Benefit of Rusfertide Maintained in Patients (Pts) With Low-Risk or High-Risk Polycythemia Vera (PV): Efficacy and Safety Subgroup Analysis From the Randomized Controlled Phase 3 VERIFY Study

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Background

- Polycythemia vera (PV) is a myeloproliferative neoplasm characterized by excessive erythrocytosis[1,2]
  - In addition to having an increased risk of thromboembolic events (TEs)[3] and secondary malignancies,[4] patients with PV frequently report debilitating symptoms, including fatigue, pruritus, and problems with concentration[5,6]
  - Treatment guidelines for patients with PV recommend controlling hematocrit (Hct) <45% to minimize the risk of TEs and help manage patient symptoms[2,7]
- Rusfertide is a first-in-class, self-administered subcutaneous peptide mimetic of the endogenous hormone hepcidin, the principal regulator of iron homeostasis[8,9]
- The ongoing phase 3 VERIFY study (NCT05210790) assessed rusfertide vs placebo added to current standard-of-care (CSC) therapy (phlebotomy with or without cytoreductive therapy [CRT]) in patients with PV who had inadequately controlled Hct and were receiving frequent phlebotomy[10]
  - Treatment with rusfertide led to statistically significant improvement in the primary endpoint of clinical response (p<0.0001) and all four key secondary endpoints (p<0.05 for each endpoint) vs placebo at Week 32[11]

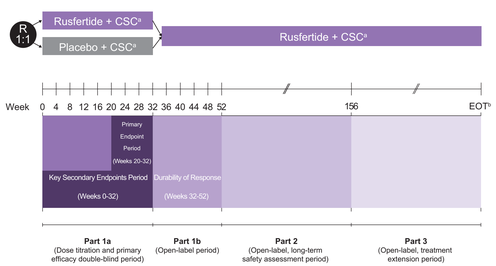
Objective

- To investigate whether clinical outcomes and safety were similar in patients with low-risk PV (ie, <60 years old and no TEs prior to study entry) or high-risk PV (≥60 years old and/or occurrence of a TE prior to study entry) in VERIFY

Methods

- In VERIFY, patients requiring frequent phlebotomy with or without CRT to achieve and maintain Hct <45% were randomized (1:1) to receive once-weekly rusfertide or placebo from baseline to Week 32 (**Figure 1**)
  - After 32 weeks, all patients were eligible to receive rusfertide during the open-label parts of the study
- The primary endpoint was the proportion of patients achieving a clinical response (defined as an absence of phlebotomy eligibility from Weeks 20-32)
  - Phlebotomy eligibility was defined as a confirmed Hct ≥45% and ≥3% (absolute) higher than the baseline Hct or Hct ≥48%
- Four key secondary endpoints were also evaluated
  - Key secondary efficacy endpoints (baseline to Week 32) included the mean number of phlebotomies[12] and the proportion of patients with Hct <45%
  - Key secondary patient-reported outcomes (PROs) included mean change from baseline at Week 32 in scores on the Patient Reported Outcomes Measurement Information System Fatigue Short Form 8a (PROMIS Fatigue SF-8a) T-score and the Myelofibrosis Symptom Assessment Form Version 4 Total Symptom Score-7 (MFSAF TSS7)
- Safety outcomes assessed throughout the study included the frequency and severity of treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs)

Figure 1. VERIFY Study Design



CSC, current standard-of-care; EOT, end of treatment; R, randomization.
[a]Current standard-of-care therapy (phlebotomy with or without cytoreductive therapy).
[b]Participation in Part 3 will end when the last randomized patient completes Part 2.

