

Presentation #S218

# Clinical Outcomes in Patients With Myelofibrosis Treated With Ruxolitinib and Anemia-Supporting Medications

Pankit Vachhani, MD,<sup>1</sup> Jennifer Repp, PharmD,<sup>2</sup> J.E. Hamer-Maansson, MSPH,<sup>2</sup> Evan Braunstein, MD, PhD,<sup>2</sup>  
Valkal Bhatt, PharmD,<sup>2</sup> Haifa Kathrin Al-Ali, MD<sup>3</sup>

<sup>1</sup>The University of Alabama at Birmingham, Birmingham, AL, USA; <sup>2</sup>Incyte Corporation, Wilmington, DE, USA; <sup>3</sup>University Hospital Halle, Halle (Saale), Germany

# Introduction

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- Patients with myelofibrosis often present with anemia<sup>1</sup>
- Transient dose-dependent anemia is a known effect of treatment with ruxolitinib (a potent, selective JAK1/JAK2 inhibitor)<sup>2</sup>
  - This can influence decisions about treatment initiation, dosing, and discontinuation
- ESAs and danazol are recommended options to manage anemia in this population<sup>3</sup>
  - There is a lack of data on clinical outcomes of patients with myelofibrosis treated with ruxolitinib and these agents

**Objective:** To evaluate the treatment patterns and clinical outcomes of patients with myelofibrosis treated with ruxolitinib and ESAs or danazol in the large phase 3b JUMP trial

ESA, erythropoiesis-stimulating agent; JAK, Janus kinase.

1. Verstovsek S. *Ann Hematol*. 2023;102(4):689-698. 2. JAKAFI® (ruxolitinib). Full Prescribing Information, Incyte Corporation, Wilmington, DE, 2023.

3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myeloproliferative Neoplasms, version 1.2025. Available at: <https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1477>. Accessed May 5, 2025.

# Study Design

## Post Hoc Analysis of JUMP

- JUMP was a large (N=2233), global, single-arm, open-label, phase 3b expanded-access study performed in a setting similar to routine clinical practice<sup>1</sup>
  - Main inclusion criteria: primary/secondary MF and baseline platelet counts  $\geq 50 \times 10^9/L$
  - Treatment: ruxolitinib 5–20 mg twice daily (based on baseline platelet count)

### Post Hoc Analysis Inclusion Criteria

- Patients with baseline anemia
  - Hemoglobin  $< 12.0$  g/dL (Hb  $< 12$ )
  - Subset with hemoglobin  $< 10.0$  g/dL (Hb  $< 10$ )
- Not receiving anemia medication at enrollment
- Initiated ESAs or danazol within 3 months of enrollment and remained on therapy for  $\geq 3$  months

### Post Hoc Assessments

**Spleen length response**  
 $\geq 50\%$  reduction from baseline in palpable spleen length

**Symptom response**  
 $\geq 6.5$ -point increase in FACT-Lym total score from baseline

FACT-Lym, Functional Assessment of Cancer Therapy–Lymphoma; Hb, hemoglobin.

1. Al-Ali HK, et al. *Br J Haematol*. 2020;189(5):888-903.

# Demographics and Clinical Characteristics

- 101 (7.3%) patients initiated ESA/danazol within 3 months and were included
- 97% (n=98) initiated ESAs (epoetin, n=81; darbepoetin, n=17); 3% (n=3) initiated danazol

Parameter at Baseline	ESA/Danazol Initiated Within 3 Months*	
	Hb<12.0 g/dL (n=101)	Hb<10.0 g/dL (n=52)
Age, median (range), y	70.0 (45–86)	71.5 (45–84)
≥65 y, n (%)	74 (73.3)	36 (69.2)
Female, n (%)	46 (45.5)	25 (48.1)
DIPSS risk, n (%)		
High risk	13 (12.9)	13 (25.0)
Intermediate-2	36 (35.6)	27 (51.9)
Intermediate-1	32 (31.7)	2 (3.8)
Low risk	1 (1.0)	0
Missing	19 (18.8)	10 (19.2)
Time since initial diagnosis, median (range), mo	18.6 (0.3–312)	12.9 (0.3–158)

\* Patients were not receiving ESA/danazol at baseline, then initiated ESA/danazol within 3 months of enrollment and remained on treatment ≥3 months. DIPSS, Dynamic International Prognostic Scoring System.

