# Pelabresib in combination with ruxolitinib for Janus kinase inhibitor treatment-naïve patients with myelofibrosis: results of the MANIFEST-2 randomized, double-blind, Phase 3 study

**Raajit Rampal**,[1] Sebastian Grosicki, Dominik Chraniuk, Elisabetta Abruzzese, Prithviraj Bose, Aaron T Gerds, Alessandro M Vannucchi, Francesca Palandri, Sung-Eun Lee, Vikas Gupta, Alessandro Lucchesi, Stephen Oh, Andrew T Kuykendall, Andrea Patriarca, Alberto Álvarez-Larrán, Ruben Mesa, Jean-Jacques Kiladjian, Moshe Talpaz, Morgan Harris, Sarah-Katharina Kays, Anna Maria Jegg, Qing Li, Barbara Brown, Claire Harrison*, John Mascarenhas*

*Both authors contributed equally

[1]Leukemia Service, Memorial Sloan Kettering Cancer Center, New York, NY, USA

# Pelabresib clinical development in myelofibrosis

- Myelofibrosis (MF) is a debilitating and progressive disease, characterized by four hallmarks: bone marrow fibrosis, cytopenias (e.g., anemia), MF-associated symptoms, and splenomegaly[1]
  - Reduction of spleen size is associated with improved overall survival[2]
- MF results from the dysregulation of the JAK/STAT pathway and BET-mediated gene modulation[3]
- JAK inhibition is the standard of care in intermediate- and high-risk MF[4]
- Unmet medical need persists due to the limited depth and durability of response and treatment-emergent adverse events[1,5]
- Pelabresib (CPI-0610) is an investigational, oral, small-molecule drug designed to inhibit BET proteins and decrease BET-mediated gene expression involved in MF pathogenesis[6,7]

**The objective of the MANIFEST-2 study is to assess the efficacy and safety of the combination of pelabresib + ruxolitinib in JAKi-naïve patients with MF**

BET, bromodomain and extraterminal domain; JAK, Janus kinase; JAKi, Janus kinase inhibitor; MF, myelofibrosis; STAT, signal transducer and activator of transcription. 1. Tefferi A. *Am J Hematol*. 2021;96(1):145-162; 2. Bewersdorf J, et al. *Hemasphere*. 2023;7(S3):1965-66; 3. Kleppe M, et al. *Cancer Cell.* 2018;33(1):29-43.e7; 4. Bose P, Verstovsek S. *Hemasphere*. 2020;4(4):e424; 5. Harrison CN, et al. *Future Oncol*. 2022;18(27):2987-29977; 6. Albrecht BK, et al. *J Med Chem*. 2016;59(4):1330-1339; 7. Mascarenhas J, et al. *J Clin Oncol*. 2023;41(32):4993-5004.

# Global, randomized, double-blind, active-control, Phase 3 study

## Study population

**JAKi-naïve patients with MF (N=430)**
(primary or post-ET/PV)

- DIPSS Int-1 or higher
- Splenomegaly (≥450 $cm^3$) by CT/MRI
- TSS ≥10 (≥3 for two symptoms, MFSAF v4.0)

Double-blind randomization (1:1)

**1:1 randomization stratified by:**

- DIPSS risk category: Int-1 vs Int-2 vs high
- Platelet count: >200 × $10^9$/L vs 100–200 × $10^9$/L
- Spleen volume: ≥1800 $cm^3$ vs <1800 $cm^3$

## Treatment arm

**Pelabresib** 125 mg* PO QD Day 1–14 + **Ruxolitinib** Per label with a 5-mg BID lower starting dose† Day 1–21

**21-day cycles**

**Placebo** PO QD Day 1–14 + **Ruxolitinib** Per label with a 5-mg BID lower starting dose† Day 1–21

## Primary endpoint

- SVR35 at Week 24

## Key secondary endpoints

- TSS absolute change from baseline at Week 24
- TSS50 at Week 24

## Safety

- AEs of all grades and serious AEs

AE, adverse event; BID, twice daily; CT, computed tomography; DIPSS, Dynamic International Prognostic Scoring System; ET, essential thrombocythemia; Int, intermediate; JAKi, Janus kinase inhibitor; MF, myelofibrosis; MFSAF, Myelofibrosis Symptom Assessment Form; MRI, magnetic resonance imagining; PO, orally; PV, polycythemia vera; QD, once daily; SVR35, ≥35% reduction in spleen volume; TSS, total symptom score; TSS50, ≥50% reduction in total symptom score. *The starting dose for pelabresib was 125 mg QD and protocol-defined dose modifications based on AEs and treatment response allowed a dose range between 50 mg and 175 mg QD; †Ruxolitinib was started at 10 mg BID (baseline platelet count 100–200 × $10^9$/L) or 15 mg BID (baseline platelet count >200 × $10^9$/L) with a mandatory dose increase by 5 mg BID after one cycle and a maximum dose of 25 mg BID per label. Harrison CN, et al. *Future Oncol*. 2022;18(27):2987-29977.

# Patient disposition

| | Pelabresib + ruxolitinib | Placebo + ruxolitinib |
|---|---|---|
| Randomized | **214 (100%)** | **216 (100%)** |
| Treated | **212 (99.1%)** | **214 (99.1%)** |
| Discontinued double-blind treatment | **58 (27.1%)** | **54 (25.0%)** |
| Adverse event | 23 (10.7%) | 14 (6.5%) |
| Physician decision (including lack of benefit) | 9 (4.2%) | 20 (9.3%) |
| Disease progression | 5 (2.3%) | 5 (2.3%) |
| Eligible for transplant | 8 (3.7%) | 9 (4.2%) |
| Other* | 13 (6.0%) | 6 (2.8%) |
| Ongoing on double-blind treatment | **154 (72.0%)** | **160 (74.1%)** |

| | Pelabresib + ruxolitinib | Placebo + ruxolitinib |
|---|---|---|
| **Mean daily dose for pelabresib (14 days per 21-day cycle)** | 108 mg | N/A |
| **Mean daily dose for ruxolitinib (daily)** | 29.3 mg | 31.3 mg |
| **Median follow-up on study (weeks)** | 45.4 | |

**Data cut off: August 31, 2023.** N/A, not applicable. *Other: non-compliance, withdrawal of consent. The study opened for enrollment in November 2020; the first patient received their initial treatment on April 22, 2021, and the last patient received their first treatment on March 2, 2023. Percentages reported are based on the number of patients randomized (intent-to-treat set).

