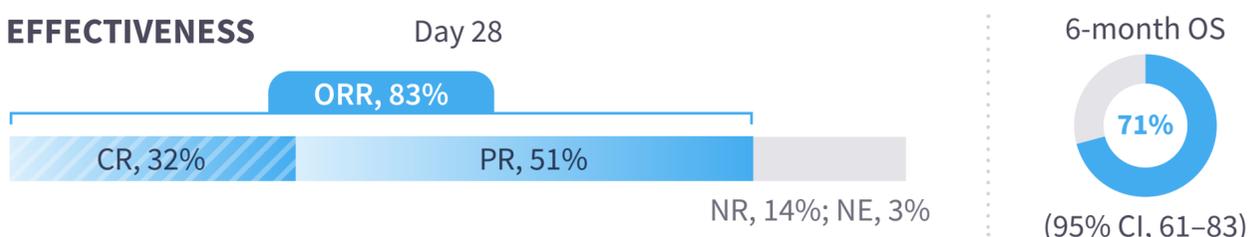
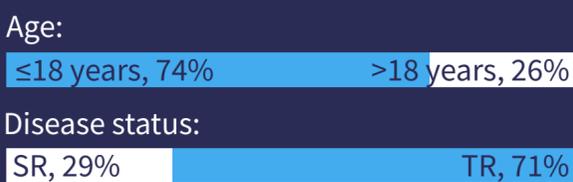


# MSCs as an alternative to ruxolitinib: Real-world use of MSC-FFM in aGvHD

A summary of four real-world studies

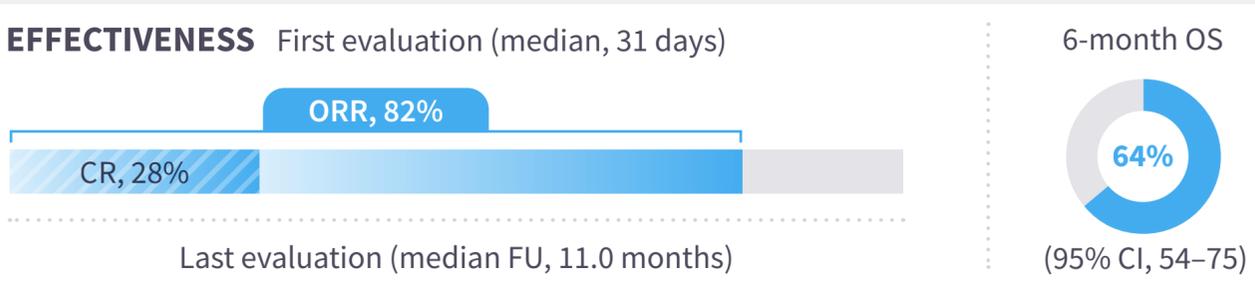
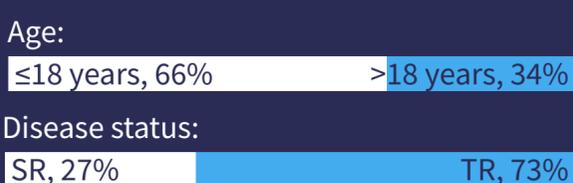
## Real-world, multicenter analysis of MSC-FFM in refractory aGvHD<sup>\*,1</sup> N = 69



**SAFETY**

- Two patients experienced ADRs (both ≤18 years old): Nausea/vomiting, n = 1; headache, n = 1.
- No other AEs were reported; no limiting acute toxicity was associated with MSC-FFM infusions.

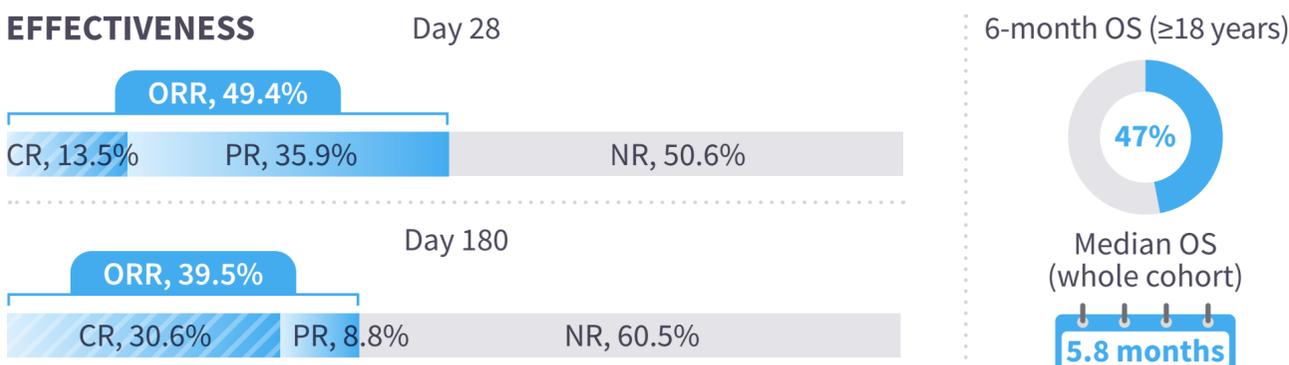
## Post-approval PV program of MSC-FFM in refractory aGvHD<sup>2</sup> N = 92



**SAFETY**

- No acute infusion toxicity reported.