Results

Patients

- The data cutoff date for this analysis was 10 December 2025
  - The median (range) duration of rusfertide exposure was 88.1 (2-158) weeks
- In VERIFY, 293 patients (median age, 57.0 years) were randomized to the rusfertide or placebo arm (**Table 1**)
  - In total, 156 patients had low-risk PV (53.2%; median age, 52.0 years); 137 had high-risk PV (46.8%; median age, 66.0 years)
- In the high-risk group, 117 patients (39.9%) received prior CRT compared with 76 (25.9%) in the low-risk group

Table 1. Patient Characteristics at Baseline Were Well Balanced Between Both Arms

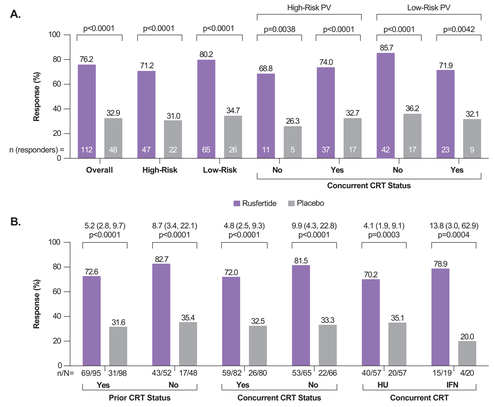
Characteristic	Rusfertide + CSC Arm (n=147)	Placebo + CSC Arm (n=146)	Total (N=293)
Age, years, median range)	58.0 (28-86)	57.0 (27-82)	57.0 (27-86)
Gender, n (%)			
Male	106 (72.1)	108 (74.0)	214 (73.0)
Female	41 (27.9)	38 (26.0)	79 (27.0)
Risk category, n (%)			
High-risk[a]	66 (44.9)	71 (48.6)	137 (46.8)
No concurrent CRT at baseline	16 (10.9)	19 (13.0)	35 (11.9)
Concurrent CRT at baseline	50 (34.0)	52 (35.6)	102 (34.8)
Hydroxyurea	43 (29.3)	42 (28.8)	85 (29.0)
Interferon[b]	6 (4.1)	8 (5.5)	14 (4.8)
Other[c]	1 (0.7)	2 (1.4)	3 (1.0)
Low-risk[d]	81 (55.1)	75 (51.4)	156 (53.2)
No concurrent CRT at baseline	49 (33.3)	47 (32.2)	96 (32.8)
Concurrent CRT at baseline	32 (21.8)	28 (19.2)	60 (20.5)
Hydroxyurea	14 (9.5)	15 (10.3)	29 (9.9)
Interferon[b]	13 (8.8)	12 (8.2)	25 (8.5)
Other[e]	5 (3.4)	1 (0.7)	6 (2.0)

CRT, cytoreductive therapy; CSC, current standard-of-care; PV, polycythemia vera; TE, thromboembolic event.
[a]High risk is defined as age ≥60 years and/or occurrence of a TE prior to study entry. [b]Interferon includes interferon, peginterferon alpha-2a, and ropeginterferon alfa-2b. [c]For the rusfertide arm, "Other" includes ruxolitinib (n=1); for placebo,"Other" includes ruxolitinib (n=1) and hydroxyurea + ruxolitinib (n=1). [d]Low risk is defined as age <60 years old and no TEs prior to study entry. [e]For the rusfertide arm, "Other" includes hydroxyurea + interferon (n=1) and ruxolitinib (n=4); for placebo, "Other" includes ruxolitinib (n=1).

