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Ruxolitinib, the First Proven Drug for Treating Steroid-refractory Acute GVHD

Acute graft-versus-host disease (GVHD) remains a major limitation of allogeneic stem-cell transplantation; not all patients respond to standard treatment with steroids. In the recent phase 3 REACH2 trial (NCT02913261), ruxolitinib improved outcomes in patients with steroid-refractory acute GVHD. The study, which included 309 patients, showed that a significantly higher percentage of patients responded to ruxolitinib than standard therapy after 28 days of treatment (62.3% vs 39.4%; $P < .001$). Detailed results were published in *The New England Journal of Medicine* in May 2020 ([DOI: 10.1056/NEJMoa1917635](https://doi.org/10.1056/NEJMoa1917635)).

In this follow-up analysis, we explored the therapy responses in different subgroups of patients of the REACH2 trial. Patient subgroups were formed based on various patient characteristics recorded at the start of the study.

Several subgroups of patients responded better to ruxolitinib than to standard therapy, including:

- Patients aged 18-65 years,
- Patients who did not respond to or progressed on high doses of steroids, and
- Patients with varying degrees of disease severity, organ involvement, related or unrelated donor, and prior GVHD therapy used.

Additionally, when compared with standard therapy, a higher percentage of patients treated with ruxolitinib had a response at day 28 and maintained response at day 56 (39.6% vs 21.9%; $P < .001$). No new or unexpected safety concerns were observed.

In summary, our study shows that ruxolitinib is more effective than standard therapy, with ruxolitinib resulting in a clinically meaningful treatment benefit for patients with steroid-refractory acute GVHD. Clinical efficacy in favor of ruxolitinib was observed across different subgroups. Ruxolitinib is the first novel agent to demonstrate superiority to standard therapy in a phase 3 trial of patients with steroid-refractory acute GVHD.

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Abstract: #S255 RUXOLITINIB VERSUS BEST AVAILABLE THERAPY IN PATIENTS WITH STEROID-REFRACTORY ACUTE GRAFT-VERSUS-HOST DISEASE: OVERALL RESPONSE RATE BY BASELINE CHARACTERISTICS IN THE RANDOMIZED PHASE 3 REACH2 TRIAL



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