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Romiplostim in adult patients with newly diagnosed or persistent immune thrombocytopenia (ITP) for up to 1 year and in those with chronic ITP for more than 1 year: a subgroup analysis of integrated data from completed romiplostim studies

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Abstract

The thrombopoietin receptor agonist romiplostim is approved for second-line use in chronic immune thrombocytopenia (ITP), but its effects in patients with ITP for ≤1 year are not well characterized. This analysis of pooled data from 9 studies included patients with ITP for ≤1 year (n = 311) or >1 year (n = 726) who failed first-line treatments and received romiplostim, placebo or standard of care. In subgroup analysis by ITP duration, patient incidences for platelet response at ≥75% of measurements were higher for romiplostim [ITP ≤1 year: 74% (204/277); ITP >1 year: 71% (450/634)] than for placebo/standard of care [ITP ≤1 year: 18% (6/34); ITP >1 year: 9% (8/92)]. Of patients with ≥9 months on study, 16% with ITP ≤1 year and 6% with ITP >1 year discontinued romiplostim and maintained platelet counts ≥50 × 10^9 /l for ≥6 months without ITP treatment (treatment-free remission). Independent of ITP duration, rates of serious adverse events and bleeding were lower with romiplostim than placebo/standard of care and thrombotic events occurred at similar rates. In this analysis, romiplostim and placebo/standard of care had similar safety profiles and romiplostim increased platelet counts in patients with either ITP ≤1 year or ITP >1 year, with more treatment-free remission in those with ITP ≤1 year.