Efficacy

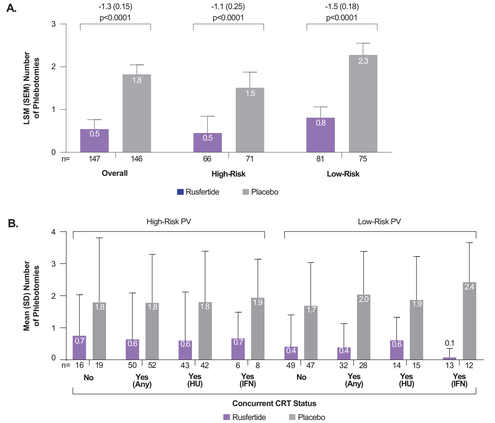
- Between Weeks 20-32, more patients in the rusfertide arm met the primary endpoint of clinical response vs placebo regardless of risk group (**Figure 2A**; p≤0.0001), concurrent CRT status (**Figure 2B**; all nominal p≤0.0001), or concurrent CRT received (**Figure 2B**; hydroxyurea or interferon; all nominal p≤0.0004)
- Among high-risk patients receiving concurrent CRT, 36/50 (72.0%) in the rusfertide arm were responders vs 17/52 (32.7%) in the placebo arm (nominal p<0.0001)
  - Proportions were similar among low-risk patients receiving concurrent CRT (rusfertide, 71.9% [23/32] vs placebo, 32.1% [9/28])
- Irrespective of risk group (**Figure 3A**) or concurrent CRT use (**Figure 3B**), more patients in the rusfertide arm had improvements in the mean number of phlebotomies received vs the placebo arm, including in high-risk rusfertide patients not receiving concurrent CRT (nominal p=0.0038)
  - Between baseline and Week 32, overall, there were 35 total phlebotomies in the rusfertide arm compared with 251 in the placebo arm
  - Among high- and low-risk patients receiving concurrent CRT, the mean (SD) number of phlebotomies was lower in the rusfertide arm vs the placebo arm (high-risk, 0.64 [1.45] vs 1.77 [1.52]; low-risk, 0.34 [0.74] vs 2.0 [1.35])
- Rusfertide use between baseline and Week 32 was associated with improved Hct control <45% vs placebo irrespective of risk category (**Figure 4A**; nominal p<0.0001) and CRT status (**Figure 4B**)
  - Among high-risk patients receiving concurrent CRT, 30/50 (60.0%) rusfertide-treated patients had Hct <45% vs 8/52 (15.4%) placebo-treated patients (nominal p<0.0001), with similar proportions seen in low-risk patients receiving concurrent CRT (rusfertide, 19/32 [59.4%] vs placebo, 3/28 [10.7%], nominal p=0.0002)

Figure 2. Patients in the Rusfertide Arm Had Improvements in Clinical Response Between Weeks 20-32 vs Placebo by (A) Risk Category and (B) CRT Status



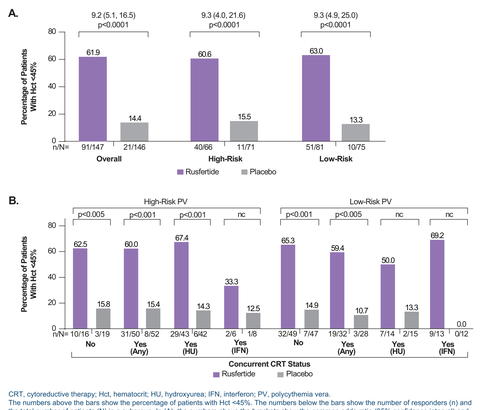
CRT, cytoreductive therapy; Hct, hematocrit; HU, hydroxyurea; IFN, interferon; PV, polycythemia vera. Numbers above the bars show the percentage of patients with a clinical response. In (A), numbers above the brackets show the nominal p-value obtained from the Cochran-Mantel-Haenszel test stratified by ongoing PV therapy. Numbers at the bottom of the bars show the number of responders (n). In (B), numbers above the brackets show the common odds ratio (95% confidence interval) and nominal p-value obtained from the Cochran-Mantel-Haenszel test stratified by ongoing PV therapy. The numbers below the bars show the number of responders (n) and the total number of patients (N) in a subgroup. Interferon (IFN) includes interferon, peginterferon alpha-2a, and ropeginterferon alfa-2b.

Figure 3. Rusfertide Reduced the Mean Number of Phlebotomies From Baseline Through Week 32 vs Placebo Irrespective of (A) Risk Category and (B) Concurrent CRT Status



ANCOVA, analysis of covariance; CRT, cytoreductive therapy; HU, hydroxyurea; IFN, interferon; LSM, least-squares means; PV, polycythemia vera; SD, standard deviation; SEM, standard error of the mean.
The numbers below the bars show the number of patients (n) in a subgroup. In (A), numbers above the brackets show the LSM difference (SEM) and p-values obtained from an ANCOVA model adjusted for pre-treatment number of phlebotomies, treatment, and stratification variable. Numbers inside the bars show the LSM (SEM) number of phlebotomies. In (B), numbers inside the bars show the mean (SD) number of phlebotomies. Interferon (IFN) includes interferon, peginterferon alpha-2a, and ropeginterferon alfa-2b.