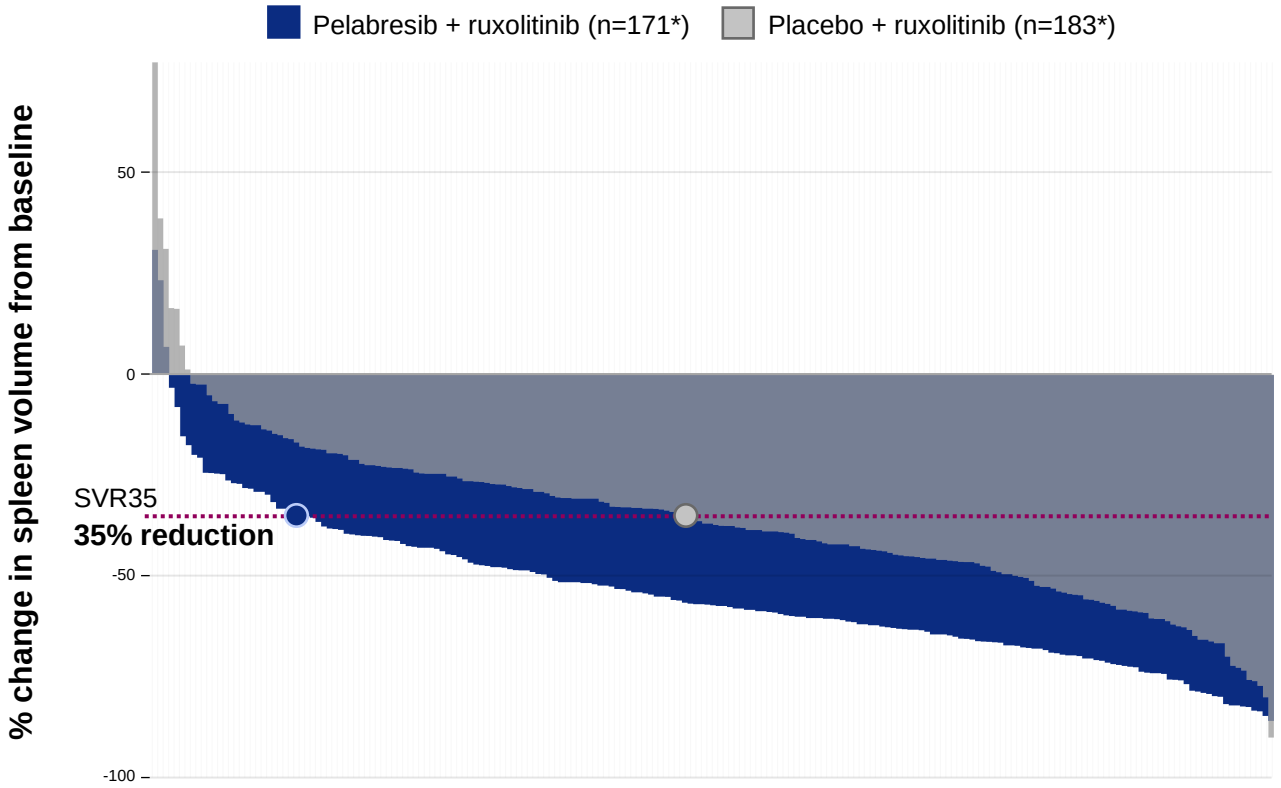
# Baseline disease characteristics

| Characteristic | | Pelabresib + ruxolitinib (N=214) | Placebo + ruxolitinib (N=216) |
|---|---|---|---|
| **Age — years** | Median (min, max) | 66 (19, 84) | 66 (26, 88) |
| **Sex — n (%)** | Female / male | 85 (39.7) / 129 (60.3) | 94 (43.5) / 122 (56.5) |
| **Race — n (%)** | White / Asian / Black<br>American Indian or Alaska Native<br>Not reported / Unknown | 160 (74.8) / 35 (16.4) / 2 (0.9)<br>1 (0.5)<br>15 (7.0) / 1 (0.5) | 163 (75.5) / 42 (19.4) / 0<br>0<br>11 (5.1) / 0 |
| **Myelofibrosis subtype — n (%)** | Primary myelofibrosis<br>Post-polycythemia vera myelofibrosis<br>Post-essential thrombocytopenia myelofibrosis | 107 (50)<br>45 (21)<br>62 (29) | 110 (50.9)<br>53 (24.5)<br>53 (24.5) |
| **Dynamic International Prognostic Scoring System — n (%)** | Intermediate-1<br>Intermediate-2<br>High-risk | 128 (59.8)<br>75 (35)<br>11 (5.1) | 127 (58.8)<br>74 (34.3)<br>15 (6.9) |
| **Mutations — n (%)*** | *JAK2* V617F<br>*CALR*<br>*MPL*<br>Triple negative<br>High-molecular risk mutations<br>Missing | 125 (67.2)<br>45 (24.2)<br>11 (5.9)<br>8 (4.3)<br>72 (38.7)<br>28 (13.1) | 122 (64.6)<br>50 (26.5)<br>13 (6.9)<br>5 (2.6)<br>88 (46.6)<br>27 (12.5) |
| **Hemoglobin — g/dL** | Median (range)<br>≤10 — n (%) | 10.9 (5.8–18.0)<br>70 (32.7) | 11.0 (6.7–17.9)<br>76 (35.2) |
| **Platelets — × $10^9$/L** | Median (min, max)<br>>200 × $10^9$/L — n (%) | 285 (99, 1303)<br>154 (72) | 287 (66, 1084)<br>157 (72.7) |
| **Peripheral blasts** | Mean (SD) | 0.8 (1.18)† | 0.8 (1.25)‡ |
| **RBC transfusions — patient n (%)** | Requiring RBC transfusion at baseline | 35 (16) | 25 (12) |
| **ECOG performance status — n (%)** | 0<br>1<br>≥2<br>Missing | 107 (50)<br>97 (45.3)<br>10 (4.7)<br>0 | 109 (50.5)<br>95 (44.0)<br>10 (4.6)<br>2 (0.9) |
| **Spleen volume (central read)§** | Median spleen volume (range) — cc | 1308.89 (200.24–7117.03) | 1382.97 (277.87–5540.45) |
| **Total symptom score¶** | Median total symptom score (range) | 26.6 (7.3–66.4) | 24.7 (9.0–68.4) |

**Data cut off: August 31, 2023**. *CALR*, calreticulin; ECOG, Eastern Cooperative Oncology Group; *JAK*, Janus kinase; max, maximum; min, minimum; *MPL*, MPL proto-oncogene, thrombopoietin receptor; RBC red blood cell; SD, standard deviation. *Results do not originate from a validated programming environment. †n=208. ‡n=207. §Randomization of patients was based on local read. ¶Patients with baseline TSS values of <10 have at least 2 individual symptoms score ≥ 3 at baseline.