# Demographics and Clinical Characteristics

- Median (range) time from enrollment to first dose of an ESA or danazol:
  - 43 (2–91) days in the Hb<12 subgroup; 34 (2–90) days in the Hb<10 subset
- 10 patients (9.9%) with Hb<12 were transfusion-dependent at baseline (7 with Hb<10)\*

ESA/Danazol Initiated Within 3 Months†		
Parameter	Hb<12.0 g/dL (n=101)	Hb<10.0 g/dL (n=52)
Hb, mean (SD), g/dL	9.9 (1.1)	9.1 (0.8)
Platelet count, mean (SD), ×10 <sup>9</sup> /L	322 (250)	297 (223)
WBC count, mean (SD), ×10 <sup>9</sup> /L	14.5 (13.3)	15.6 (16.2)
Palpable spleen, n (%)	92 (91.1)	46 (88.5)
Length, mean (SD), cm below LCM	13.0 (6.6)	12.1 (6.1)
Median (range) follow-up duration, mo	17.5 (4.6–57.1)	16.7 (4.6–53.7)
Median (range) duration of ESA/danazol treatment, mo	10.2 (3.3–44.3)	9.2 (3.4–40.8)

LCM, left costal margin.

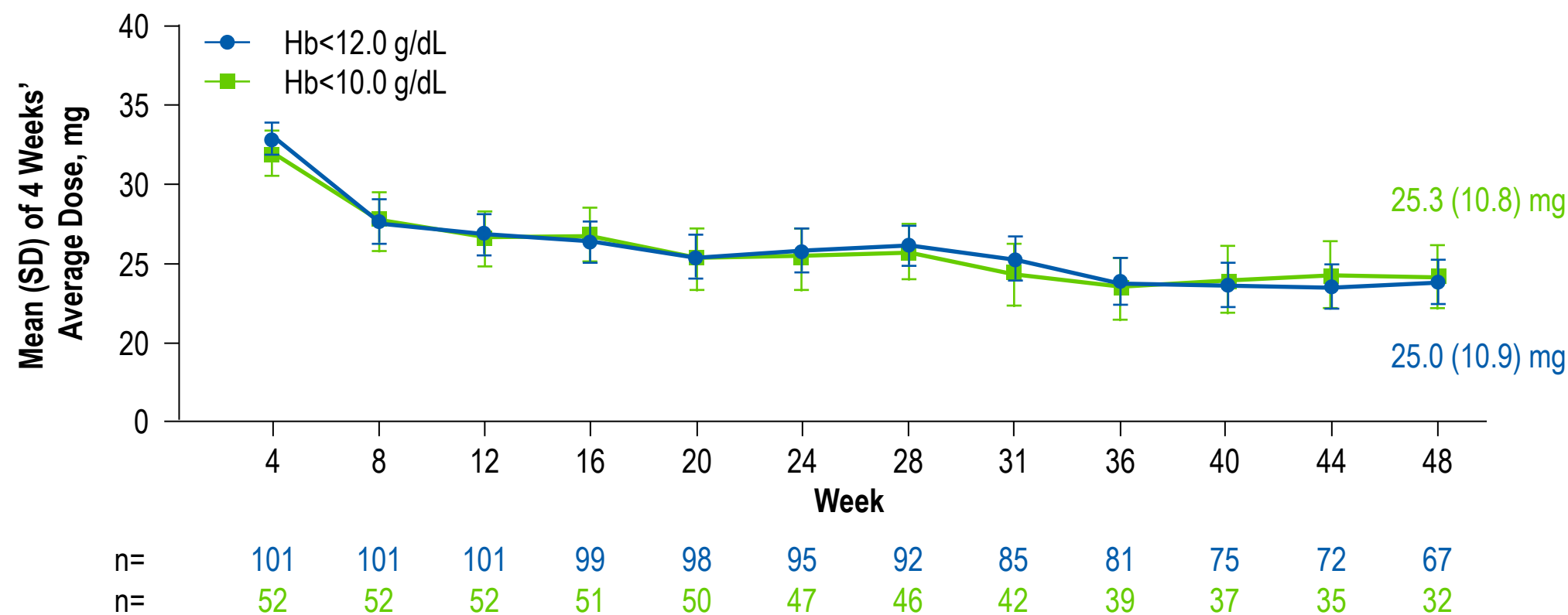
\* Transfusion dependence was defined as ≥3 units of red blood cells in the 12 weeks before Day 1.

† Patients were not receiving ESA/danazol at baseline, then initiated ESA/danazol within 3 months of baseline and remained on treatment ≥3 months.

WBC, white blood cell.

