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Self-Injection of Romiplostim by Patients with Chronic Immune Throbocytopenic Purpura (ITP)

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Abstract

Romiplostim is an investigational Fc-peptide fusion protein (peptibody) that has demonstrated the ability to increase platelet counts over prolonged periods in thrombocytopenic patients with chronic ITP. Self-injection of romiplostim offers a convenient treatment option for some patients. The safety and efficacy of romiplostim self-injections were explored in patients participating in a long-term open-label extension study. Patients with chronic ITP (diagnosis per ASH guidelines) were eligible for the openlabel extension study if they had completed a prior romiplostim study and had platelet counts $<50x10^9$/L. Romiplostim was injected subcutaneously once weekly, initially by healthcare providers at study centers, with a starting dose of 1 µg/kg and subsequent dose adjustments to maintain a platelet count between 50 and $250x10^9$/L. After achieving a platelet response, patients who received the same romiplostim dose for ≥3 weeks were permitted to self-inject weekly romiplostim or have the injection administered at home by a caregiver. Patients/caregivers were trained to self-inject and were required to return to the study center for platelet count evaluation and dose adjustment every 4 weeks, and to receive the next month's medication and supplies. Of 143 patients enrolled, 90 (63%) initiated self-injection. Their median

age was 53 years (range 21 to 80), and most (62%) were splenectomized. Self-injection was initiated after a median of 12 weeks (range 1 to 99) of romiplostim treatment; and patients continued to receive romiplostim for a median of 64 weeks (range 5 to 117), maintaining self-injection for a median of 74% of their subsequent time on treatment. To compare changes in efficacy and safety following the switch from office-based injection to self-injection, we analyzed data 8 weeks before and 8 weeks after initiation of self-injection. The median average weekly dose was comparable in the 8 weeks before (4 µg/kg, range 1 to 19 µg/kg) and after (5 µg/kg, range 1 to 16 µg/kg) the start of self-injection. The median maximum dose (5 µg/kg) did not change. Platelet counts increased as patients achieved a stable dose of romiplostim and then stabilized once self-injection was initiated: mean (±SD) platelet counts 8 weeks before, at initiation, and 4 and 8 weeks after initiation of self-injection were 85 (±91), 125 (±96), 123 (±121) and 121 (±96), respectively. A similar number of patients experienced adverse events in the 8 weeks before (54/90; 60%) and after (59/90; 66%) initiating self-injection. The most common adverse events before initiation of self-injection were headache (13%), and fatigue and upper respiratory tract infection (both 8%), and after were nasopharyngitis (9%), headache (8%), and diarrhea (6%). The patient incidence of treatment-related adverse events was 14 (16%) 8 weeks before and 9 (10%) 8 weeks after the start of self-injection. Serious adverse events occurred in 2 (2%) patients before and 5 (6%) patients after self-injecting. One treatment-related serious adverse event occurred: an event of thrombosis in a self-injecting patient. No deaths were reported either before or after self-injection. These results indicate that most patients were able to achieve and maintain self-injection of romiplostim with no apparent changes in either their platelet response or safety profiles. Self-injection of romiplostim represented a convenient, effective, and well-tolerated treatment option for ITP patients.

Footnotes

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