# MANIFEST-2 study achieved its primary endpoint: SVR35 at Week 24

## Significantly greater response in patients treated with pelabresib + ruxolitinib vs placebo + ruxolitinib



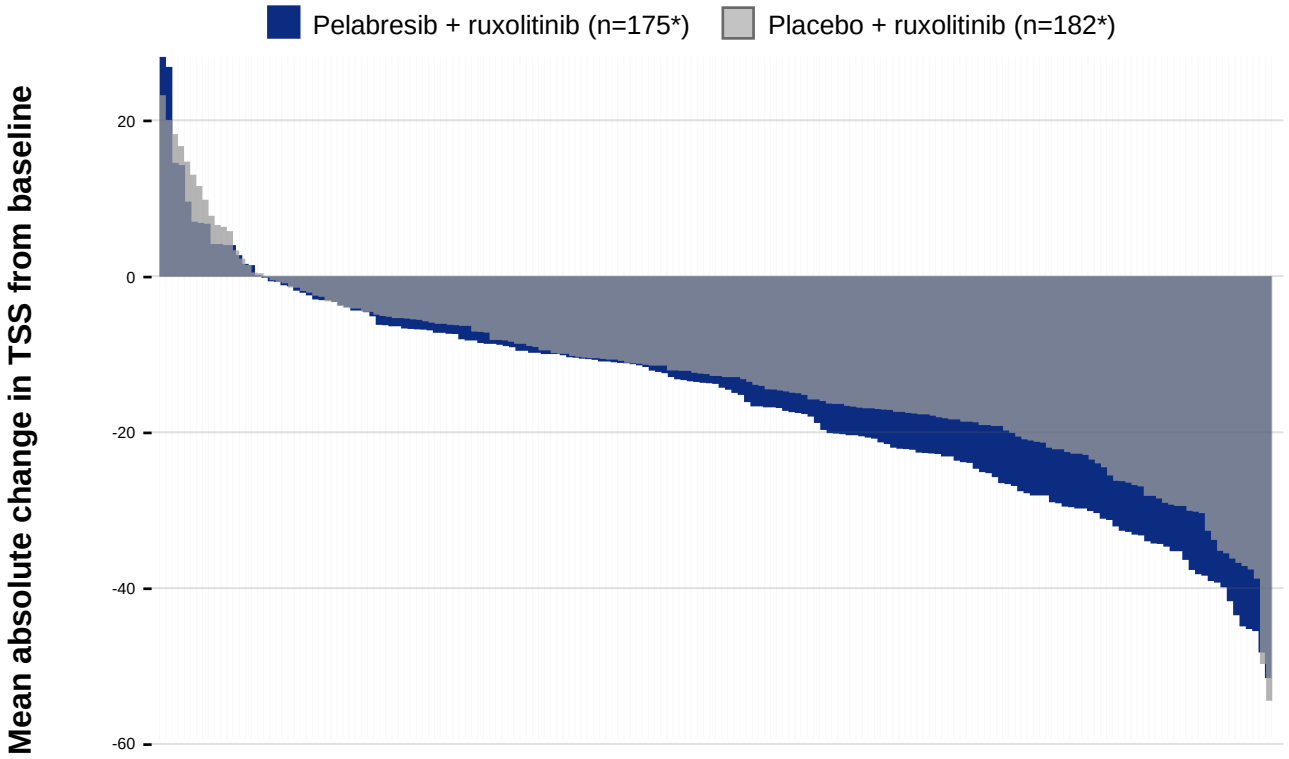

ITT population

| | Pelabresib + ruxolitinib (N=214) | Placebo + ruxolitinib (N=216) | p-value |
|---|---|---|---|
| **SVR35 at Week 24** | 65.9% | 35.2% | |
| **Difference† (95% CI)** | 30.4 (21.6, 39.3) | | <0.001 |
| **Mean % change in spleen volume at Week 24‡** | -50.6 (n=171) | -30.6 (n=183) | |
| **95% CI** | -53.2, -48 | -33.7, -27.5 | |

**Data cut off: August 31, 2023.** CI, confidence interval; ITT, intent-to-treat; SVR35, ≥35% reduction in spleen volume. Spleen volume assessed by central read. *Waterfall plots represent patients who have baseline and Week 24 data. †Calculated by stratified Cochran–Mantel–Haenszel test; ‡Patients without Week 24 assessment are considered non-responders.

# Absolute TSS at Week 24

## Strong numerical improvements for patients treated with pelabresib + ruxolitinib vs placebo + ruxolitinib




ITT population

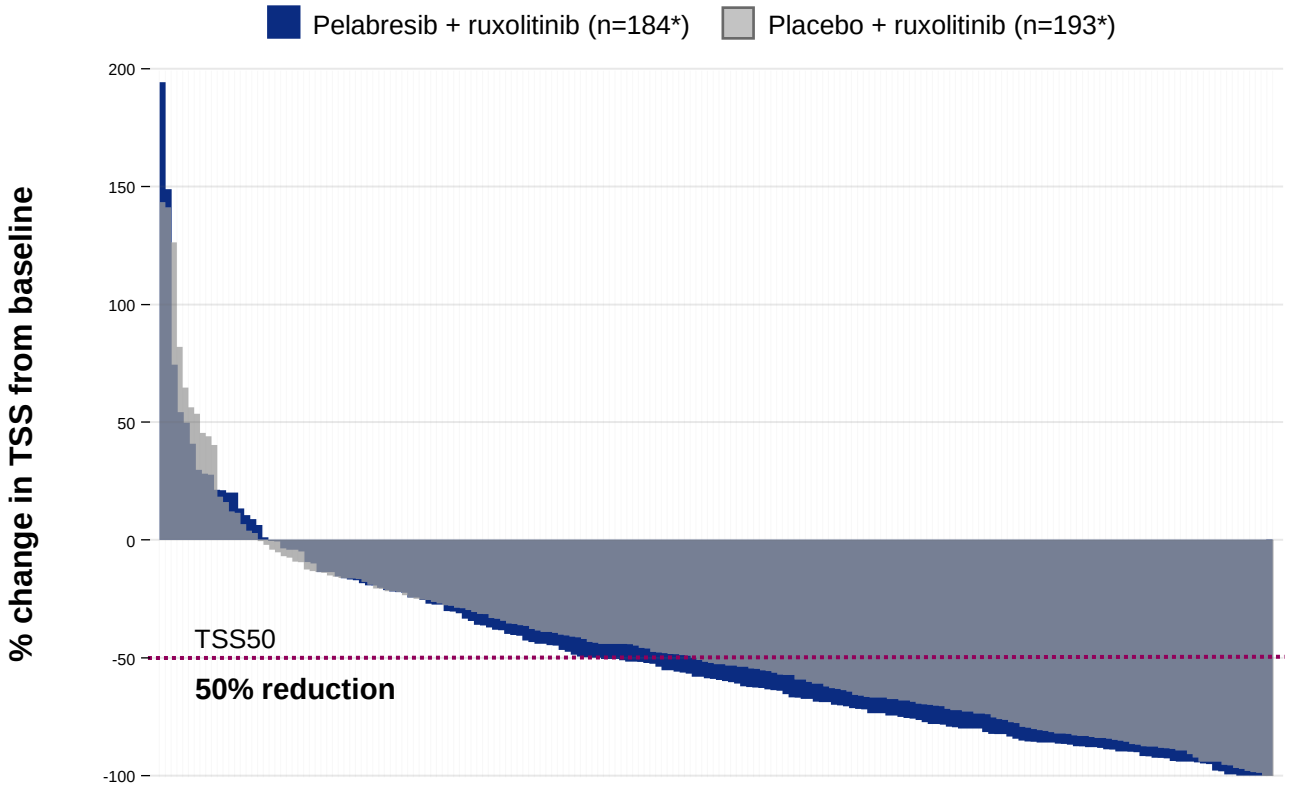
| | Pelabresib + ruxolitinib (N=214) | Placebo + ruxolitinib (N=216) | p-value |
|---|---|---|---|
| **TSS change† from baseline at Week 24** | -15.99 | -14.05 | |
| **Mean difference‡ (95% CI)** | -1.94 (-3.92, 0.04) | | 0.0545 |

- **Absolute change in TSS is a continuous endpoint** that estimates magnitude of symptom burden reduction with enhanced precision

**Data cut off: August 31, 2023.** ANCOVA, analysis of covariance; CI, confidence interval; ITT, intent-to-treat; TSS, total symptom score. *Waterfall plots represent patients who have baseline and Week 24 data. †Change from baseline determined by ANCOVA model using Multiple Imputation. ‡Least square mean difference from ANCOVA model using baseline DIPSS, baseline platelet count and baseline spleen volume as factors, and baseline TSS as covariate.

