

**From:** [REDACTED] [mailto:[REDACTED]@gsk.com]

**Sent:** 11 January 2011 17:02

**To:** TA Comm B

**Cc:** [REDACTED]; Jeremy Powell

**Subject:** Thrombocytopenic purpura - romiplostim - Appraisal consultation document

Dear Jeremy

Thank you for the opportunity to comment on the Appraisal Consultation Document for romiplostim.

We would like to point out that there is an inconsistency in the numbers for the trial population presented in the extended dosing study on pages 5 and 6 of the ACD, which suggests that 83 and 42 patients were in the romiplostim and placebo arms respectively (consistent with Kuter et al, 2008). However, figure 1 of the Gernsheimer 2010 paper suggests that the corresponding numbers were 84 and 41 patients. This may require clarification, depending on which is correct.

Kuter DJ, Bussel JB, Lyons RM, Pullarkat V, et al. Efficacy of romiplostim in patients with chronic immune thrombocytopenic purpura: a double-blind randomized controlled trial. *Lancet* 2008; 371: 395–403

Gernsheimer TB, George JN, Aledort LM, Tarantino MD et al. Evaluation of bleeding and thrombotic events during long-term use of romiplostim in patients with chronic immune thrombocytopenia (ITP). *J Thromb Haemost* 2010; 8:1372–82

Otherwise we have no further comments.

Kind regards

[REDACTED]  
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[REDACTED]