

LIMBER trial: Safety and tolerability of INCB057643 in patients with MF and other advanced MPN (NCT04279847)

N = 88
As of March 17, 2025.
Total estimated enrollment N = 231.

DESIGN Phase I, open-label 3+3 dose-escalation/expansion study

PART 1: Dose escalation (N = 18) followed by dose expansion (N = 34)

PART 2: Combination therapy dose escalation (N = 23) followed by dose expansion (N = 13)

INCB057643 monotherapy
4 mg → 12 mg QD

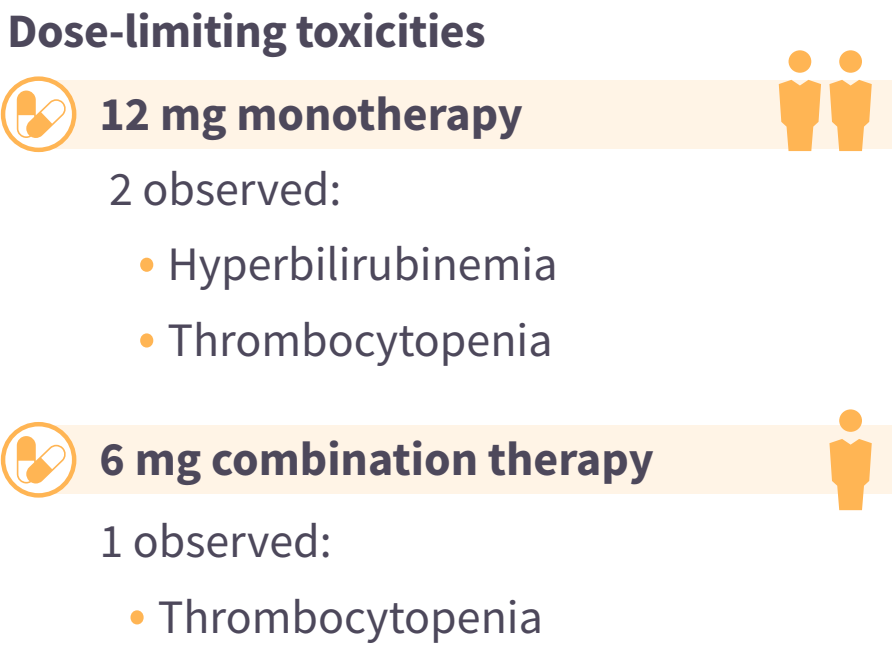
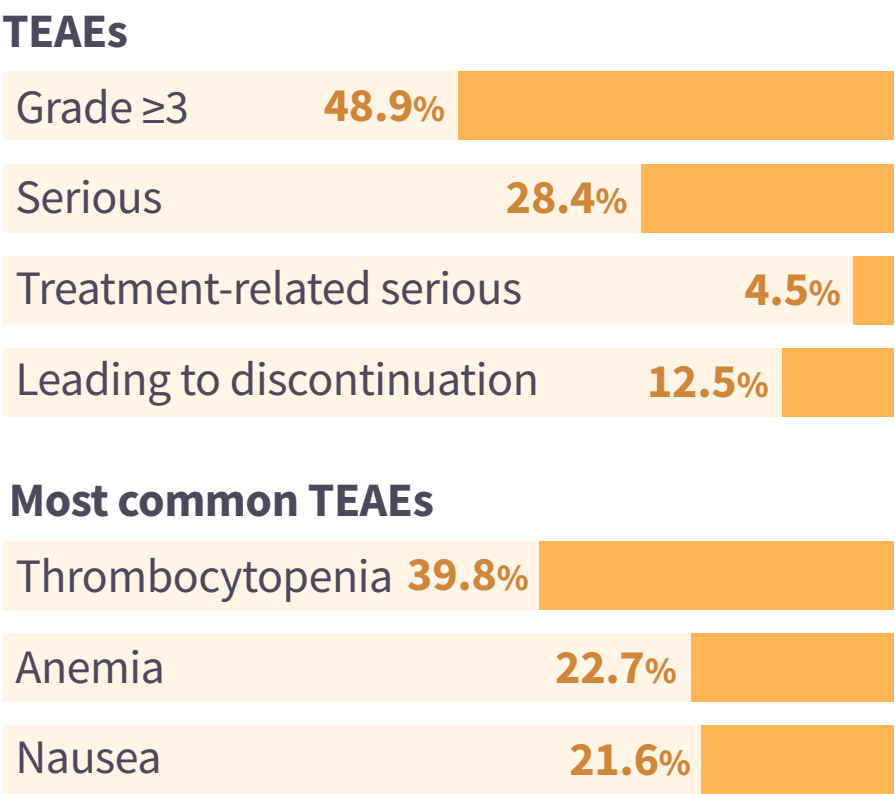
INCB057643
4 mg → 12 mg QD

