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Impact of Rusfertide on Polycythemia Vera (PV)-Related Symptoms and Patient-Reported Outcome-Related Items in the Randomized, Double-Blind Phase 3 VERIFY Study

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INTRODUCTION

- Polycythemia vera (PV) is a myeloproliferative neoplasm characterized by erythrocytosis, increased thrombotic risk, and substantial symptom burden, including fatigue, pruritus, and cognitive difficulties[1-4]
- Rusfertide is a first-in-class, subcutaneous hepcidin mimetic peptide that controls erythrocytosis by restricting iron availability in the bone marrow for erythropoiesis[5-7]
- In the phase 3 VERIFY study (NCT05210790) that enrolled patients with PV who had poorly controlled hematocrit (Hct), rusfertide added to current standard-of-care (CSC) met the prespecified primary endpoint and all four prespecified key secondary endpoints vs placebo with CSC, including patient-reported outcomes (PROs) that were assessed by the Patient-Reported Outcome Measurement Information System (PROMIS) Fatigue Short Form (SF)-8a and the Myeloproliferative Neoplasm Symptom Assessment Form (MFSAF) v4.0

OBJECTIVE

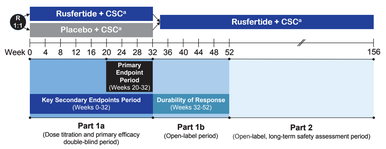
- To further characterize change from baseline at Week 32 in individual items and scores from the PROMIS Fatigue SF-8a and MFSAF v4.0 questionnaires used in the phase 3 VERIFY study

METHODS

Study design and patients

- In VERIFY, patients requiring frequent phlebotomy with or without cytoreductive therapy (CRT) to achieve and maintain Hct <45% were randomized to once-weekly rusfertide or placebo added to CSC (**Figure 1**)

Figure 1. VERIFY Study Design



CSC, current standard-of-care; R, randomization.
[a]Current standard-of-care therapy (phlebotomy with or without cytoreductive therapy).

Patient-reported outcomes (PROs)

- PROs were collected via an electronic diary (eDiary) prior to dosing at baseline and at scheduled time points

PROMIS Fatigue SF-8a

- The PROMIS SF-8a is an 8-item fatigue measure developed by the National Institutes of Health that assesses patients' experiences of fatigue over the past 7 days[8]
- Patients completed the PROMIS Fatigue SF 8a at home or at scheduled visits[8]
  - For each of the eight items, patients responded to each item using a five-point response option ("1, Not at All" to "5, Very Much"), with responses to each item summed to create a raw score that was then converted to a T-score (mean 50, standard deviation [SD] 10)
    - Lower T scores indicate less fatigue; higher T-scores indicate more fatigue
- Mean change from baseline in T-score was analyzed using a mixed model for repeated measures (MMRM) and included treatment, timepoint, and stratification as fixed factors; treatment-by-timepoint and baseline-by-timepoint interactions; and baseline scores as a covariate
  - A lower T-score at Week 32 vs baseline indicates improvement; a higher T-score at Week 32 from baseline indicates worsening

MFSAF v4.0

- The MFSAF v4.0 questionnaire, developed by the Patient-Reported Outcome Consortium's Myelofibrosis Working Group, focuses on seven core symptoms of myelofibrosis, including fatigue, night sweats, pruritus (itching), abdominal discomfort, pain under the ribs on the left side, early satiety (feeling of fullness), and bone pain[9]
  - These seven items were completed by patients daily to evaluate their symptoms over the past 24 hours on a scale from 0 ("absent") to 10 ("worst imaginable")
  - Baseline scores were the average score of the 7-day interval immediately on or prior to first dose date, with mean (SD) scores for the MFSAF Total Symptom Score-7 (TSS7) calculated at baseline in both arms
  - The weekly TSS7 was calculated at each scheduled visit (eg, Week 32) by averaging daily total symptom scores over a 7-day interval leading to the scheduled visit
  - Mean change from baseline in the TSS7 was analyzed using an MMRM that included treatment, timepoint, and stratification as fixed factors; treatment-by-timepoint and baseline-by-timepoint interactions; and baseline scores as a covariate
    - Lower scores vs baseline indicate improvement; higher scores from baseline indicate worsening
  - Mean (SEM) change from baseline in score at Week 32 was also calculated for each individual item

