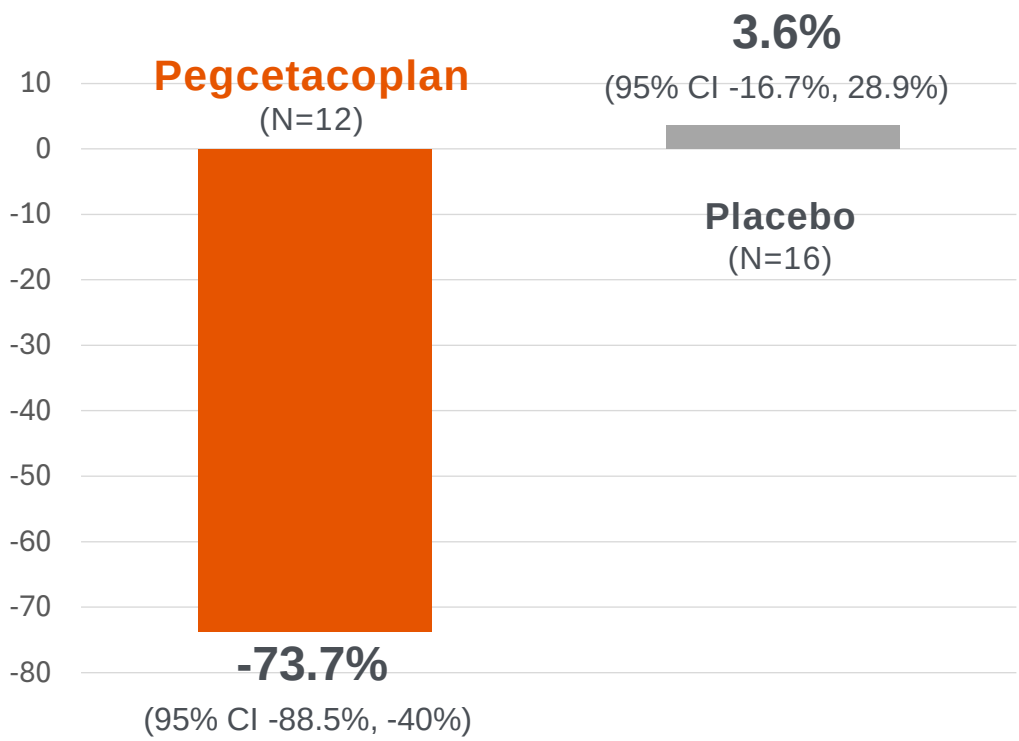
C3G (N=96)



65.9% (p<0.0001)

Relative percent reduction between pegcetacoplan and placebo at Week 26

IC-MPGN (N=28)



74.7% (p=0.0015)

Relative percent reduction between pegcetacoplan and placebo at Week 26

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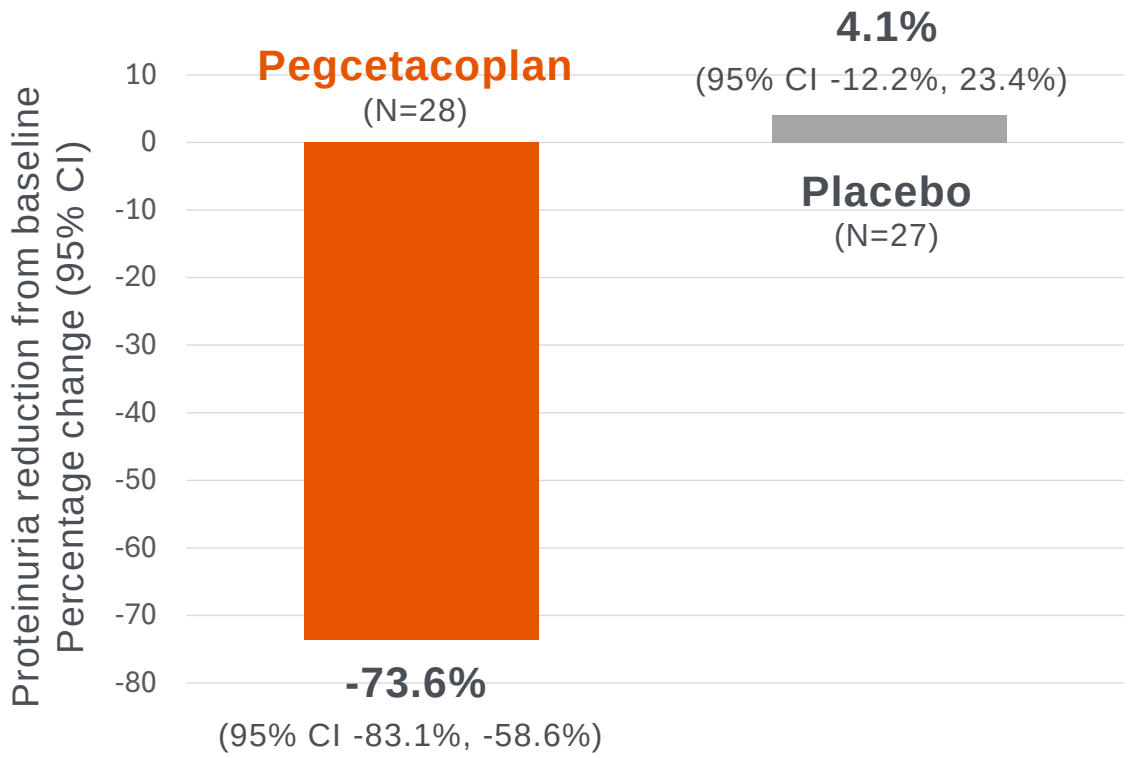
Positive effects consistent across subgroups: adolescent and adult

