



PRESS RELEASE

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Trial Assesses Antibody Therapy for Chronic Active Antibody-Mediated Kidney Transplant Rejection

Highlights

- Despite encouraging results from an earlier phase 2 study, results from an interim analysis of a phase 3 trial did not support continuing the study of clazakizumab for treating kidney transplant recipients experiencing chronic active antibody-mediated rejection.
- The findings of the final analysis after study termination will be presented at ASN Kidney Week 2024 October 23–27.

San Diego, CA (October 26, 2024) — Chronic active antibody-mediated rejection (caAMR) is a common cause of allograft loss after transplantation, with no approved therapies. Clazakizumab, a monoclonal antibody that targets the inflammatory cytokine interleukin-6 (IL-6), stabilized kidney transplant recipients' kidney function in a phase 2 trial. Investigators now have data from a phase 3 trial with clazakizumab. The findings from the Phase 3 IMAGINE trial, the largest placebo-controlled study in kidney transplant recipients with caAMR, will be presented at ASN Kidney Week 2024 October 23– 27.

The international IMAGINE double-blind phase 3 trial was the first study in transplantation to have a reasonably likely surrogate endpoint (1-year estimated glomerular filtration rate [eGFR] slope—a measure of changes in kidney function) accepted by the U.S. Food and Drug Administration. The trial aimed to recruit approximately 350 kidney transplant recipients with caAMR, randomized 1:1 to clazakizumab or placebo.

In an interim analysis conducted when approximately 100 participants completed 1 year of the study, independent investigators found that the study was unlikely to meet the primary efficacy outcome (time to a composite of all-cause allograft loss or irreversible loss of allograft function), and the data and safety monitoring board recommended to stop the study.

The final analysis following early termination after 1-year interim analysis of eGFR showed that there was no difference in Least Squares mean change from baseline in eGFR at week 52 for clazakizumab compared with placebo. There were no safety concerns observed in the study.

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“Treating patients with caAMR remains a challenge, and while we are disappointed by these results, we will continue to advance research for kidney transplant patients,” said corresponding author Arjang Djamali, MD, of Maine Medical Center. “We want to extend our gratitude to all those involved in the trial, including our patients, research sites and study sponsor, CSL, for their commitment to addressing the unmet needs of these patients.”

Study: “Clazakizumab in Chronic Active Antibody-Mediated Kidney Transplant Rejection: Results of the IMAGINE Phase 3 Study”

Join ASN and approximately 12,000 other kidney professionals from across the globe at Kidney Week 2024 in San Diego, CA. The world's premier nephrology meeting, Kidney Week, provides participants with exciting and challenging opportunities to exchange knowledge, learn the latest scientific and medical advances, and listen to engaging and provocative discussions with leading experts in the field. Early programs begin on October 23, followed by the Annual Meeting from October 24-27. Follow the conversation at #KidneyWk.

About ASN

Since 1966, ASN has been leading the fight to prevent, treat, and cure kidney diseases throughout the world by educating health professionals and scientists, advancing research and innovation, communicating new knowledge and advocating for the highest quality care for patients. ASN has nearly 21,000 members representing 140 countries. For more information, visit www.asn-online.org and follow us on [Facebook](#), [X](#), [LinkedIn](#), and [Instagram](#).

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