# TSS50 response at Week 24

## Numerically greater in patients treated with pelabresib + ruxolitinib vs placebo + ruxolitinib



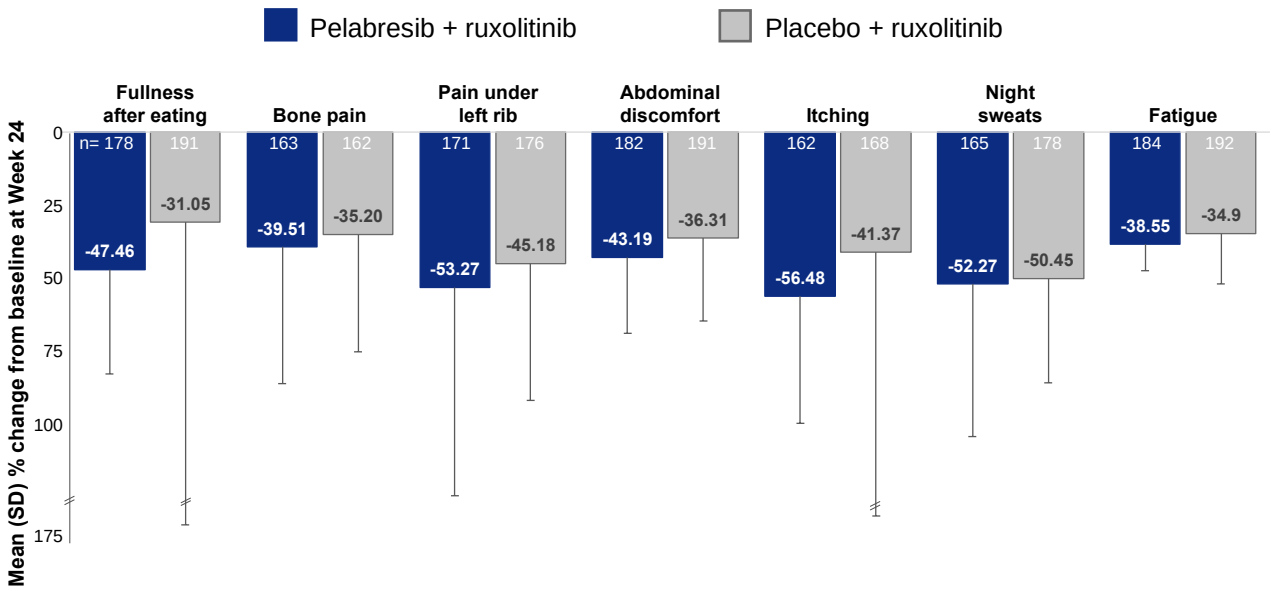

ITT population

| | Pelabresib + ruxolitinib (N=214) | Placebo + ruxolitinib (N=216) | p-value |
|---|---|---|---|
| **TSS50 at Week 24** | 52.3% | 46.3% | |
| **Difference† (95% CI)** | 6.0 (-3.5, 15.5) | | 0.216 |

**Data cut off: August 31, 2023.** CI, confidence interval; ITT, intent-to-treat; TSS, total symptom score; TSS50, ≥50% reduction in total symptom score. Patients are evaluable for TSS50 at Week 24 if they have had Week 24 TSS assessment by the data cutoff date or discontinued without Week 24 assessment at any time. *Waterfall plots represent patients who have baseline and Week 24 data. †Difference in treatment groups analyzed by stratified Cochran–Mantel–Haenszel test (weighted 95% CI adjusted across strata).

# TSS domains at Week 24

## Numerically greater in patients treated with pelabresib + ruxolitinib vs placebo + ruxolitinib with benefit balanced across all TSS domains




ITT population

| | Pelabresib + ruxolitinib (N=214) | Placebo + ruxolitinib (N=216) | p-value |
|---|---|---|---|
| **TSS50 at Week 24** | 52.3% | 46.3% | |
| **Difference† (95% CI)** | 6.0 (-3.5, 15.5) | | 0.216 |

**Data cut off: August 31, 2023.** CI, confidence interval; ITT, intent-to-treat; TSS, total symptom score; TSS50, ≥50% reduction in total symptom score. Patients are evaluable for TSS50 at Week 24 if they have had Week 24 TSS assessment by the data cutoff date or discontinued without Week 24 assessment at any time. †Difference in treatment groups analyzed by stratified Cochran–Mantel–Haenszel test (weighted 95% CI adjusted across strata).

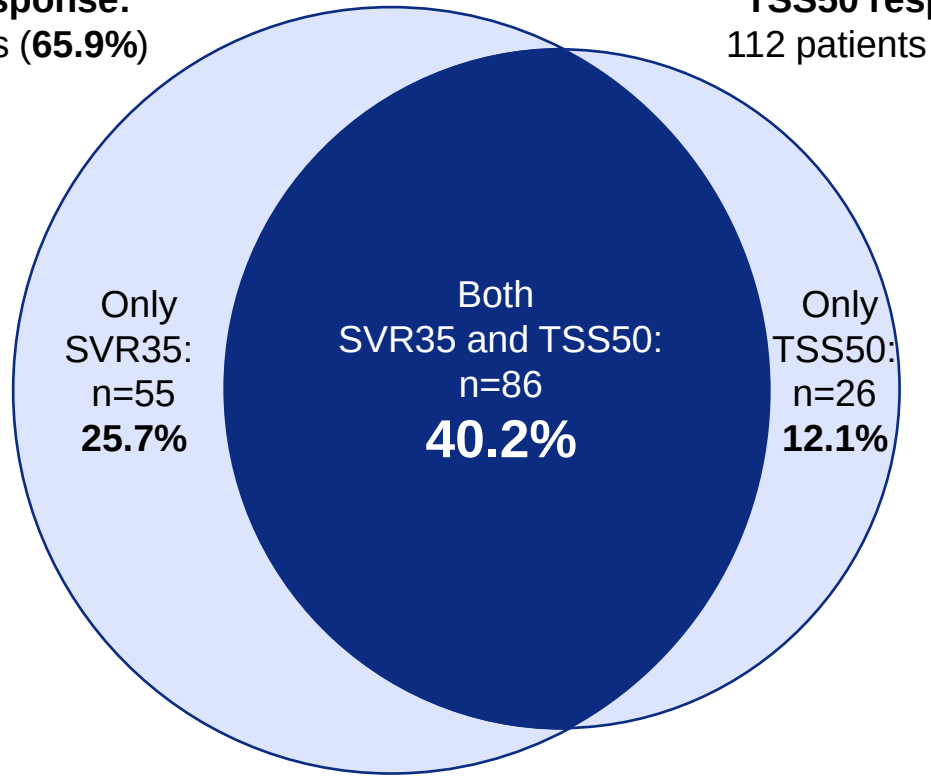
# Dual SVR35 / TSS50 responders at Week 24

## Two-fold increase in patients achieving both SVR35 and TSS50 with pelabresib + ruxolitinib vs placebo + ruxolitinib

### Pelabresib + ruxolitinib (N=214)

**SVR35 response:**
141 patients (**65.9%**)

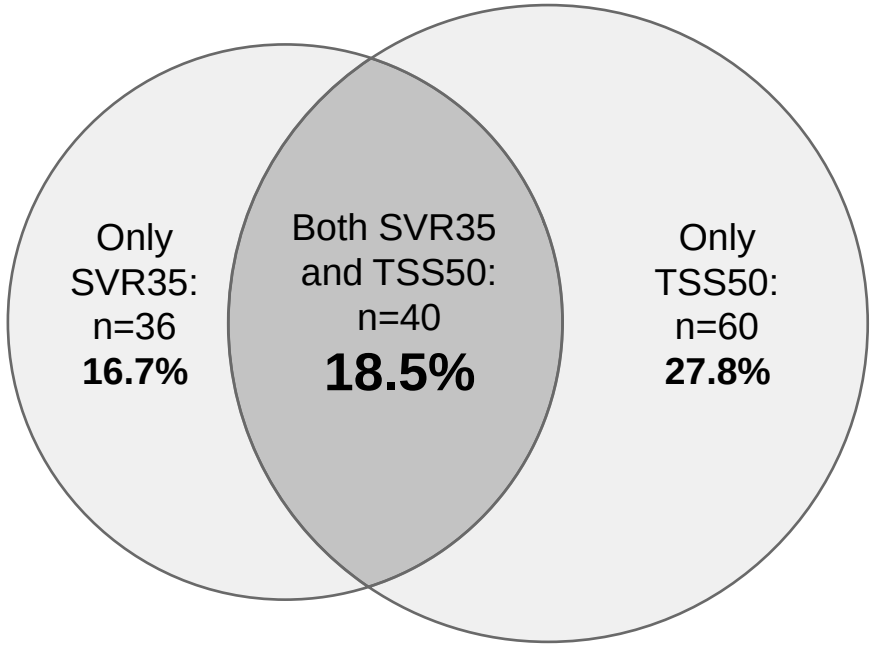
**TSS50 response:**
112 patients (**52.3%**)