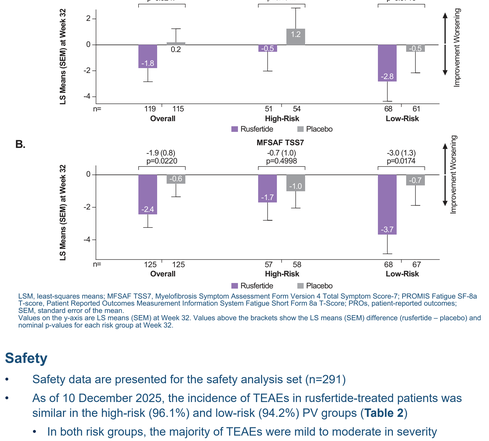
Figure 4. Rusfertide Improved Hct Control <45% From Baseline Through Week 32 vs Placebo Irrespective of (A) Risk Category and (B) Concurrent CRT Status



CRT, cytoreductive therapy; Hct, hematocrit; HU, hydroxyurea; IFN, interferon; PV, polycythemia vera.
The numbers above the bars show the percentage of patients with Hct <45%. The numbers below the bars show the number of responders (n) and the total number of patients (N) in a subgroup. In (A), the numbers above the brackets show the common odds ratio (95% confidence interval) and p-value obtained from the Cochran-Mantel-Haenszel test stratified by ongoing PV therapy. In (B), the numbers above the brackets show the nominal p-values obtained from the Cochran-Mantel-Haenszel test stratified by ongoing PV therapy. nc, not calculated (Mantel-Fleiss criterion <5).

- There were numeric improvements in the PROMIS Fatigue SF-8a T-Score and MFSAF TSS7 at Week 32 in both risk groups with rusfertide vs placebo (**Figure 5**)

Figure 5. (A) PROMIS Fatigue SF-8a T-Score and (B) MFSAF TSS7 Score at Week 32 for Rusfertide vs Placebo in Both Risk Groups



LSM, least-squares means; MFSAF TSS7, Myelofibrosis Symptom Assessment Form Version 4 Total Symptom Score-7; PROMIS Fatigue SF-8a T-score, Patient Reported Outcomes Measurement Information System Fatigue Short Form 8a T-Score; PROs, patient-reported outcomes; SEM, standard error of the mean.
Values on the y-axis are LS means (SEM) at Week 32. Values above the brackets show the LS means (SEM) difference (rusfertide – placebo) and nominal p-values for each risk group at Week 32.

Safety

- Safety data are presented for the safety analysis set (n=291)
- As of 10 December 2025, the incidence of TEAEs in rusfertide-treated patients was similar in the high-risk (96.1%) and low-risk (94.2%) PV groups (**Table 2**)
  - In both risk groups, the majority of TEAEs were mild to moderate in severity
- Serious AEs were reported in 14.7% of patients with high-risk PV vs 6.4% of patients with low-risk PV (**Table 2**)
- There were no deaths on study in either risk group
- TEAEs led to rusfertide discontinuation in 10 (7.8%) high-risk and 10 (6.4%) low-risk patients

Table 2. TEAEs in Patients Treated with Rusfertide by Risk Group

Patients with TEAEs, n (%)	High-Risk Group (n=129)	Low-Risk Group (n=156)
Any TEAE	124 (96.1)	147 (94.2)
Grade 1 TEAEs	121 (93.8)	140 (89.7)
Grade 2 TEAEs	104 (80.6)	113 (72.4)
Grade 3 or 4 TEAEs	35 (27.1)	27 (17.3)
Grade 5 TEAEs	0	0
Any SAE	19 (14.7)	10 (6.4)
TEAEs leading to discontinuation of rusfertide	10 (7.8)	10 (6.4)

SAE; serious adverse event; TEAE, treatment-emergent adverse event.

