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Poster Session

DISORDERS OF PLATELET NUMBER OR FUNCTION POSTER III

Home Administration of Romiplostim by Patients with Chronic Immune Thrombocytopenia (ITP).

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Introduction: Romiplostim is a peptibody protein designed to increase platelet production by binding to and activating the thrombopoietin receptor; it is approved for the treatment of thrombocytopenia in patients with chronic ITP. Home administration of romiplostim may offer a desirable treatment option for some patients. We evaluated the safety and efficacy of romiplostim home administration during a 52-week study in adult ITP patients.

Patients and Methods: This was a phase 3b, multi-center, randomized, standard of care (SOC) controlled, open-label study comparing the incidence of splenectomy and treatment failure in ITP patients receiving either romiplostim or medical SOC for ITP. Eligible patients were nonsplenectomized adult ITP patients who had received at least 1 prior therapy for ITP, with a baseline platelet count < 50 x 10^9/L. Romiplostim was administered by weekly subcutaneous injections with dose adjustments to target a platelet count of 50 to 200 x 10^9/L. After study week 8, patients who achieved platelet counts within the target range and a stable dose of romiplostim for at least 3 consecutive weeks were offered the opportunity to receive romiplostim outside the physician's office. Eligible patients were trained to self-inject and were required to return to the study center for platelet count evaluation and to obtain romiplostim for subsequent treatment every 4 weeks. We report data from romiplostim-treated patients, comparing the time 3 weeks before initiating home administration to the time after initiating home administration (either until the end of the treatment or until a 6-week interruption of home administration). Since the observation periods before and after initiation of home administration were not equal, exposure-adjusted data were calculated.

Results: The 157 patients who were randomized to romiplostim had a median age of 58 (range 18 to 90) years and 85 (54%) were female. Home administration was initiated by 69% (109/157) of the patients who received romiplostim, and home administration was continued for a median of 36 weeks (Interquartile range, 14). Home administration was interrupted for 6 consecutive weeks or more in 24/109 (22%) patients. Of the109 patients who started home administration, 93 (85%) continued to home administer until the end of the study. For each patient, their most frequently used dose of romiplostim was determined. The median of patients' most frequently used dose remained stable after home administration was initiated (Table). There was no difference in the percentage of weeks with a platelet response (defined as a platelet count > 50 x 10^9/L, excluding those within 8 weeks of rescue medication use) during the time before (83%) and the time after (88%) the start of home administration (p=0.147). The rate of adverse events appeared lower after

patients began home administration, and did not appear to increase with longer duration of treatment (Table). No deaths occurred either before or after home administration.

Conclusions: The safety and efficacy profile of romiplostim was not impaired when patients changed from in-office administration to home administration. Home administration of romiplostim appears to be a convenient treatment option for some ITP patients.

	Week of Home Administration[a]				
	Week -3 to -1 (N = 109) (Pt-wk = 327)	Week 1 to 12 (N = 109) (Pt-wk = 1281)	Week 13 to 24 (N = 105) (Pt-wk = 1226)	Week 25 to 36 (N = 99) (Pt-wk = 1120)	≥ Week 37 (N = 77) (Pt-wk = 529)
Most frequently used dose, µg/kg - median (Q1, Q3)	3 (3, 5)	3 (3, 5)	3 (3, 5)	4 (3, 5)	3 (3, 5)
Any Adverse Events, n (r)	86 (26.3)	231 (18.0)	182 (14.9)	147 (13.1)	91 (17.2)
Serious Adverse Events, n (r)	1 (0.3)	5 (0.4)	9 (0.7)	8 (0.7)	0
Treatment-Related Adverse Events, n (r)	25 (7.7)	29 (2.3)	21 (1.7)	11 (1.0)	2 (0.4)
Treatment-Related Serious Adverse Events, n (r)	0	1 (0.1)	1 (0.1)	1 (0.1)	0
Study Withdrawal Due to Adverse Events, n (r)	0	1 (0.1)	0	1 (0.1)	0

Pt-wk = Total patient weeks on study.

n = Number of adverse events.

r = Study duration adjusted event rate per 100 patient-weeks (number of events per patient-week on study, multiplied by 100).

[a] The first study week that patients started home administration is defined as Week 1. Any study weeks prior to Week 1 of home administration are defined as negative weeks starting from -1 in backwards.

Disclosures: Lyons: *Amgen Inc.:* Consultancy, Honoraria, Research Funding, Speakers Bureau; *Celgene:* Consultancy; *Johnson&Johnson:* Consultancy, Honoraria, Speakers Bureau; *GlaxoSmithKline:* Consultancy, Speakers Bureau. **Boccia:** *Amgen Inc.:* Consultancy, Honoraria, Research Funding, Speakers Bureau. **Macik:** *Amgen Inc.:* Research Funding; *Eisai Inc.:* Research Funding. **Mandanas:** *Genzyme:* Membership on an entity's Board of Directors or advisory committees; *Novartis:* Speakers Bureau; *Pfizer:* Speakers Bureau. **Wang:** *Amgen Inc.:* Employment, Equity Ownership. **Lizambri:** *Amgen Inc.:* Employment, Equity Ownership. **Berger:** *Amgen Inc.:* Employment, Equity Ownership.

Footnotes

[*] Asterisk with author names denotes non-ASH members.