Refractory to Immunosuppressive Therapy: 1-Year Interim Analysis of Phase 2 Clinical Trial" Blood (2016) 128:3910

Non Patent Literature 2: Lee et al., "Hematologic Response to Romiplostim Treatment Is Associated with Stimulation of Primitive Stem/Progenitor Cells and Stromal Cells in Patients with Aplastic Anemia Refractory to Immunosuppressive Therapy: A 2-Year Interim Exploratory Analysis of a Phase 2 Clinical Trial" Blood (2017) 130:1167

Summary

Technical Problem

[0012]

An object of the present invention is to provide an effective method for treating aplastic anemia using Romiplostim.

Solution to Problem

[0013]

As a result of intensive studies, the inventors have found that high efficacy and safety can be obtained in the treatment of aplastic anemia by administering Romiplostim at a specific dose and administration, and completed the present invention.

[0014]

In a first aspect, the present invention refers to the use of Romiplostim as an active ingredient in the manufacture of a pharmaceutical composition for treating aplastic anemia, wherein the pharmaceutical composition is to be administered subcutaneously once a week, and
wherein the pharmaceutical composition is to be administered at 10 µg Romiplostim/kg/week for 4 weeks from the start of administration, and is to be administered at more than 10 µg Romiplostim/kg/week and a maximum of 20 µg Romiplostim/kg/week ~~after~~ from week 5. In yet

another aspect, the present invention refers to the use of Romiplostim as an active ingredient in the manufacture of a pharmaceutical composition for treating aplastic anemia, wherein the pharmaceutical composition is to be administered subcutaneously once a week, and wherein the pharmaceutical composition is to be administered at 10 μg Romiplostim/kg/week for 4 weeks from the start of administration, and a dose increment of Romiplostim ~~after~~ from week 5 is 5 μg Romiplostim/kg.

That is, also disclosed herein is the following (1) to (8).

(1) A pharmaceutical composition for treating aplastic anemia, comprising Romiplostim as an active ingredient, wherein the pharmaceutical composition is administered subcutaneously once a week, and wherein Romiplostim is administered at 10 μg/kg/week for 4 weeks from the start of administration, and administered at more than 10 μg/kg/week and a maximum of 20 μg/kg/week after week 5.

(2) The pharmaceutical composition according to (1), wherein the same dose is maintained for 4 weeks or more after a dose change.

(3) The pharmaceutical composition according to (1), wherein Romiplostim is administered at 15 μg/kg/week from week 5 to week 8 and administered at a maximum of 20 μg/kg/week after week 9, and wherein the same dose is maintained for 4 weeks or more after a dose change.

(4) The pharmaceutical composition according to (1), wherein Romiplostim is administered at 15 μg/kg/week from week 5 to week 8, administered at 20 μg/kg/week from week 9 to week 12, and administered at 5 to 20 μg/kg/week after week 13, and wherein the same dose is maintained for 4 weeks or more after a dose change.

(5) The pharmaceutical composition according to (1), wherein Romiplostim is administered at 15 or 20 μg/kg/week after week 5, and wherein the same dose is maintained for 4 weeks or more after a dose change.

(6) The pharmaceutical composition according to any of (1) to (4), wherein a dose increment of Romiplostim after week 5 is 5 μg/kg.

(7) A pharmaceutical composition for treating aplastic anemia, comprising Romiplostim as an active ingredient, wherein the pharmaceutical composition is administered subcutaneously once a week, and wherein Romiplostim is administered at 10 μg/kg/week for 4 weeks from the start

Claims

[Claim 1]

Use of Romiplostim as an active ingredient in the manufacture of a pharmaceutical composition for treating aplastic anemia, wherein the pharmaceutical composition is to be administered subcutaneously once a week, and

wherein the pharmaceutical composition is to be administered at 10 μg Romiplostim/kg/week for 4 weeks from the start of administration, and is to be administered at more than 10 μg Romiplostim/kg/week and a maximum of 20 μg Romiplostim/kg/week ~~after~~from week 5.

[Claim 2]

The use according to claim 1, wherein the same dose is to be maintained for 4 weeks or more after a dose change.

[Claim 3]

The use according to claim 1, wherein the pharmaceutical composition is to be administered at 15 μg Romiplostim/kg/week from week 5 to week 8 and is to be administered at a maximum of 20 μg Romiplostim/kg/week ~~after~~ from week 9, and

wherein the same dose is to be maintained for 4 weeks or more after a dose change.

~~[Claim 4]~~

~~The use according to claim 1, wherein the pharmaceutical composition is to be administered at 15 μg Romiplostim/kg/week from week 5 to week 8, is to be administered at 20 μg Romiplostim/kg/week from week 9 to week 12, and is to be administered at 5 to 20 μg~~

~~Romiplostim/kg/week after week 13, and~~

~~wherein the same dose is to be maintained for 4 weeks or more after a dose change.~~

[Claim ~~5~~4]

The use according to claim 1, wherein the pharmaceutical composition is to be administered at 15 or 20 μg Romiplostim/kg/week ~~after~~from week 5, and

wherein the same dose is to be maintained for 4 weeks or more after a dose change.

[Claim ~~6~~5]

The use according to any one of claims 1 to ~~4~~3, wherein a dose increment ~~after~~from week 5 is 5 μg Romiplostim/kg.

[Claim ~~7~~6]

Use of Romiplostim as an active ingredient in the manufacture of a pharmaceutical composition for treating aplastic anemia, wherein the pharmaceutical composition is to be administered subcutaneously once a week, and

wherein the pharmaceutical composition is to be administered at 10 μg Romiplostim/kg/week for 4 weeks from the start of administration, and a dose increment of Romiplostim ~~after~~from week 5 is 5 μg Romiplostim/kg.

[Claim ~~8~~7]

The use according to claim ~~7~~6, wherein the same dose is to be maintained for 4 weeks or more after a dose change.