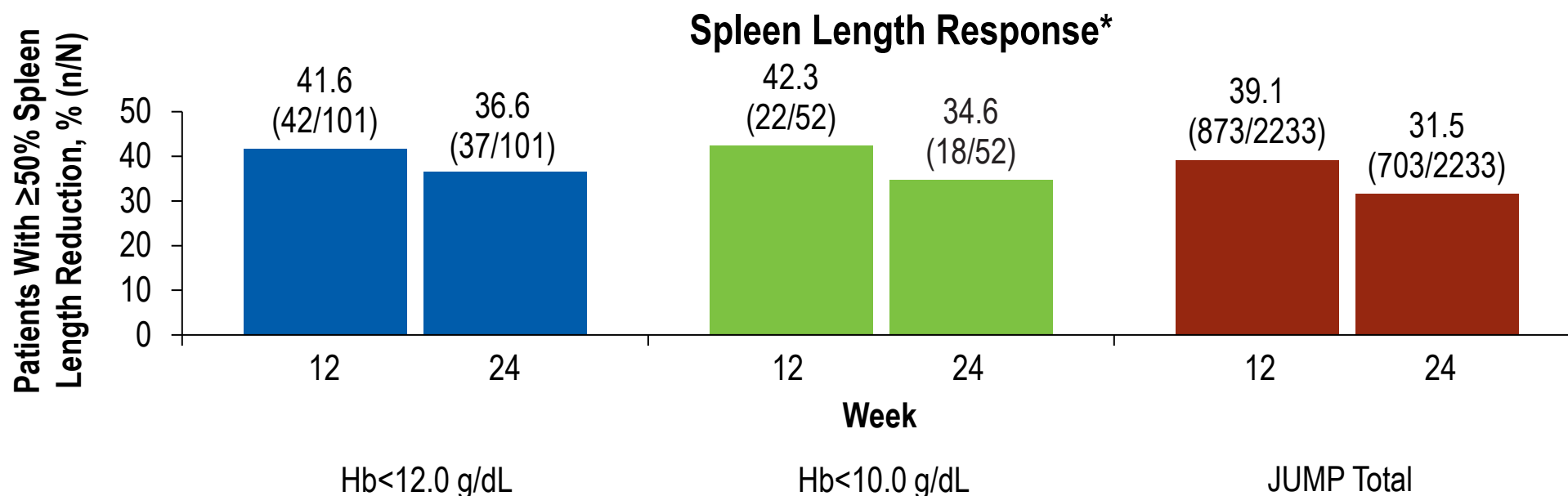
# Mean Total Daily Dose of Ruxolitinib

- 4-week average ruxolitinib doses remained above 25 mg/d for most study visits
  - Mean total daily dose decreased over time



# Spleen Length Response

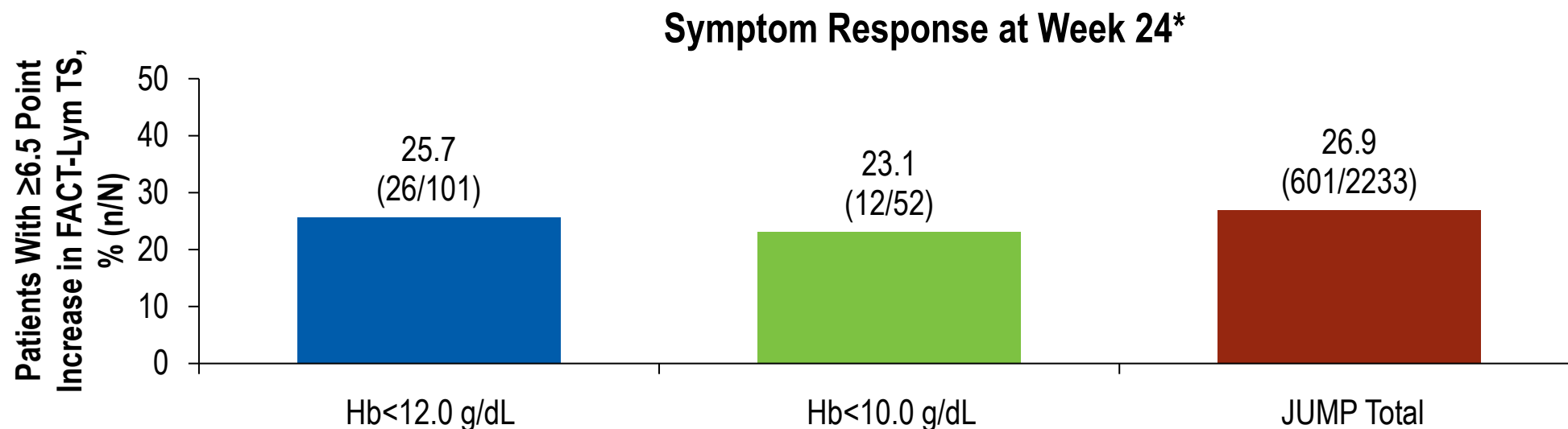
- Spleen length response rates were comparable between the Hb<12.0 g/dL and Hb<10.0 g/dL groups
  - These rates were consistent with the total JUMP population