- In the high-risk group, 41 patients (31.8%) had a history of TE(s) prior to study entry; 19 patients (14.7%) were <60 years old
- In Part 1a (baseline to Week 32), the frequency of TEs was similar in the rusfertide and placebo arms irrespective of risk group (**Table 3**)
  - One TE (rusfertide arm) occurred in a patient with low-risk PV
  - There were no TEs in patients with high-risk PV in either arm
- In patients treated with rusfertide during Parts 1b and 2 (ie, open-label periods), TEs were reported in 3 patients with low-risk PV and 3 patients with high-risk PV
  - Of these 6 patients, 5 (83.3%) remained on study at the cutoff date (1 patient discontinued due to disease progression [transformation to myelofibrosis])
- Five of the 7 patients with on-study TEs had other risk factors that may have contributed to TE onset, including high-risk PV (n=3), history of hypertension (n=2), superficial vein thrombosis (n=1), and coronary heart disease (n=1)
- All TEs were deemed to be not related or unlikely to be related to rusfertide by the investigator

Table 3. Thromboembolic Events By Risk Group

Patients with Events, n (%)	Part 1a		Part 1b	Part 2	Part 3	Any Part
High-risk group	**Rusfertide (n=64)**	**Placebo (n=71)**	**Rusfertide (n=123)**	**Rusfertide (n=120)**	**Rusfertide (n=1)**	**All Rusfertide (n=129)**
Patients with TEs prior to study entry[a]	17 (25.8)	28 (39.4)	41 (33.3)	40 (33.3)	1 (100)	41 (31.8)
Patients with TE(s) on study	0	0	0	3 (2.5)	0	3 (2.3)
Acute myocardial infarction	0	0	0	1 (0.8)	0	1 (0.8)
Ischemic stroke	0	0	0	1 (0.8)	0	1 (0.8)
Splenic infarction	0	0	0	1 (0.8)	0	1 (0.8)
Low-risk group	**Rusfertide (n=81)**	**Placebo (n=75)**	**Rusfertide (n=151)**	**Rusfertide (n=146)**	**Rusfertide (n=6)**	**All Rusfertide (n=156)**
Patients with TE(s) on study	1 (1.2)	0	1 (0.7)	2 (1.4)	0	4 (2.6)
Acute myocardial infarction	1 (1.2)	0	0	1 (0.7)	0	2 (1.3)
Deep vein thrombosis	0	0	1 (0.7)	1 (0.7)	0	2 (1.3)

TE, thromboembolic event. TEAEs identified as PV complications include thromboembolic events identified using the FMQ-narrow term for Thrombosis. Data are shown for the safety analysis set (n=291) except as noted. [a]Intention-to-treat population (N=293).

Conclusions

- Results from this post hoc analysis of the phase 3 VERIFY study in PV demonstrate that the benefit of rusfertide was maintained for the primary endpoint (clinical response) and all key secondary endpoints of reduction in phlebotomies and Hct control vs placebo irrespective of whether patients had low-risk or high-risk PV at baseline
  - For these endpoints, the benefit of rusfertide was maintained in both risk groups regardless of whether patients were also receiving concurrent CRT at baseline
  - Improvements in the PROMIS Fatigue SF-8a T-score and MFSAF TSS7 PROs at Week 32 were also observed for both risk groups with rusfertide vs placebo
- To date, the incidence of TEAEs in rusfertide-treated patients has been similar in the high-risk and low-risk PV groups
  - The ongoing, open-label portions of the phase 3 VERIFY trial will provide additional information on the long-term safety and tolerability of rusfertide in patients with PV

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PREVIOUS PRESENTATION AND PUBLICATION INFORMATION

García-Gutiérrez V, et al. Benefit of rusfertide maintained in patients (pts) with low-risk or high-risk polycythemia vera (PV): efficacy and safety subgroup analysis from the randomized controlled phase 3 VERIFY study. *HemaSphere*. 2026; Abstract PF892.