GraftAssure CORE™
Personalized Transplant Monitoring

Kidney

Clinical Publication Summary

A Randomized Phase 2 Trial of Felzartamab in Antibody-Mediated Rejection

Mayer KA, Schrezenmeier E, Diebold M, et al. (2024) NEJM DOI: 10.1056/NEJMoa2400763.

Practical Clinical Utility

By incorporating GraftAssureCORE donor-derived cell-free DNA (dd-cfDNA) measurements, the study provided robust evidence of felzartamab's efficacy in treating late and chronic active antibody-mediated rejection (AMR) and highlighted the potential need for ongoing treatment and monitoring to maintain these benefits.

Endpoints and Goals

Primary: Assess the safety and efficacy of felzartamab, a CD38 monoclonal antibody, in treating kidney transplant patients with active AMR at least 180 days following transplantation

Secondary: Assess dd-cfDNA levels and ability to reflect treatment effectiveness over the six-month observation period

Methods

Design: Phase 2, double-blind, randomized, placebo-controlled clinical drug trial

Participants: 22 patients with biopsy-proven AMR occurring at least 180 days post-transplantation

Intervention: Patients (n=11) received nine infusions of felzartamab (16 mg/kg) or placebo (n=11) over six months, followed by a six-month observation period

Outcomes measures: Renal biopsies, donor-specific antibody levels (DSA), peripheral NK-cell counts, and dd-cfDNA levels were assessed at weeks 24 and 52

Results

82% of felzartamab-treated patients showed resolution of morphologic AMR in biopsy by week 24, compared to 20% in the placebo group.

Significant differences in dd-cfDNA levels were observed between the intervention and control groups.

dd-cfDNA median values

	Week 12	Week 24
Experimental	0.33%	0.31%
Control	0.95%	0.82%

By week 52, dd-cfDNA levels in both groups increased towards baseline, indicating a potential need for ongoing treatment to maintain benefits.

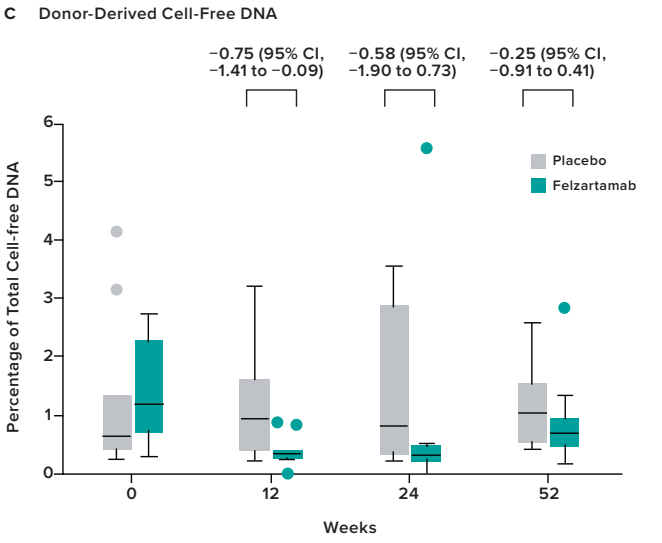

FIGURE 2. The horizontal line in each box represent the median, the tops and bottoms of the boxes represent the upper and lower limits of the interquartile range, and the I bars represent 1.5 times the interquartile range.

Conclusion

Felzartamab demonstrates significant efficacy in reducing antibody-mediated rejection underscored by the use of dd-cfDNA as a non-invasive biomarker for monitoring treatment response and graft injury.

This publication suggests that longitudinal monitoring of dd-cfDNA may be useful in managing kidney transplant recipients with active AMR.

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