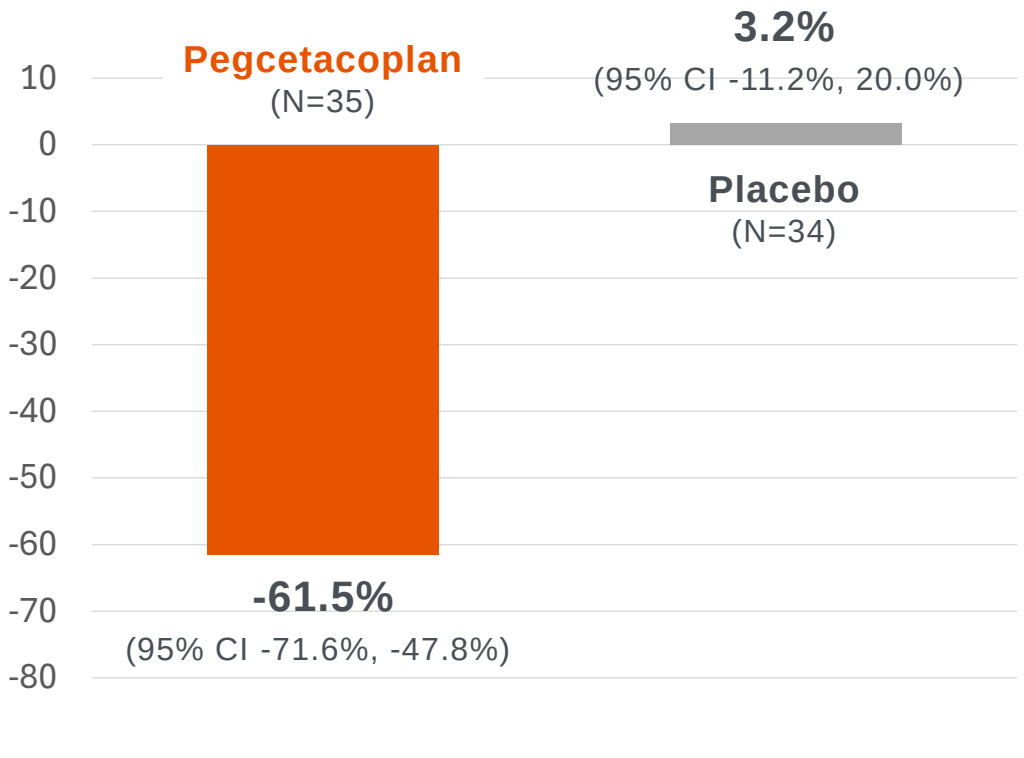
Adolescent (N=55)



74.6% (p<0.0001)

Relative percent reduction between pegcetacoplan and placebo at Week 26

Adult (N=69)



62.7% (p<0.0001)

Relative percent reduction between pegcetacoplan and placebo at Week 26

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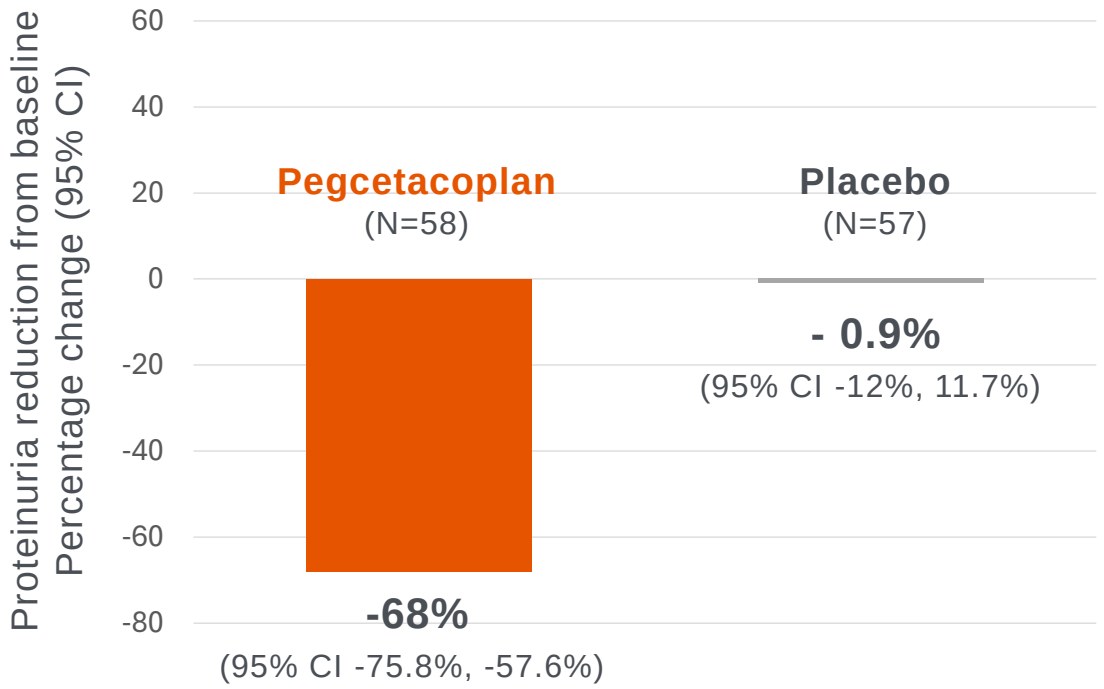
Positive effects consistent across subgroups: native kidney and transplant

