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Blood (ASH Annual Meeting Abstracts) 120: 2185.

Abstract 1 of 1 **Poster Sessions**

311. Disorders of Platelet Number or Function: Poster II

Integrated Analysis of Long Term Safety in Patients (pts) with Chronic Immune Thrombocytopenia (ITP) Treated with Romiplostim.

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Abstract 2185

Introduction: ITP is characterized by low platelet counts due to increased platelet destruction and suboptimal platelet production. Romiplostim, which is approved for the treatment of chronic ITP in adults, is an Fc-peptide fusion protein (peptibody) that binds and activates the thrombopoietin receptor to stimulate platelet production. Results from a safety analysis of pooled data from ITP romiplostim clinical studies were previously reported (Rodeghiero et al, *Haematologica* 2010;95(s2) abstr 0184). Here we update the safety findings with the most inclusive clinical dataset of patients (pts) with ITP.

Methods: Data from 13 studies of ITP were analyzed. Pts received romiplostim, placebo or medical standard of care (SOC) treatment at some time from July 2002 to June 2011. Data from the placebo/SOC arms were pooled. Results were adjusted for study duration and reported as rates per 100 patient-years (pt-yr) to reflect the unequal study time between pts given romiplostim and pts given placebo/SOC. In cases where pts enrolled in ≥ 1 study, data from the first and extension studies were combined. Data for pts who started on placebo/SOC and then received romiplostim were recorded as follows: data before pts received the first dose of romiplostim were included in the placebo/SOC group; data on or after the first dose of romiplostim were included in the romiplostim group regardless of any subsequent change in treatment.

Results: Pts (N = 1,059) were mostly female (61%) and white (85%); 23 pediatric pts were included in the analysis. All pts had received prior ITP treatment per protocol entry criteria. Age, sex, race and prior ITP treatment were similar between groups. In studies where prior information on splenectomy was collected, 47% of pts had a splenectomy. Mean baseline platelet count: 21×10^9/L (standard deviation, 17×10^9/L). In total 921 pts received romiplostim, 65 received placebo/SOC, and 73 received placebo/SOC in the first study and romiplostim in subsequent studies. Mean weekly romiplostim dose: 4.2 µg/kg. Patient exposure to romiplostim: ≤ 1 yr, 47%; >1–2 yr, 26%; >2–3 yr, 15%; >3–4 yr, 6%; > 4 yr, 6%. Nineteen percent and 22% of pts who received romiplostim and placebo/SOC, respectively, did not complete participation in their first ITP study. Adverse events (AE) were reported in 94.2% and 93.5% of pts in the romiplostim and placebo/SOC groups, respectively. Most frequently reported AE (rates per 100 pt-yr) in the romiplostim vs

placebo/SOC groups: headache (61 vs 58), contusion (48 vs 50) and epistaxis (35 vs 53). AE with > 10% difference in the romiplostim vs placebo/SOC groups: headache (36% vs 24%), arthralgia (24% vs 12%), nausea (20% vs 9%). Three pts developed neutralizing antibodies to romiplostim but did not develop neutralizing antibodies to thrombopoietin and did not become refractory to romiplostim. The Table summarizes AE.

	Romiplostim N = 994 pt-yr = 1,520			Placebo/SOC N =138 pt-yr = 110		
	n	rate per 100 pt-yr	95% CI	n	rate per 100 pt-yr	95% CI
Summary of AE						
All AE	17,129	1,127	1,110-1,144	1,268	1,152	1,090-1,218
Serious AE	910	60	56-64	107	97	80-118
Fatal AE	40	3	2-4	8	7	3-14
Treatment-Related AE	1,739	114	109-120	168	153	131-178
Treatment-Related Serious AE	118	8	6-9	18	16	10-26
Treatment-Related Fatal AE	5	0.3	0.1-0.8	0	0	0-3
AE of Interest						
Hemorrhage Events						
Any grade	3,115	205	198-212	289	263	233-295
Grade ≥ 3	182	12	10-14	19	17	10-27
Thrombotic Events	83[a]	5	4-7	6[b]	5	2-12
Bone Marrow Reticulin Events[c]	15	1	1-2	0	0	0-3
Solid Tumor Events	34	2	2-3	4	4	1-9
Hematopoietic Malignancies/MDS Events	7[d]	0.5	0.2-1	3[e]	3	1-8

[a] Forty-four events occurred within the first 6 months of treatment, of which 9 were arterial events.

[b] One event occurred within the first 6 months of treatment, which was an arterial event.

[c] Bone marrow biopsies were performed per investigators' discretion. Analysis excludes study 20080009 because bone marrow evaluations were collected differently than in other studies. Romiplostim, N = 825, pt-yr = 1,388; placebo/SOC, N = 138.

[d] Includes 1 event each of lymphoma, B-cell lymphoma and non-Hodgkin lymphoma.

[e] Includes 1 event of lymphoma. CI, confidence interval; MDS, myelodysplastic syndrome; n, number of events; pt-yr, total patient yr on study.

Conclusions: This integrated analysis of all available clinical studies to date involving the use of romiplostim in ITP provides long term safety information with some pts receiving romiplostim for over five yr. The AE profile was consistent with previously reported studies.

Disclosures: Cines: *GlaxoSmithKline:* Consultancy; *Amgen Inc.:* Consultancy; *Eisai:* Consultancy. **Gernsheimer:** *Amgen Inc.:* Consultancy, Honoraria; *Symphogen:* Consultancy; *Laboratorios Raffo SA:* Honoraria; *Clinical Options:* Consultancy; *Hemedicus Corporation:* Honoraria; *Glaxo-Smith Kline:* Consultancy; *Shionogi:* Research Funding; *Cangene:* Consultancy. **Wasser:** *Amgen Inc.:* Membership on an entity's Board of Directors or advisory committees, Speakers Bureau. **Altomare:** *Amgen Inc.:* Membership on an entity's Board of Directors or advisory committees, Speakers Bureau. **Wang:** *Amgen Inc.:* Employment, Equity Ownership. **Woodard:** *Amgen Inc.:* Employment, Equity Ownership.

Footnotes

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

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