### Placebo + ruxolitinib (N=216)

**SVR35 response:**
76 patients (**35.2%**)

**TSS50 response:**
100 patients (**46.3%**)



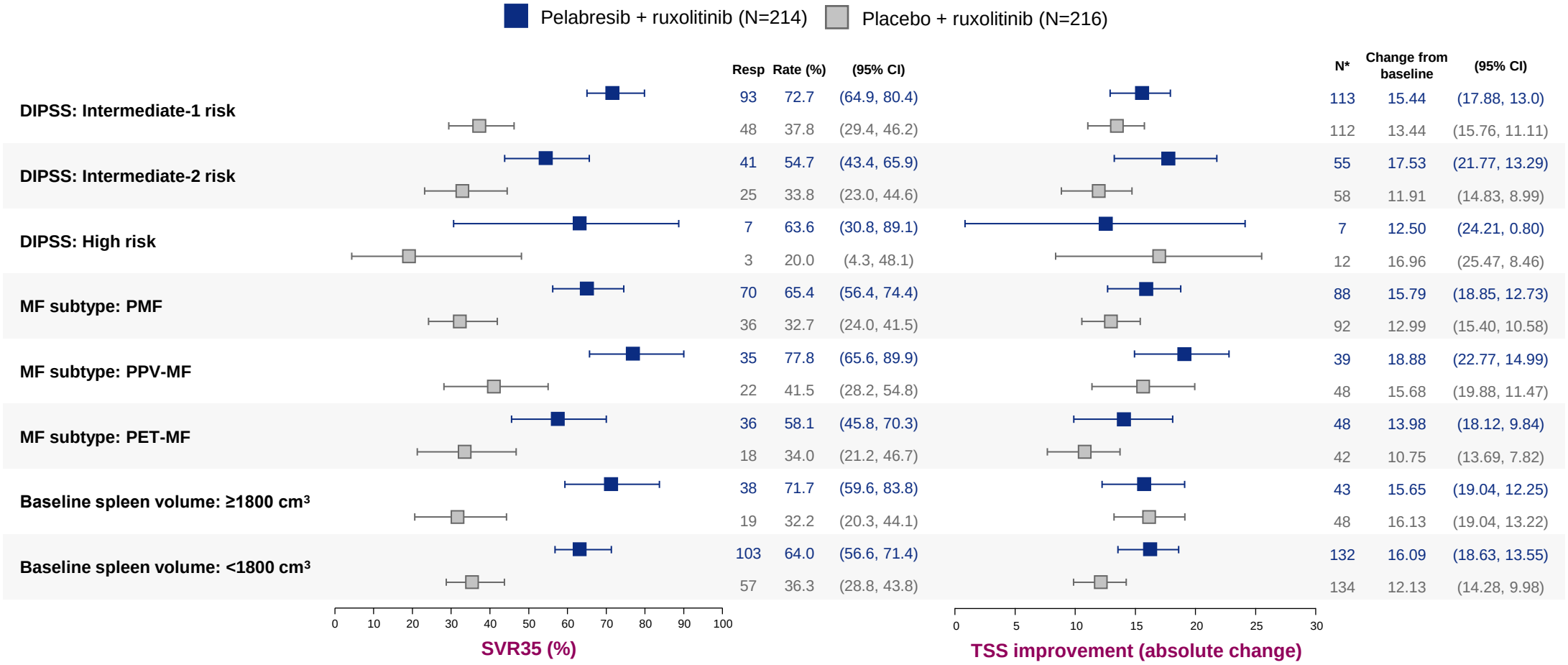

**Data cut off: August 31, 2023.** N, number of patients; SVR35, ≥35% reduction in spleen volume; TSS50, ≥50% reduction in total symptom score. Diagrams are not drawn to scale.

Rampal R, et al. ASH 2023. Oral 628

**Pelabresib (CPI-0610) is an investigational new drug and has not been approved by any regulatory authority**

# Prespecified subgroup analyses at Week 24

## SVR35 response consistently higher in pelabresib + ruxolitinib vs placebo + ruxolitinib across all predefined subgroups



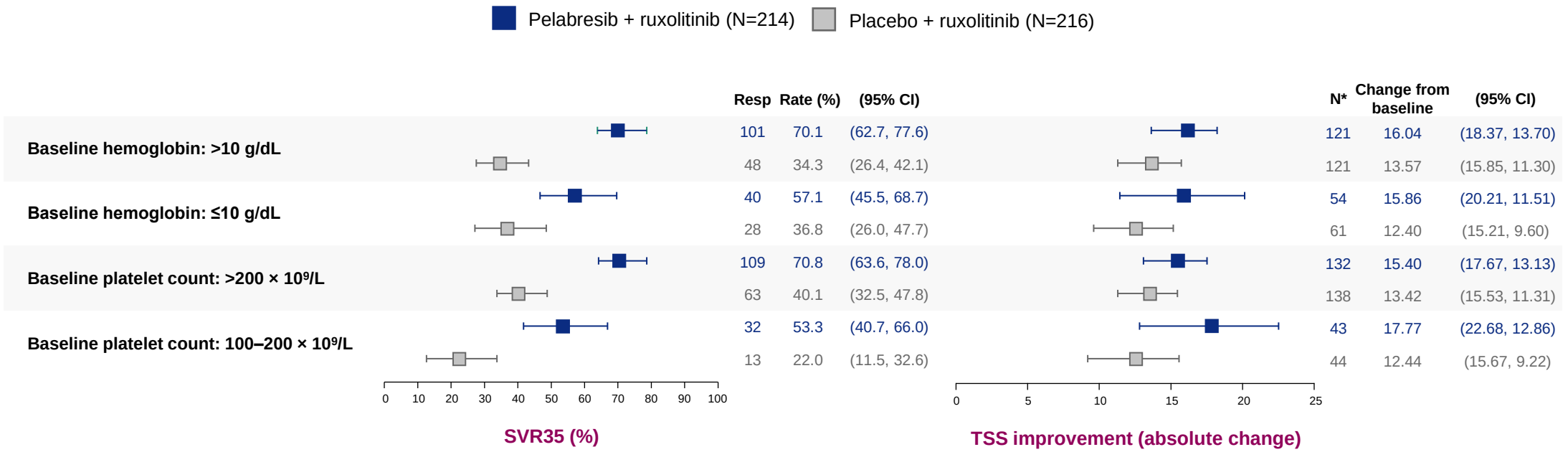

**Data cut off: August 31, 2023.** CI, confidence interval; DIPSS, Dynamic International Prognostic Scoring System; MF, myelofibrosis; PET-MF, post-essential thrombocythemia myelofibrosis; PMF, primary myelofibrosis; PPV-MF, post-polycythemia vera myelofibrosis; Resp, number of responders; SVR35, ≥35% reduction in spleen volume; TSS, total symptom score. *Number of patients with Week 24 observations.