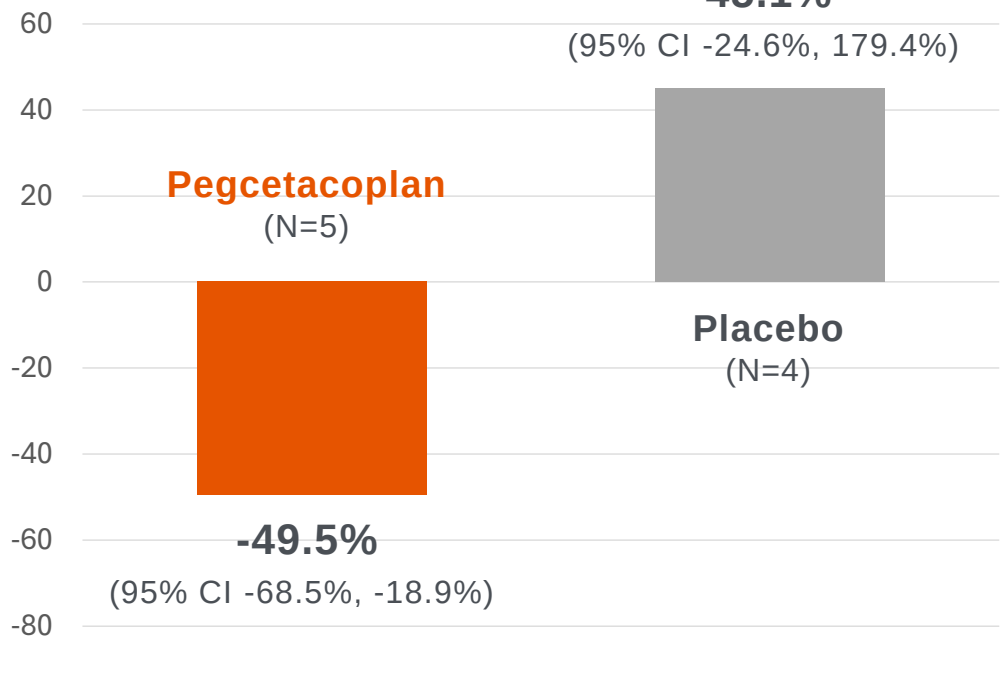
Nontransplant (N=115)



67.7% (p<0.0001)

Relative percent reduction between pegcetacoplan and placebo at Week 26

Transplant (N=9)



65.2% (p=0.0228)

Relative percent reduction between pegcetacoplan and placebo at Week 26

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Secondary endpoints all favor pegcetacoplan treatment

Secondary Endpoint	Results
Proportion of patients who meet criteria for achieving a composite renal endpoint[1]	Statistically significant (p<0.0001)
Proportion of participants with a reduction of ≥50% from baseline in uPCR	Statistically significant (p<0.0001)
Change from baseline in the activity score of the C3G histologic index score[2]	Not met, numerical improvement (p=0.2753)
The proportion of participants with evaluable renal biopsies showing decreases in C3c staining on renal biopsy from baseline[2]	Nominally significant (p<0.0001)
Change from baseline in eGFR	Nominally significant (p=0.0322)

1. Defined as stable or improved eGFR compared to the baseline visit (≤15% reduction in eGFR), and a ≥50% reduction in uPCR compared to the baseline visit
2. Activity score and C3c staining endpoints are only assessed for adult patients with evaluable biopsies.

Favorable safety and tolerability, consistent with established profile

- Pegcetacoplan was well tolerated in patients with C3G and IC-MPGN
- Rates of adverse events (AEs), serious AEs and AEs leading to study drug discontinuation were similar between the pegcetacoplan and placebo groups
- No cases of meningitis or serious infections attributed to encapsulated bacteria

Andrew Bomback, M.D.

Principal investigator for the VALIANT study and Director of Clinical Research, Division of Nephrology at Columbia University Medical Center

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