PROMIS Fatigue SF-8a and MFSAF v4.0: Defining severity cutoffs at baseline

- The validated single-item Patient Global Impression of Severity (PGI-S) anchor was used to measure a patient's perception of the severity of their PV
  - Patients assessed their illness using responses that followed a Likert scale (ie, "None," "Mild," "Moderate," or "Severe")
- PGI-S was used to calculate severity cutoff values for both the PROMIS Fatigue SF-8a and MFSAF v4.0
  - In brief, severity cutoff values were produced by calculating half the difference between the first and third quartile of the relevant PRO score per the adjacent PGI-S groups (ie, "None," "Mild," "Moderate," and "Severe") and adding it to the less severe PGI-S group to create an upper bound for each value
  - "Moderate" and "Severe" were combined to account for small sample sizes in the "Severe" group

Meaningful change analyses

- Meaningful change thresholds of improvement in the PROMIS Fatigue SF-8a T-score and MFSAF TSS7 were estimated using anchor-based approaches supplemented with empirical cumulative distribution function (eCDF) and probability density function (PDF) curves
- In addition, distribution-based estimates were used to contextualize, rather than define, the anchor-based thresholds
- Analyses were performed on the intention-to-treat population according to the treatment assigned at randomization and on patients with moderate or severe symptoms at baseline (assessed using the single-item PGI-S anchor)

RESULTS

- At randomization, 293 patients (median age, 57 years; 46.8% with high-risk PV) were enrolled in the rusfertide (n=147) or placebo (n=146) arms (**Table 1**)
- A total of 275 patients (134 [91.2%] and 141 [96.6%] in each respective arm) completed 32 weeks of treatment (data cutoff date: 27 May 2025)
- Between 25-34% of patients in each arm had moderate or severe symptoms at baseline (assessed using the PGI-S, PROMIS Fatigue SF-8a, and MFSAF; **Table 1**)
  - For the PROMIS Fatigue SF-8a, patients with a T-score ≥58.8 based on the severity cutoff were classified as having moderate or severe symptoms at baseline
  - For the MFSAF TSS7, patients with a TSS7 ≥12 based on the severity cutoff were classified as having moderate or severe symptoms at baseline

Table 1. Patient Demographics and Disease Characteristics at Baseline

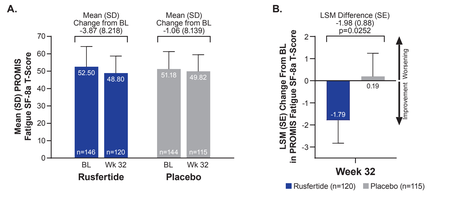
	Rusfertide + CSC (n=147)	Placebo + CSC (n=146)	Total (N=293)
Age, years, median (range)	58.0 (28-86)	57.0 (27-82)	57.0 (27-86)
Sex, n (%)			
Male	106 (72.1)	108 (74.0)	214 (73.0)
Female	41 (27.9)	38 (26.0)	79 (27.0)
Race, n (%)			
White	129 (87.8)	133 (91.1)	262 (89.4)
Other[a]	18 (12.2)	13 (8.9)	31 (10.6)
Ethnicity, n (%)			
Hispanic/Latino	8 (5.4)	6 (4.1)	14 (4.8)
Not Hispanic Latino	134 (91.2)	132 (90.4)	266 (90.8)
Unknown/Not reported	5 (3.4)	8 (5.5)	13 (4.4)
PV duration, years, median (range)	2.8 (0.2-26.4)	3 (0.2-29.2)	2.9 (0.2-29.2)
Disease risk			
High-risk, n (%)[b]	66 (44.9)	71 (48.6)	137 (46.8)
Low-risk, n (%)	81 (55.1)	75 (51.4)	156 (53.2)
Cytoreductive therapy at baseline, n (%)			
Concurrent CRT	82 (55.8)	80 (54.8)	162 (55.3)
No concurrent CRT	65 (44.2)	66 (45.2)	131 (44.7)
PROMIS Fatigue SF-8a			
T-score, mean (SD)	52.5 (11.7)	51.2 (10.1)	51.8 (10.9)
Frequency distribution, n (%)[c]			
<48.5 (No symptoms)	52 (35.4)	53 (36.3)	105 (35.8)
≥48.5 to <58.8 (Mild symptoms)	44 (29.9)	54 (37.0)	98 (33.4)
≥58.8 (Moderate or severe symptoms)	50 (34.0)	37 (25.3)	87 (29.7)
Missing data	1 (0.7)	2 (1.4)	3 (1.0)
MFSAF v4.0			
TSS7, mean (SD)	10.7 (11.4)	9.5 (10.2)	10.1 (10.8)
Frequency distribution, n (%)[c]			
<4 (No symptoms)	47 (32.0)	55 (37.7)	102 (34.8)
4 to <12 (Mild symptoms)	52 (35.4)	50 (34.2)	102 (34.8)
≥12 (Moderate or severe symptoms)	47 (32.0)	40 (27.4)	87 (29.7)
Missing data	1 (0.7)	1 (0.7)	2 (0.7)