Rampal R, et al. ASH 2023. Oral 628

**Pelabresib (CPI-0610) is an investigational new drug and has not been approved by any regulatory authority**

# Prespecified hematologic subgroup analyses at Week 24

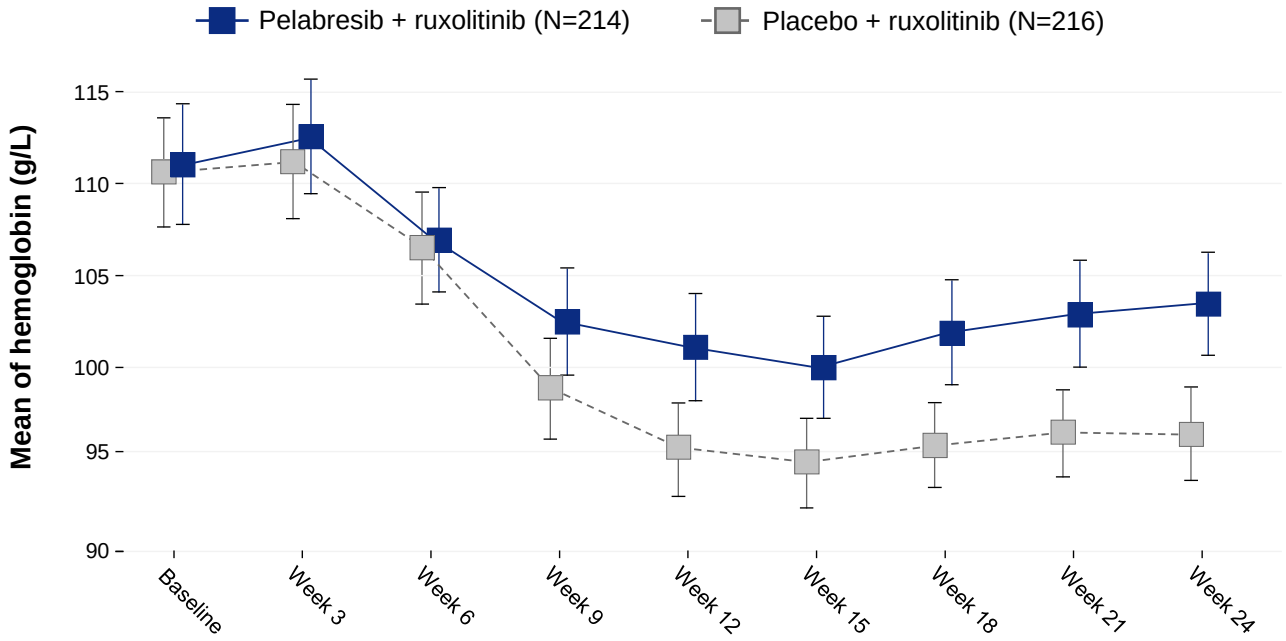
## SVR35 response consistently higher in pelabresib + ruxolitinib combination vs placebo + ruxolitinib across hematologic subgroups




**Data cut off: August 31, 2023.** CI, confidence interval; Resp, number of responders; SVR35, ≥35% reduction in spleen volume; TSS, total symptom score. *Number of patients with Week 24 observations.

# Hemoglobin response

## A numerically greater proportion of patients achieved hemoglobin response with pelabresib + ruxolitinib vs placebo + ruxolitinib




Number of patients

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Pelabresib + ruxolitinib | 212 | 204 | 209 | 199 | 193 | 189 | 186 | 185 | 184 |
| Placebo + ruxolitinib | 214 | 206 | 211 | 209 | 207 | 205 | 204 | 199 | 196 |

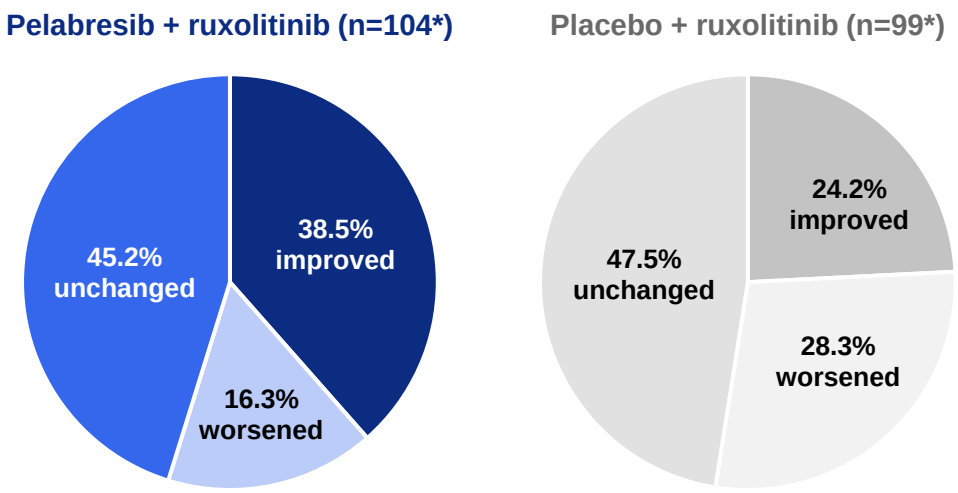
ITT population

| | Pelabresib + ruxolitinib (N=214) | Placebo + ruxolitinib (N=216) |
|---|---|---|
| **Hemoglobin response* ≥1.5 g/dL mean increase (95% CI)** | 9.3% (5.45, 13.25) | 5.6% (2.50, 8.61) |
| **Patients requiring RBC transfusion during screening, n (%)** | 35 (16.4) | 25 (11.6) |
| **Patients requiring RBC transfusion during first 24 weeks of study treatment, n (%)** | 66 (30.8) | 89 (41.2) |

**Preliminary Analyses from Data cut off: August 31, 2023.** CI, confidence interval; RBC, red blood cell. *Hemoglobin response is defined as a ≥1.5 g/dL mean increase in hemoglobin from baseline in the absence of transfusions during the previous 12 weeks. Baseline hemoglobin defined as the last assessment prior to or on Cycle 1 Day 1, regardless of blood transfusions. A similar effect was observed across DIPSS categories.

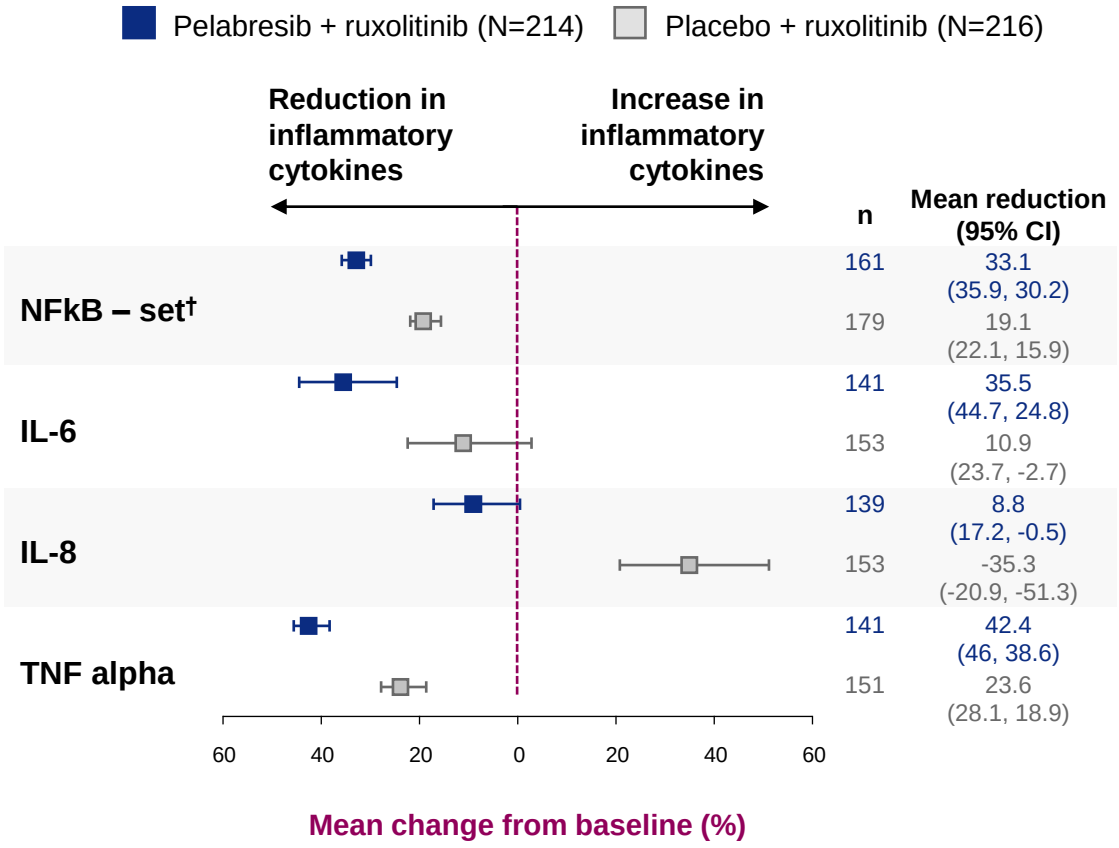
# Reduction in bone marrow fibrosis and inflammatory cytokines