\* For patients with Hb<12.0 g/dL, data were missing for 28 (27.7%) patients at Week 12 and for 42 (41.6%) at Week 24; for patients with Hb<10.0 g/dL, data were missing for 16 (30.8%) at Week 12 and 25 (48.1%) at Week 24; for the total JUMP population, data were missing for 590 (26.4%) at Week 12 and 953 (42.7%) at Week 24. Patients with missing data were considered non-responders.

# Symptom Response

- Symptom response rates were also comparable between the Hb<12.0 g/dL and Hb<10.0 g/dL groups
  - These rates were consistent with the total JUMP population



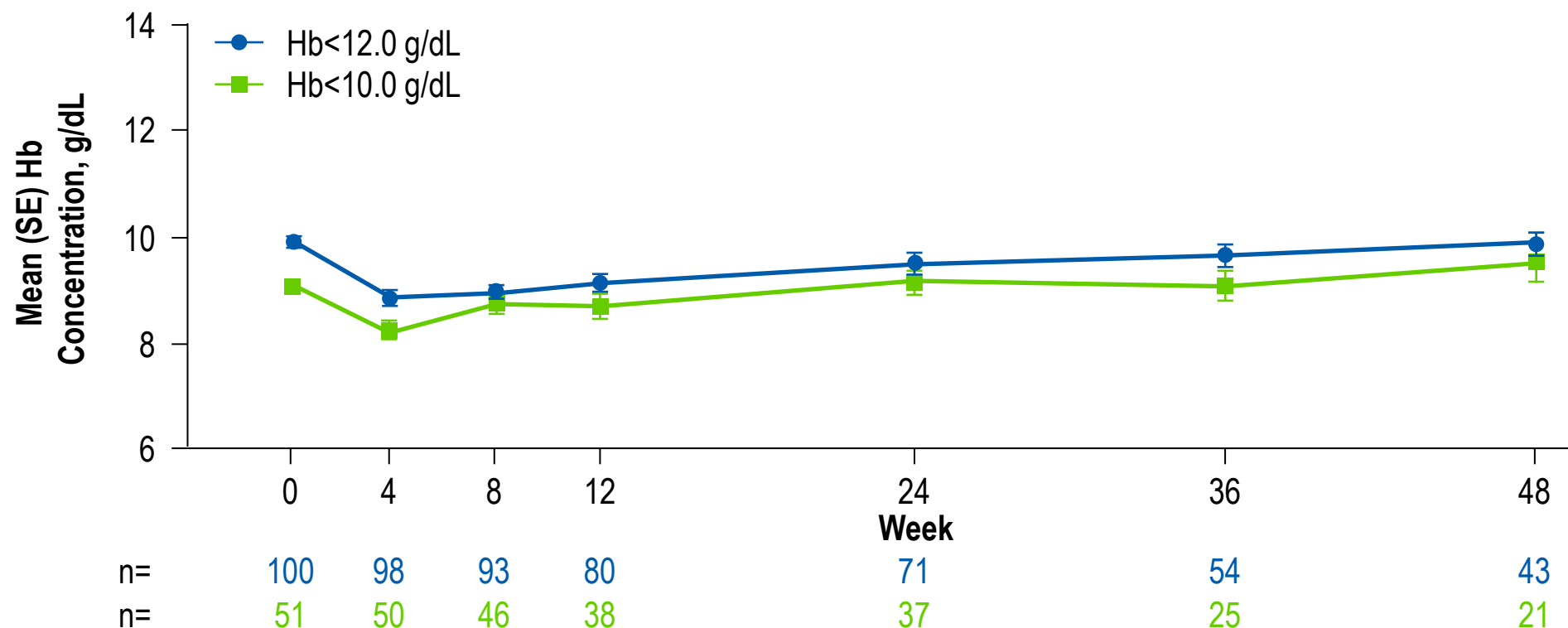
FACT-Lym TS, Functional Assessment of Cancer Therapy–Lymphoma total score.