CRT, cytoreductive therapy; CSC, current standard-of-care; MFSAF, Myelofibrosis Symptom Assessment Form; PROMIS Fatigue SF-8a, Patient-Reported Outcomes Measurement Information System Fatigue Short Form 8a; PV, polycythemia vera; TE, thromboembolic event; TSS-7, Total Symptom Score-7.
[a]Includes other, multiple, not reported, and unknown categories.
[b]High risk is defined as age ≥60 years and/or occurrence of a TE prior to study entry.
[c]The single-item PGI-S anchor evaluated the severity of PV symptoms during the 24-hour period prior to dosing on a 0 ("None") to 3 ("Severe") scale and was used to establish severity categories of "None," "Mild," "Moderate," and "Severe" for the PROMIS Fatigue SF-8a and MFSAF.

PROMIS Fatigue SF-8a

- **Mean (SD) change from baseline at Week 32 in the PROMIS Fatigue SF-8a T-score was significantly greater in the rusfertide arm (-3.87 ± 8.218) vs placebo arm (-1.06 ± 8.139) (least-squares [LS] means difference [rusfertide – placebo] ± SE: -1.98 ± 0.88; p=0.0252) (Figure 2)**

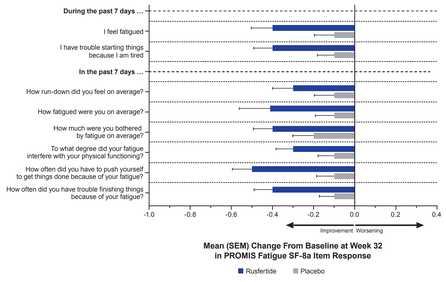
Figure 2. PROMIS Fatigue SF-8a T-Scores: (A) Mean Scores at Baseline and Week 32 and (B) LSM Change From Baseline at Week 32



BL, baseline; LSM, least-squares means; PROMIS Fatigue SF-8a, Patient-Reported Outcomes Measurement Information System Fatigue Short Form 8a.

- **Although mean change from baseline at Week 32 improved in both arms for each of the eight fatigue-related items in the PROMIS Fatigue SF-8a, numeric improvements were greater in the rusfertide arm for each item (Figure 3)**

Figure 3. PROMIS Fatigue SF-8a: Change from Baseline at Week 32



PROMIS Fatigue SF-8a, Patient-Reported Outcomes Measurement Information System Fatigue Short Form 8a; SEM, standard error of the mean.

- **Among patients who had moderate or severe symptoms at baseline, fewer patients randomized to the rusfertide arm (36.6%) had PROMIS Fatigue SF-8a T-scores of moderate or severe at Week 32 vs 48.3% in the placebo arm (Table 2)**
  - Mean (SD) change from baseline to Week 32 in PROMIS Fatigue SF-8a T-score in patients with moderate or severe symptoms at baseline was -9.8 (8.8) in the rusfertide arm vs -5.2 (8.3) in the placebo arm

Table 2. Mean Change From Baseline at Week 32 in the PROMIS Fatigue SF-8a T-Score Among Patients Who Had Moderate or Severe Symptoms at Baseline

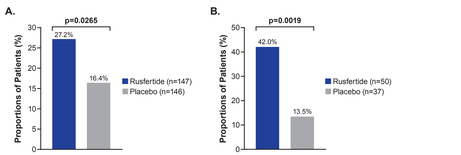
	Rusfertide		Placebo	
	Baseline (n=50)	Week 32 (n=41)	Baseline (n=37)	Week 32 (n=29)
PROMIS Fatigue SF-8a				
Frequency distribution, n (%)				
<48.5 (No symptoms)		11 (26.8)		3 (10.3)
≥48.5 to <58.8 (Mild symptoms)		15 (36.6)		12 (41.4)
≥58.8 (Moderate or severe symptoms)	50 (100)	15 (36.6)	37 (100)	14 (48.3)
Mean (SD) T-score	65.1 (4.9)	55.1 (9.4)	63.4 (3.8)	58.4 (7.4)
Mean (SD) T-score change from baseline at Week 32		-9.8 (8.8)		-5.2 (8.3)
LS means (SEM)		-7.6 (1.8)		-3.8 (2.1)
LS means (SEM) difference (Rusfertide – Placebo)		-3.8 (1.9)		
p-value		0.0496		