## Improvement of reticulin fibrosis grade in central read by Week 24




| | Pelabresib + ruxolitinib | Placebo + ruxolitinib | Odds ratio |
|---|---|---|---|
| Worsened ≥1 grade (%) | 16.3 | 28.3 | 0.47 (0.23-0.92) |
| Improved ≥1 grade (%) | 38.5 | 24.2 | 2.09 (1.14-3.93) |

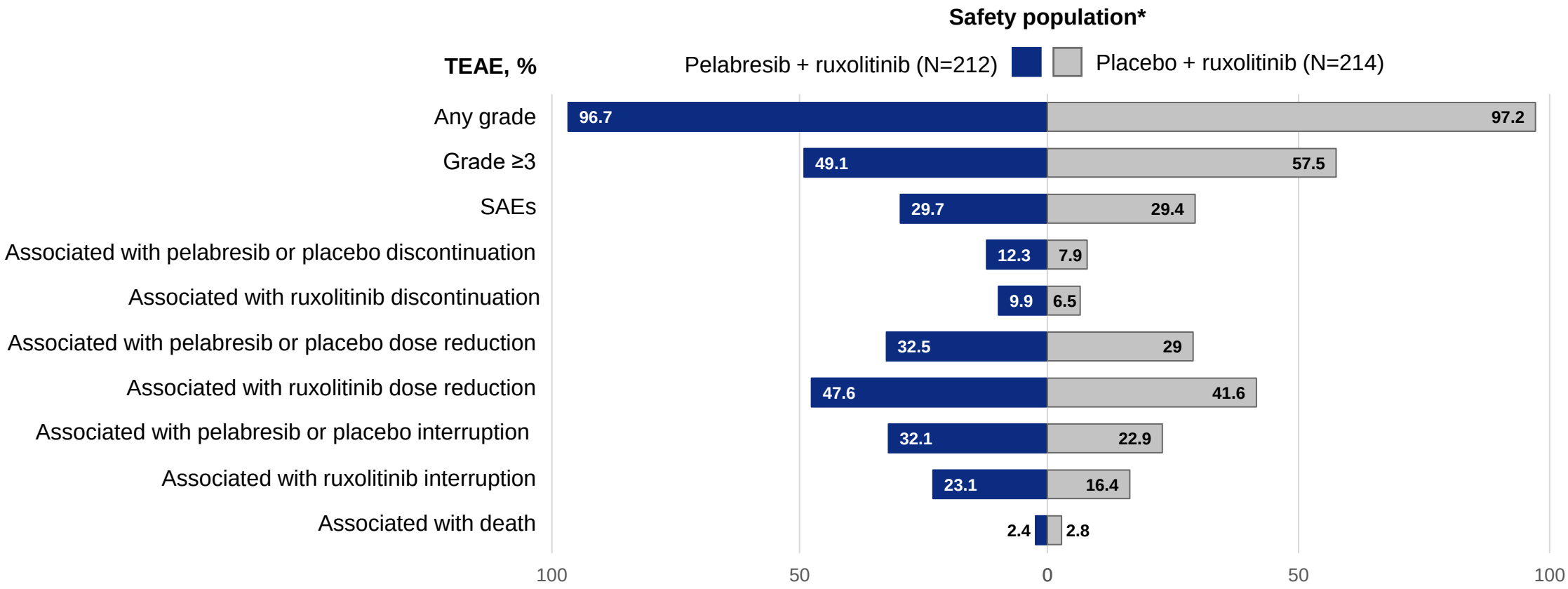
## Reduction of inflammatory cytokines by Week 24




**Preliminary Analyses from Data cut off: August 31, 2023.** IL-6, interleukin 6; IL-8, interleukin 8; NF$\kappa$B, Nuclear factor kappa-light-chain-enhancer of activated B cells; TNF, tumor necrosis factor. *n=203 evaluable patients (baseline & C9D1). †NF$\kappa$B - set includes: B2M, CRP, CD40-L, HEPCIDIN, IL-6, IL-12p40, MIP-1 BETA, MPIF-1, RANTES, TNFR2, TNF alpha, VCAM-1.

# Summary of safety

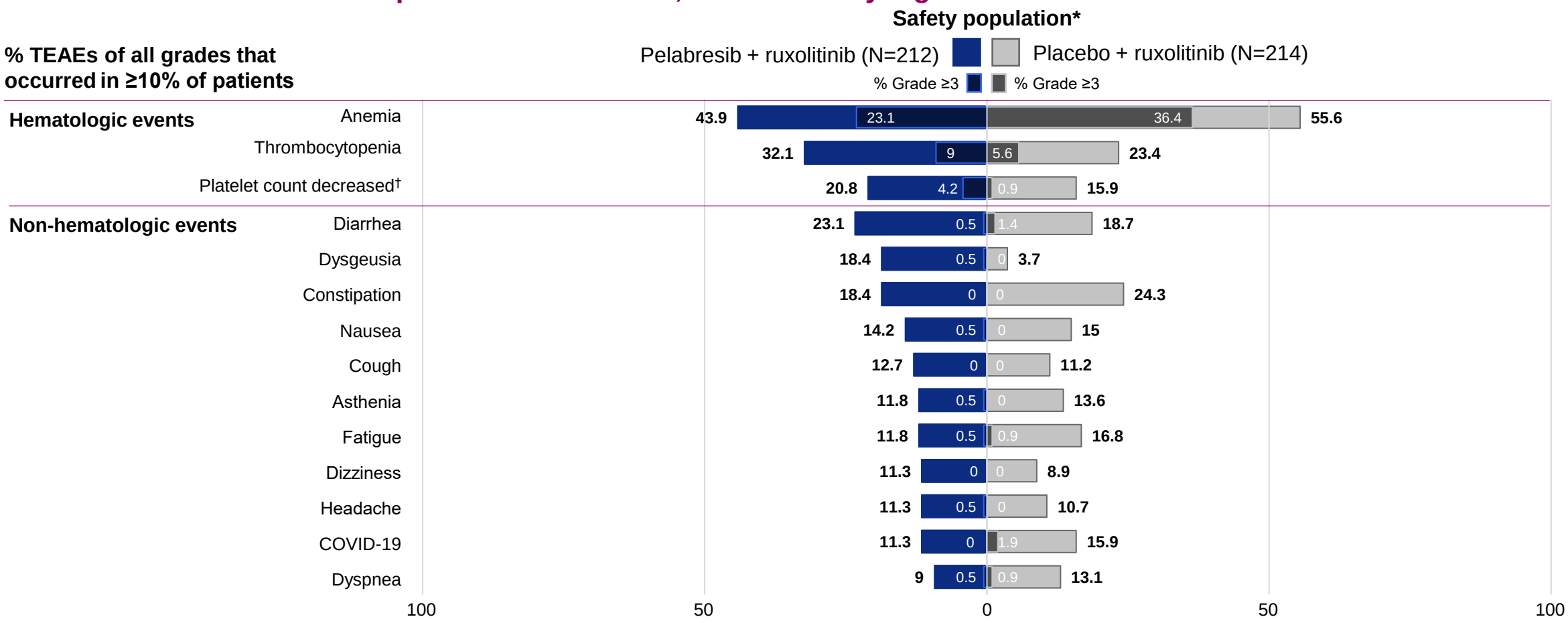
## The safety profile of the pelabresib + ruxolitinib combination was consistent with prior trials




**Preliminary Analyses from Data cut off: August 31, 2023.** TEAE, treatment-emergent adverse event; SAE, serious adverse event. *Safety population: received at least one dose of study drug. TEAEs are regardless of relationship to study drug. A TEAE for the double-blinded treatment period is defined as an adverse event that has a start date on or after the first dose of the pelabresib/placebo and before 30 days after the last dose of pelabresib/placebo or before the start of alternative (off-study) treatment for MF, whichever occurs first. MF, myelofibrosis.

