[0005] Data is emerging on the use of romiplostim in children with chronic immune thrombocytopenia. Treatment of children with chronic immune thrombocytopenia is often guided by data from adult studies, pilot studies in children, and expert opinion. There have been three large randomized controlled studies in children with ITP that have demonstrated that treatment with TPO receptor agonists was associated with greater efficacy compared to placebo with no surprising or unexpected adverse events. However, data on long-term effects of treatments in children with ITP are lacking.

[0006] Romiplostim can induce platelet responses in approximately 80–90% of patients with ITP (Bussel et al, 2009; Kuter et al, 2010), but long-term treatment may be required to maintain platelet responses. Long-term treatment, however, may be associated with compliance issues and substantial costs (Ghanima et al, 2012).

[0007] Emerging data suggest that certain patients, many of whom had relapsed or refractory disease, may achieve lasting remission after discontinuation of romiplostim (Vlachaki et al, 2011; Ghadaki et al, 2013; Thachil et al, 2013; Mahevas et al, 2014; Provan et al, 2014; Tarantino et al. 2016, Tarantino et al, ASH 2017, abstract 14 as at: https://ash.confex.com/ash/2017/webprogram/Paper100126.html). Newland et al., 2016, conducted a systematic prospective evaluation of remission with romiplostim but ultimately concluded that no statistically significant predictors of remission were found when examining other demographic or baseline characteristics; however, higher mean platelet count during the first two months of treatment was associated with remission. The field would benefit from discovery of predictors of remission and methods of treatment exploiting such predictors.

SUMMARY

[0007a] In one aspect, the present disclosure refers to a use of romiplostim in the manufacture of a medicament for treating idiopathic thrombocytopenia purpura (ITP) in a patient having ITP, wherein the use comprises that: (a) the medicament is to be administered weekly to the patient, wherein an initial dose is 1 μg /kg; (b) the weekly dose of the medicament is to be increased in increments of 1 μg/kg until a platelet count of at least 50 to 200 x 10^9/L is reached; (c) the weekly dose of the medicament is to be decreased in increments of 1 μg/kg if the platelet count remains $\geq$ 200 x 10^9/L for two consecutive weeks; (d) administration of the medicament is to be discontinued if (i) the platelet count has remained $\geq$ 200 x 10^9/L for two consecutive weeks when the weekly dose is 1 μg/kg or (ii) the platelet count is $\geq$ 400 x 10^9/L; and (e) if a platelet count $\geq$ 200 x 10^9/L is reached within the first 4 to 12 weeks of treatment, maintaining a treatment-free period of at least 24 weeks during which the patient receives none of the medicament.

What is claimed is:

1. Use of romiplostim in the manufacture of a medicament for treating idiopathic thrombocytopenia purpura (ITP) in a patient having ITP, wherein the use comprises that:
    a. the medicament is to be administered weekly to the patient, wherein an initial dose is 1 μg /kg;
    b. the weekly dose of the medicament is to be increased in increments of 1 μg/kg until a platelet count of at least 50 to 200 x 10^9/L is reached;
    c. the weekly dose of the medicament is to be decreased in increments of 1 μg/kg if the platelet count remains $\geq$ 200 x 10^9/L for two consecutive weeks;
    d. administration of the medicament is to be discontinued if (i) the platelet count has remained $\geq$ 200 x 10^9/L for two consecutive weeks when the weekly dose is 1 μg/kg or (ii) the platelet count is $\geq$ 400 x 10^9/L; and
    e. if a platelet count $\geq$ 200 x 10^9/L is reached within the first 4 to 12 weeks of treatment, maintaining a treatment-free period of at least 24 weeks during which the patient receives none of the medicament.
2. The use of claim 1, which comprises that the weekly dose is to be maintained so long as the platelet count is within 50 to 200 x 10^9/L.
3. The use of claim 1, wherein the platelet count in step e is $\geq$ 200 x 10^9/L in the first four weeks of treatment.
4. The use of claim 1, wherein the platelet count in step e is $\geq$ 200 x 10^9/L in the first eight weeks of treatment.
5. The use of claim 1, wherein the patient's platelet count remains $\geq$ 50 x 10^9/L during the treatment-free period.
6. The use of claim 1, wherein the patient receives no ITP medications during the treatment-free period.

What is claimed is:

1. Use of romiplostim in the manufacture of a medicament for treating idiopathic thrombocytopenia purpura (ITP) in a patient having ITP, wherein the use comprises that:
    a. the medicament is to be administered weekly to the patient, wherein an initial dose is 1 μg /kg;
    b. the weekly dose of the medicament is to be increased in increments of 1 μg/kg until a platelet count of at least 50 to 200 x 10^9/L is reached;
    c. the weekly dose of the medicament is to be decreased in increments of 1 μg/kg if the platelet count remains $\geq$ 200 x 10^9/L for two consecutive weeks;
    d. administration of the medicament is to be discontinued if (i) the platelet count has remained $\geq$ 200 x 10^9/L for two consecutive weeks when the weekly dose is 1 μg/kg or (ii) the platelet count is $\geq$ 400 x 10^9/L; and
    e. if a platelet count $\geq$ 200 x 10^9/L is reached within the first 4 to 12 weeks of treatment, maintaining a treatment-free period of at least 24 weeks during which the patient receives none of the medicament.
2. The use of claim 1, which comprises that the weekly dose is to be maintained so long as the platelet count is within 50 to 200 x 10^9/L.
3. The use of claim 1, wherein the platelet count in step e is $\geq$ 200 x 10^9/L in the first four weeks of treatment.
4. The use of claim 1, wherein the platelet count in step e is $\geq$ 200 x 10^9/L in the first eight weeks of treatment.
5. The use of claim 1, wherein the patient's platelet count remains $\geq$ 50 x 10^9/L during the treatment-free period.
6. The use of claim 1, wherein the patient receives no ITP medications during the treatment-free period.