+ Ruxolitinib
5–25 mg BID

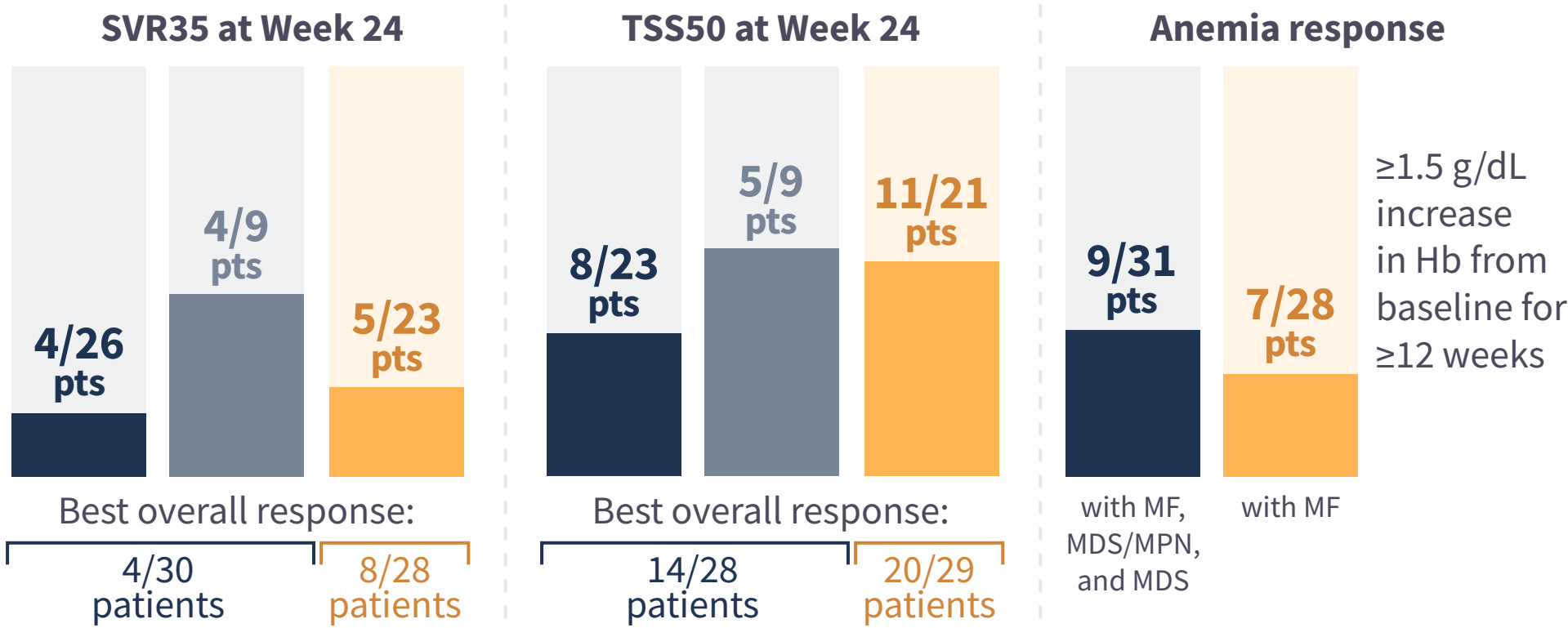
Admin route: Oral, administered continuously in 28-day cycles

Primary endpoint: Safety/tolerability, including DLTs
Key eligibility: Relapsed/refractory primary MF or secondary MF (post-PV MF, post-ET MF)

SAFETY Monotherapy and combination therapy N = 88



EFFICACY Monotherapy: Any dose ≥10 mg Combination



INCB057643 was generally well tolerated as monotherapy and in combination with ruxolitinib, with few serious TEAEs and no treatment-related fatal events. Improvements were observed in anemia, spleen size, and symptom burden.

Monotherapy dose expansion (6 mg and 10 mg in patients with MF and 6 mg and 12 mg in patients with ET), combination dose expansion (4 mg and 8 mg), and combination therapy dose escalation studies with INCB057643 are ongoing. Enrollment is ongoing for the JAKi-naïve combination therapy group.

BID, twice daily; ET, essential thrombocythemia; Hb, hemoglobin; MDS, myelodysplastic syndromes; MF, myelofibrosis; MPN, myeloproliferative neoplasms; MTD, maximum tolerated dose; pts, patients; PV, polycythemia vera; QD, once daily; SVR35, spleen volume reduction ≥35%; TEAE, treatment-emergent adverse event; TSS50, ≥50% reduction in total symptom score.

Watts JM. Poster Abstract #PS1822. Presented at: European Hematology Association 2025 Congress; Jun 12–15, 2025; Milan, IT.