LS, least-squares; PROMIS Fatigue-SF-8a, Patient-Reported Outcomes Measurement Information System Fatigue Short Form 8a; SEM, standard error of the mean

Meaningful within-person change in PROMIS Fatigue SF-8a

- A significantly greater proportion of patients in the rusfertide arm had a clinically meaningful within-person change (improvement of at least 6.60 points) in their PROMIS Fatigue SF-8a T-score at Week 32 vs patients in the placebo arm (**Figure 4A**)
- Similarly, a greater proportion of patients in the rusfertide arm who had moderate or severe symptoms at baseline had a clinically meaningful within-person change (improvement of 9.30 or more) in their PROMIS Fatigue SF-8a T-score at Week 32 vs placebo (**Figure 4B**)

Figure 4. Proportion of Patients With Clinically Meaningful Within-Person Change in the PROMIS Fatigue SF-8a T-Score at Week 32 in (A) the Intention-to-Treat Population and (B) Patients with Moderate or Severe Symptoms at Baseline

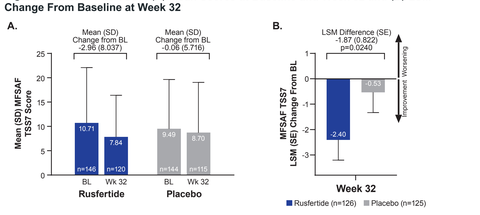


PROMIS Fatigue SF-8a, Patient-Reported Outcomes Measurement Information System Fatigue Short Form 8a.

MFSAF v4.0

- **Mean (SD) change from baseline at Week 32 in the MFSAF TSS7 was significantly greater in the rusfertide arm (-2.96 ± 8.037) vs placebo arm (-0.06 ± 5.716) (LS means difference [rusfertide – placebo] ± SEM: -1.87 ± 0.822; p=0.0240) (Figure 5)**

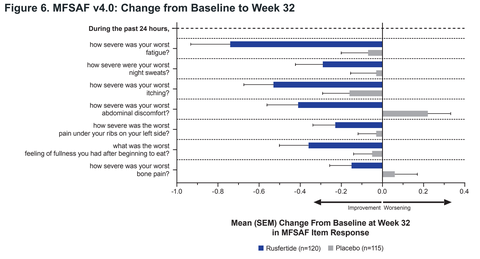
Figure 5. MFSAF v4.0 TSS7: (A) Mean Scores at Baseline and Week 32 and (B) LSM Change From Baseline at Week 32



BL, baseline; LSM, least-squares means; MFSAF v4.0 TSS7, Myelofibrosis Symptom Assessment Form Version 4 Total Symptom Score-7 items.

- Mean change from baseline at Week 32 improved in the rusfertide arm for all seven individual items in the MFSAF (**Figure 6**)
  - In contrast, two items (abdominal discomfort and worst bone pain) worsened in the placebo arm
- Numerically, improvements in all items were more favorable in the rusfertide arm than in the placebo arm, including those items where improvements were also recorded in the placebo arm

Figure 6. MFSAF v4.0: Change from Baseline to Week 32



MFSAF, Myelofibrosis Symptom Assessment Form; SEM, standard error of the mean.

- Among patients who had moderate or severe symptoms at baseline, a greater percentage of patients randomized to the rusfertide arm (48.8%) had MFSAF TSS7 scores of none or mild at Week 32 vs 20.7% in the placebo arm (**Table 3**)
  - Mean (SD) change from baseline at Week 32 in MFSAF TSS7 score in patients with moderate or severe symptoms at baseline was -9.54 (9.54) in the rusfertide arm vs -2.13 (8.83) in the placebo arm, indicating a greater improvement in the rusfertide arm

Table 3. Mean Change From Baseline at Week 32 in the MFSAF TSS7 Among Patients Who Had Moderate or Severe Symptoms at Baseline