\* Symptom response was not assessed at Week 12. All patients provided a Week 24 symptom assessment.



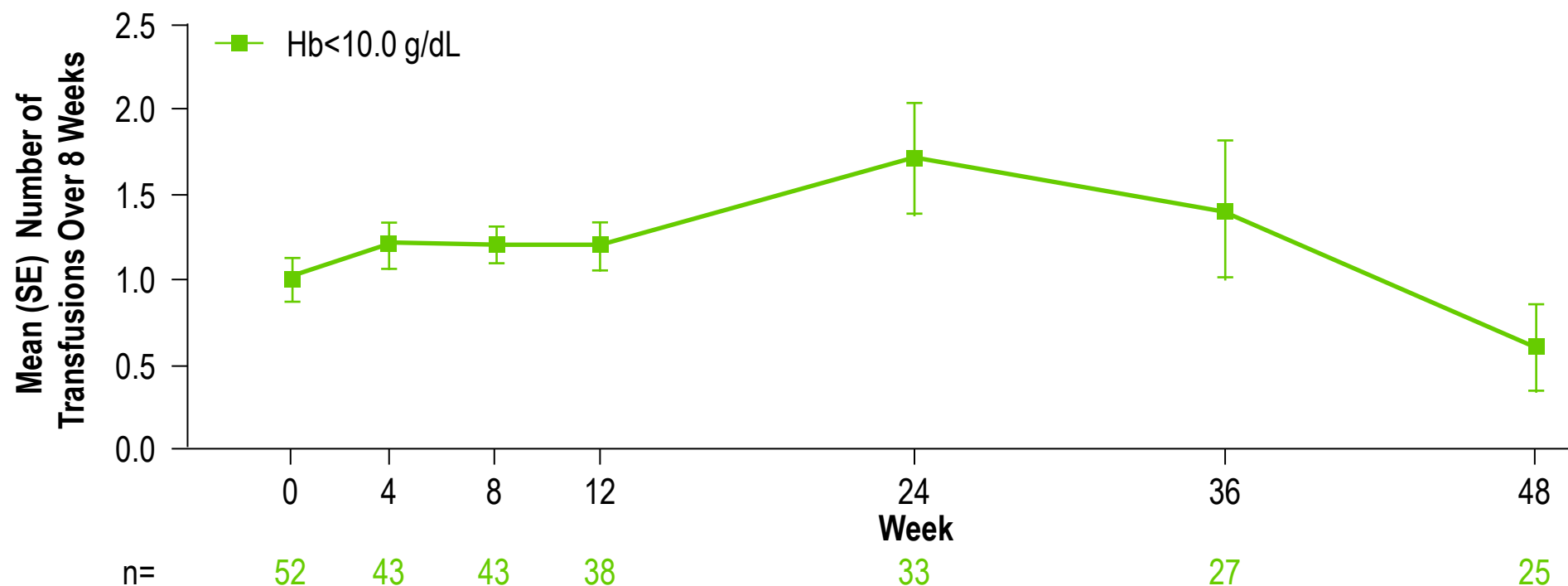
# Hemoglobin Levels Over Time

- Mean Hb reached a nadir at Week 4 and steadily increased thereafter to Week 48
  - Mean percentage change from baseline to Week 48:
    - +1.5% in the Hb<12 group
    - +6.5% in the Hb<10 subset



# Transfusion Requirement

- Transfusion requirements decreased between baseline and Week 48
- 4 patients (57%) with Hb<10 and transfusion dependency at baseline were no longer transfusion dependent at 24 weeks, including 3 who became transfusion independent\*



Values for transfusions are the mean number of recorded transfusions per patient over a rolling 8-week period preceding each time point. Values were set to 0 for patients who did not have a transfusion.

\* Transfusion dependence was defined as  $\geq 3$  units of red blood cells in the 12 weeks before Week 24. Transfusion independence was defined as 0 red blood cell transfusions in the 12 weeks before Week 24.

# Conclusions

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- For patients with anemia at myelofibrosis diagnosis who received ESAs or danazol in combination with ruxolitinib, spleen and symptom response rates were similar to those reported in the total JUMP study population
- In addition, most patients tolerated doses of ruxolitinib >25 mg daily and post-enrollment maintained an Hb level within 1.0 g/dL of baseline throughout the study period
- These results support the use of an ESA or danazol as an option for anemia supportive care in combination with ruxolitinib and may allow for maintenance of ruxolitinib dose intensity in myelofibrosis patients with anemia

# Acknowledgments

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