# Treatment-emergent adverse events

## Adverse events of anemia were reported less frequently with pelabresib + ruxolitinib combination than with placebo + ruxolitinib; no new safety signals were observed




**Preliminary Analyses from Data cut off: August 31, 2023.** TEAE, treatment-emergent adverse event. *Safety population: received at least one dose of study drug. †Platelet count decreased was classified under the system organ class of investigation. TEAEs are regardless of relationship to study drug. A TEAE for the double-blinded treatment period is defined as an adverse event that has a start date on or after the first dose of the pelabresib/placebo and before 30 days after the last dose of pelabresib/placebo or before the start of alternative (off-study) treatment for MF, whichever occurs first. MF, myelofibrosis; COVID-19, coronavirus disease 2019.

# Conclusions

- **Pelabresib in combination with ruxolitinib compared with placebo in combination with ruxolitinib in JAK inhibitor treatment-naïve patients at Week 24:**
  - Significantly reduced splenomegaly (SVR35: 66% vs 35%; p<0.001)
  - Demonstrated strong trends in reducing the mean absolute TSS (p=0.0545) and improving TSS50 response
  - Doubled the percentage of patients with dual SVR35 / TSS50 response
- **Fewer anemia adverse events, higher rates of hemoglobin responses and fewer patients with transfusion requirement**
- **The safety profile appeared generally comparable to the established safety profile of ruxolitinib with fewer grade ≥ 3 events**
- **Pelabresib in combination with ruxolitinib showed reduction of pro-inflammatory cytokines, and improvement in bone marrow fibrosis and anemia response, addressing the four hallmarks of myelofibrosis**

**These results support a potential paradigm shift in the treatment of patients with myelofibrosis**

JAK, Janus kinase; SVR35, ≥35% reduction in spleen volume; TSS50, ≥50% reduction in total symptom score.

# Acknowledgments


- Thank you to the patients, caregivers, and study investigators of the MANIFEST-2 trial

**Australia:** David Ross, Ian Irving, Patricia Walker, Paul Yeh, Peter Tan, Sorab Shavaksha, **Austria:** Albert Woelfler, Clemens Schmitt, Richard Greil, Veronika Buxhofer-Ausch, **Belgium:** Benjamin Bailly, Gaelle Vertenoeil, Nikki Granacher, Timothy Devos, Violaine Havelange, **Canada:** Elena Liew, Natasha Szuber, Pierre Villeneuve, Selay Lam, Shireen Sirhan, Sonia Cerquozzi, Vikas Gupta, **Czech Republic:** Antonin Hlusi, Petra Belohlavkova, **France:** Antoine Machet, Dana Ranta, Eric Jourdan, Etienne Paubelle, Fiorenza Barraco, Jean-Jacques Kiladjian, Kamel Laribi, Lydia Roy, Marc Bernard, Michael Loschi, Régis Costello, Silvia Maria Bezsera, **Germany:** Andreas Hochhaus, Haifa Kathrin Al-Ali, Konstanze Döhner, Madlen Jentzsch, Markus Bangerter, Philippe Schafhausen, **Greece:** Panayiotis Panayiotidis, **Hong Kong:** Raymond Siu Ming Wong, Vivien Wai-Man Mak, **Hungary:** Laszlo Rejto, Szabolcs Kosztolanyi, **Israel:** Adi Shaham-Abulafia, Anna Gourevitch, David Lavie, Elena Mishchenko, Galia Bartfeld-Stemer, Itay Silbershatz, Kirgner Ilya, Maya Koren-Michowitz, Noa Lavi, **Italy:** Alessandra Tucci, Alessandra Iurlo, Alessandro Lucchesi, Alessandro Rambaldi, Alessandro Vannucchi, Andrea Patriarca, Brociner Marco, Camen Fava, Elisabetta Abruzzese, Francesca Palandri, Francesco Cavazzini, Francesco Passamonti, Gianni Binotto, Marco Santoro, Marco De Gobbi, **Malaysia:** Chieh Lee Wong, Hong Keng Liew, Lily Wong, Sharifah Shahnaz Syed Abd Kadir, Sui Keat Tan, Yang Liang Boo, **Netherlands:** Gwendolyn Van Gorkom, Marielle Wondergem, **Poland:** Dominik Chraniuk, Maciej Kazmierczak, Piotr Centkowski, Sebastian Grosicki, Witold Prejzner, **South Korea:** Byung Soo Kim, Chul Won Jung, Gyeong-Won Lee, Ho Jin Shin, Jae Hoon Lee, Jae-Yong Kwak, Jeong-A Kim, June Won Cheong, Sang Kyun Sohn, Sung Hwa Bae, Sung-Eun Lee, Sung-Soo Yoon, Sungnam Lim, Won Sik Lee, Yoo Jin Lee, Young Woo Jeon, **Spain:** Alberto Álvarez Larrán, Ángeles Fernández Rodríguez, Aranzazu Alonso Alonso, Beatriz Cuevas, Blanca Xicoy, Francisca Ferrer Marín, Jesús María Hernández Rivas , Juan Antonio Vera Goñi, Juan Carlos Hernández Boluda, Luis Felipe Casado Montero, María Antonia Durán Pastor, María Laura Fox, María Teresa Gómez Casares, Raquel Mata Serna, Víctor Higuero Saavedra, **Taiwan:** Cheng-Hsien Lin, Chien-Chin Lin, Chih-Cheng Chen, Su-Peng Yeh, **Thailand:** Chantiya Chanswangphuwana, Daolada Kongkabpan, Kunapa Iam-Arunthai, Manassamon Hirunmassuwan, Theerin Lanamtieng, **Turkey:** Ahmet Muzaffer Demir, Ali Ünal, Anıl Tombak, Burak Deveci, Fevzi Altuntaş, Mehmet Turgut, Nur Soyer, Ozgür Mehtap, Selami Kocak Toprak, Vahap Okan, **United Kingdom:** Adam Mead, Andrew Innes, Anna Godfrey, Ciro Rinaldi, Claire Harrison, Ionnis Koutsavlis, Jonathan Lambert, Naumann Butt, Steven Knapper, **United States:** Aaron Gerds, Andrew Kuykendall, Candido Rivera, Casey O'Connell, Catriaona Jamieson, Daniel Egan, Don Stevens, Gary Schiller, James Wade, Joseph Scandura, Kalyan Nadiminti, Karleung Siu, Luke Akard, Marina Kremyanskaya, Mikhail Shtivelband, Moshe Talpaz, Nikolai Podoltsev, Pankit Vachhani, Prithviraj Bose, Raajit Rampal, Ronan Swords, Stephen Oh, Subramanyeswara Arekapudi, Zohra Nooruddin

- This study was sponsored by Constellation Pharmaceuticals, Inc., a MorphoSys Company
- The development of pelabresib was funded, in part, by the Leukemia and Lymphoma Society (LLS)
- Editorial and writing support was provided by Laura Travers, PhD, of LiNK Health, funded by MorphoSys AG