METHODS

INTRODUCTION

A secondary goal of the IMerge Phase 3 trial was to leverage anemia management with fewer transfusions (thereby improving patient’s fatigue and reducing the associated risks) to improve the quality of life of patients, most of whom are elderly and frail.

A recent report showed that the IMerge Hb was clinically meaningful to patients earlier than the general population and fatigue worsened with increasing IPS if RBC transfusion was not frequent.

Figure 1. IMerge Phase 3 Trial Design (MDS3001; NCT02598661)

Table 1. PRO Items for FACIT-Fatigue

RESULTS

Demographics and Disease Characteristics

The PRO population, which included all patients in the ITT analysis, included 228 patients at baseline. Compared with 130 patients in the investigator arm and 93 patients in the placebo arm, for a total of 228 patients (Table 2).

Table 2. PRO Population Demographics

No prior treatment with lenalidomide or HMAs (ESA ineligible)

Patients treated with imetelstat reported a lower rate than placebo of sustained meaningful deterioration in fatigue at 8-24 weeks (26.3% vs 45.6%) and of 43.2% vs 45.6% (ITT analysis), indicating that imetelstat resulted in greater clinical benefit than placebo.

Figure 3. Mean change in FACIT Fatigue Score over time

Figure 4. Model-Based Mean Change From Baseline in FACIT-Fatigue Scores by RMMM

Figure 5. Model-Based Mean Change From Baseline in FACIT-Fatigue Scores by RMMM

REFERENCES


CONCLUSIONS

The IMerge Phase 3 is the first randomized, global trial of patients with IA-MDS who had a transfusion burden of ≥5 weeks. It showed sustained meaningful improvement in fatigue at 24 weeks.

The PRO endpoints reported in this study are consistent with the primary endpoint of time to first sustained meaningful improvement in fatigue (Fig. 5).

Figure 6. End Point: PRO Fatigue

Figure 7. End Point: PRO Fatigue

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All authors contributed to and approved the presentation.

A key point of MDS treatment is to manage anemia with fewer transfusions (thereby improving patient’s fatigue and reducing patient’s associated risks). In a recent report published by the genealogical-affecting stem cell therapy in Hb, hemoglobin-H (H), hematopoietic stem cell transplantation (HSCT), HSCT, HSCT, HSCT, HSCT.

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Table 1. PRO Items for FACIT-Fatigue

The IMerge study population consisted of patients with baseline transfusion-dependent low risk myelodysplastic syndromes (LR-MDS), including higher rates of patients with prior RBC transfusion burden (≥4 to ≤6 vs >6 RBC units/8 weeks).

No prior treatment with lenalidomide or HMAs (ESA ineligible).

CONCLUSIONS

The PRO endpoints collected in IMerge were scrutinized to identify any association with alternate definitions of meaningful deterioration and to specify exploratory PRO endpoints in the study.

Table 1. PRO Items for FACIT-Fatigue

RESULTS (CONT.)

Sustained Meaningful Deterioration for ≥2 Cycles

In the IMerge investigator arm, a higher proportion of patients with ≥2 cycles (50.0% vs 41.2%) of ≥2 cycles (50.0% vs 41.2%) reported a lower rate than placebo of sustained meaningful deterioration in fatigue at 8-24 weeks (26.3% vs 45.6%)

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