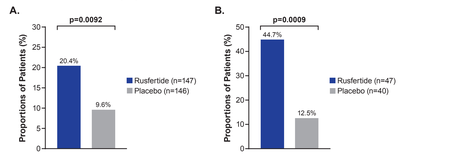
	Rusfertide		Placebo	
	Baseline (n=47)	Week 32 (n=41)	Baseline (n=40)	Week 32 (n=29)
MFSAF TSS7				
Frequency distribution, n (%)				
<4 (No symptoms)		4 (9.8)		1 (3.4)
4 to <12 (Mild symptoms)		16 (39.0)		5 (17.2)
≥12 (Moderate or severe symptoms)	47 (100)	21 (51.2)	40 (100)	23 (79.3)
Mean (SD) TSS7	23.5 (11.4)	13.8 (10.4)	22.9 (9.4)	21.2 (12.6)
Mean (SD) TSS7 change from baseline to Week 32		-9.5 (9.5)		-2.1 (8.8)
LS means (SEM)		-11.2 (2.0)		-5.2 (2.2)
LS means (SEM) difference (Rusfertide – Placebo)		-5.9 (2.2)		
p-value		0.0098		

LS, least-squares; MFSAF TSS7, Myelofibrosis Symptom Assessment Form Total Symptom Score 7 items; SEM, standard error of the mean.

Meaningful within-person change in MFSAF TSS7

- In the rusfertide arm, a significantly greater proportion of patients had a clinically meaningful within-person change (improvement of at least 6.73 points) in the MFSAF TSS7 at Week 32 vs those randomized to the placebo arm (**Figure 7A**)
- A greater proportion of patients in the rusfertide arm with moderate or severe symptoms at baseline had a clinically meaningful within-person change (improvement of 8.55 or more) in their MFSAF TSS7 at Week 32 vs placebo (**Figure 7B**)

Figure 7. Proportion of Patients With Clinically Meaningful Within-Person Change in MFSAF TSS7 at Week 32 in the (A) Intention-to-Treat Population and (B) Patients with Moderate or Severe Symptoms at Baseline



MFSAF TSS7, Myelofibrosis Symptom Assessment Form Total Symptom Score 7 items.

CONCLUSIONS

- In the phase 3 VERIFY study, mean change from baseline at Week 32 in the PROMIS Fatigue SF-8a T-score and MFSAF TSS7 improved by a statistically significant margin in the rustertide vs placebo arm (ITT population)
- In the rusfertide arm, a significantly greater proportion of patients had a clinically meaningful within-person change in the PROMIS Fatigue SF-8a and MFSAF TSS7 at Week 32 vs placebo
  - These findings were more pronounced in both PRO instruments for patients with moderate to severe symptoms at baseline
- The positive benefit seen in rusfertide-treated patients exceeded the observed placebo effect and was consistent across all questionnaire items
- These findings further support the clinical superiority of rusfertide vs placebo in patients with PV

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MLF: Research support paid to institution from Protagonist; advisory role with GSK, Keros/Takeda, Novartis.
AMV: Honoraria from AbbVie, AOP, Blueprint, Incyte, Italfarmaco, GSK, Menarini Stemline, Novartis.
SKo: Research funding: Geron, Janssen, AOP Pharma, Novartis; consulting fees: Pfizer, Incyte, Ariad, Novartis, AOP Pharma, Bristol Myers Squibb, Celgene, Geron, Janssen, CTI BioPharma, Roche, Bayer, GSK, Sierra Oncology, PharmaEssentia, Protagonist, Takeda; payment or honoraria: Novartis, BMS/Celgene, Pfizer, AstraZeneca, iOMEDICO, Takeda; travel/accommodation support: Alexion, Novartis, Bristol Myers Squibb, Incyte, AOP Pharma, CTI BioPharma, Pfizer, Celgene, Janssen, Geron, Roche, AbbVie, GSK, Sierra Oncology, Kartos, AstraZeneca, Protagonist, iOMEDICO; patent issued for a BET inhibitor at RWTH Aachen University; participated on advisory boards for Pfizer, Incyte, Ariad, Novartis, AOP Pharma, BMS, Celgene, Geron, Janssen, CTI BioPharma, Roche, Bayer, GSK, Sierra Oncology, PharmaEssentia, Protagonist, Takeda.
DC: Research support to institution from Pfizer, Merck/EMD Serono, Novartis, Boehringer-Ingelheim. Consultancy/advisory role with Pfizer, Novartis, Takeda, Disc, Protagonist, AbbVie, Telix, Celcuity, Exact Sciences, Epirium, BMS.
PD, JX, APM, VV, SK, AM: Employment with Protagonist Therapeutics and may have an equity interest in the company.
ATK: Research support: Protagonist Therapeutics, Novartis, Janssen, Geron, GlaxoSmithKline, BMS, Kartos, Blueprint; Honoraria/consulting: Agios, Incyte, Protagonist, PharmaEssentia, Deciphera/Ono, Karyopharm, BMS, AbbVie, GSK, Silence.

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