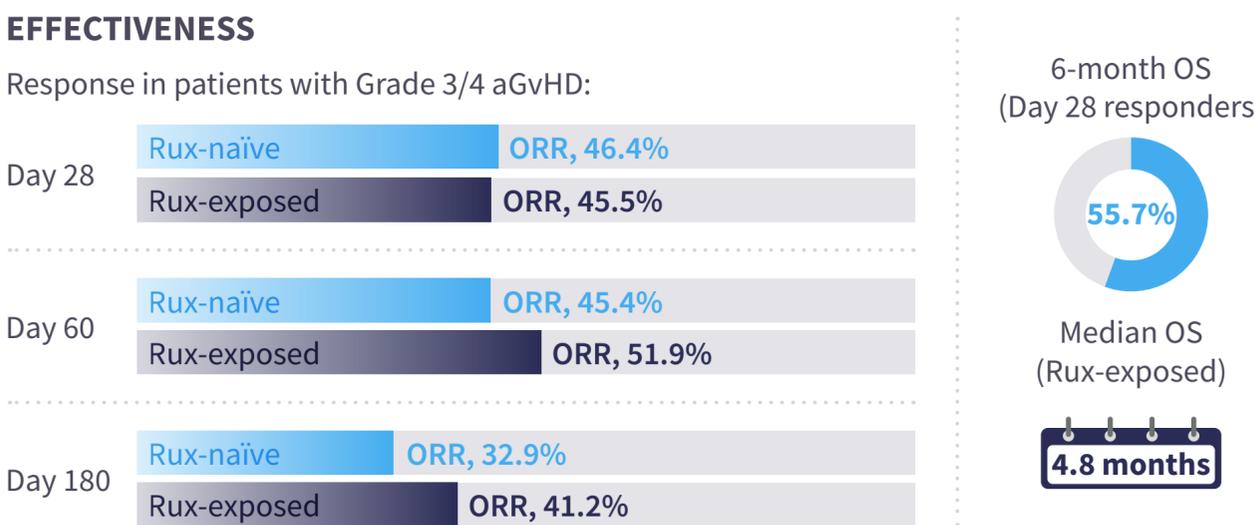
## Multicenter analysis of MSC-FFM in patients with RR-aGvHD<sup>\*,3</sup> N = 156



**SAFETY**

- Five ADRs were observed in three patients: Chills, 1; BK virus cystitis, 1; increased CRP, 2; and nausea, 1.
- No ADRs led to MSC-FFM discontinuations or dose reductions.

## Retrospective analysis of real-world outcomes of MSC-FFM in aGvHD (regulator-mandated PV)<sup>4</sup> N = 242



**SAFETY**

- Five temporary, non-serious mild-moderate ADRs were observed in three patients.
- Most frequently reported causes of death: GvHD (especially in Rux-exposed patients), infections.

Real-world data of MSC-FFM in patients with refractory aGvHD show favorable responses, survival outcomes, and safety findings. Effectiveness was consistent regardless of previous exposure to Rux, supporting a role for MSC-FFM in patients with RR-aGvHD, as well as those without prior exposure to Rux. The ongoing phase II BALDER (NCT06075706) and phase III IDUNN (NCT04629833) trials are investigating first-line MSC-FFM vs BAT, including Rux, in pediatric and adult patients with SR-aGvHD.<sup>5,6</sup>

\*Percentages may not sum to 100 due to rounding.

ADR, adverse drug reaction; AE, adverse event; aGvHD, acute GvHD; BAT, best available therapy; CI, confidence interval; CR, complete response; CRP, C-reactive protein; FU, follow-up; GvHD, graft-versus-host disease; LoT, line of therapy; MSC, mesenchymal stromal cell; MSC-FFM, MSC-Frankfurt am Main; NE, not evaluable; NR, no response; NS, not serious; ORR, overall response rate; OS, overall survival; PR, partial response; PV, pharmacovigilance; Rux, ruxolitinib; RR, Rux-refractory; SR, steroid-refractory; TR, treatment-refractory.

1. Bader P, et al. *Bone Marrow Transplant*. 2018;53(7):852-862; 2. Bonig H, et al. *Cells*. 2019;8(12):1577; 3. Bonig H, et al. *J Transl Med*. 2023;21(1):837; 4. Bonig H, et al. *Cytotherapy*. 2025;27(5):S20; 5. ClinicalTrials.gov. <https://clinicaltrials.gov/study/NCT06075706>. Updated Jan 27, 2026. Accessed Feb 10, 2026; 6. ClinicalTrials.gov. <https://clinicaltrials.gov/study/NCT04629833>. Updated Aug 13, 2025. Accessed Feb 10, 2026.