[PTL 3] WO 2006/109592
[PTL 4] WO 2012/067176
[PTL 5] WO 2015/194233

[Non-Patent Literature]

[0008]

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[NPL 2] Nature 312, 330-337 (1984)
[NPL 3] Nature 312, 337-342 (1984)
[NPL 4] Biochim.Biophys.Acta 871, 268-278 (1986)
[NPL 5] Nature Medicine 18, 1570-1574(2012)
[NPL 6] PLOS ONE 8, 1-13(2013)
[NPL 7] J Thromb Haemost. 12, 206-213(2014)
[NPL 8] Blood 127(13), 1633-1641(2016)
[NPL 9] N Engl J Med. 374(21), 2044-2053(2016)
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[NPL 11] Japanese Journal of Thrombosis and Hemostasis 28(6), 715-747 (2017)
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[Summary ~~of Invention~~]

[0008a]

In one aspect, the present disclosure provides a use of emicizumab in the manufacture of a pharmaceutical composition for treating acquired hemophilia A and/or reducing the incidence of acquired hemophilia A, wherein emicizumab is to be administered at an antibody dose of 6 mg/kg on Day 1, at an antibody dose of 3 to 6 mg/kg on Day 2, and at an antibody dose of 1.5 to 3 mg/kg weekly from Day 8, wherein the weekly administration from Day 8 is to be repeated one or more times.

In yet another aspect, the present disclosure provides a use of emicizumab in the manufacture of a pharmaceutical composition for treating acquired hemophilia A and/or reducing the incidence of acquired hemophilia A, wherein emicizumab is to be administered at an antibody dose of 6 mg/kg on Day 1, at an antibody dose of 3 to 6 mg/kg on Day 2, and at an antibody dose of 3 to 4 mg/kg every 2 weeks from Day 8, or at an antibody dose of 6 mg/kg every 4 weeks from Day 8, wherein the administration every 2 weeks or every 4 weeks from Day

8 is to be repeated one or more times. In a further aspect, the present disclosure provides a use of emicizumab in the manufacture of a pharmaceutical composition for treating acquired hemophilia A and/or reducing the incidence of acquired hemophilia A, wherein emicizumab is to be administered at an antibody dose of 6 mg/kg on Day 1, at an antibody dose of 3 to 6 mg/kg on Day 2, at an antibody dose of 1.5 to 3 mg/kg on Day 8, and at an antibody dose of 3 to 4 mg/kg every 2 weeks from Day 15, or at an antibody dose of 6 mg/kg every 4 weeks from Day 15, wherein the administration every 2 weeks or every 4 weeks from Day 15 is to be repeated one or more times.

[Technical Problem]

[0009]

This disclosure was made in view of such circumstances, and one of the objectives is to provide optimal emicizumab administration regimens for the treatment of acquired hemophilia A.

[Solution to Problem]

[0010]

The inventors of the present disclosure conducted diligent research to achieve the above objective and succeeded in discovering more effective administration regimens of pharmaceutical compositions comprising emicizumab for the prevention and/or treatment of acquired hemophilia A. More specifically, the present inventors discovered that by administering emicizumab for at least two _PPH days (daily loading administration), an effective plasma emicizumab concentration can be obtained at an early stage after the start of administration, and that after approximately one week and thereafter following the initial

[CLAIMS]

1. Use of emicizumab in the manufacture of a~~A~~ pharmaceutical composition for ~~use in~~ treating acquired hemophilia A and/or reducing the incidence of acquired hemophilia A, ~~wherein the composition comprises emicizumab,~~ wherein emicizumab is to be administered at an antibody dose of 6 mg/kg on Day 1, at an antibody dose of 3 to 6 mg/kg on Day 2, and at an antibody dose of 1.5 to 3 mg/kg weekly from Day 8, wherein the weekly administration from Day 8 is to be repeated one or more times.

2. The ~~pharmaceutical composition~~use of claim 1, wherein the administration on Day 1, the administration on Day 2, and the weekly administration from Day 8 are each to be performed in a single dose.

3. The ~~pharmaceutical composition~~use of claim 1 or 2, wherein the administration on Day 1, the administration on Day 2, and the weekly administration from Day 8 are each to be performed subcutaneously.

4. The ~~pharmaceutical composition~~use of any one of claims 1 to 3, wherein emicizumab is to be administered at an antibody dose of 3 mg/kg on Day 2.

5. The ~~pharmaceutical composition~~use of any one of claims 1 to 4, wherein emicizumab is to be administered at an antibody dose of 1.5 mg/kg weekly from Day 8, wherein the weekly administration from Day 8 is to be repeated one or more times.

6. The ~~pharmaceutical composition~~ use of any one of claims 1 to 5, wherein the pharmaceutical composition ~~which~~ is used under administration of an immunosuppressive drug.

7. The ~~pharmaceutical composition~~use of claim 6, wherein the immunosuppressive drug is a steroid drug.

~~8. A product comprising (i) a container; (ii) a pharmaceutical composition comprising emicizumab in the container, and (iii) a document instructing that emicizumab be administered at an antibody dose of 6 mg/kg on Day 1, at an antibody dose of 3 to 6 mg/kg on Day 2, and at an antibody dose of 1.5 to 3 mg/kg weekly from Day 8, and that the weekly administration from Day 8 be repeated one or more times.~~

~~9. The product of claim 8, wherein the administration on Day 1, administration on Day 2, and weekly administration from Day 8 are each performed in a single dose.~~

~~10. The product of claim 8 or 9, wherein the administration on Day 1, administration on Day 2, and weekly administration from Day 8 are each performed subcutaneously.~~

~~11. The product of any one of claims 8 to 10, wherein emicizumab is administered at an antibody dose of 3 mg/kg on Day 2.~~

~~12. The product of any one of claims 8 to 11, wherein emicizumab is administered at an antibody dose of 1.5 mg/kg weekly from Day 8, wherein the weekly administration from Day 8 is repeated one or more times.~~

~~13. The product of any one of claims 8 to 12, which comprises said document instructing that emicizumab be used in combination with an immunosuppressive drug.~~

~~14~~8. Use of emicizumab in the manufacture of a~~A~~ pharmaceutical composition for ~~use in~~ treating acquired hemophilia A and/or reducing the incidence of acquired hemophilia A, ~~which comprises emicizumab,~~ wherein emicizumab is to be administered at an antibody dose of 6 mg/kg on Day 1, at an antibody dose of 3 to 6 mg/kg on Day 2, and at an antibody dose of 3 to 4 mg/kg every 2 weeks from Day 8, or at an antibody dose of 6 mg/kg every 4 weeks from Day 8, wherein the administration every 2 weeks or every 4 weeks from Day 8 is to be repeated one or more times.

~~15~~9. Use of emicizumab in the manufacture of a~~A~~ pharmaceutical composition for ~~use in~~ treating acquired hemophilia A and/or reducing the incidence of acquired hemophilia A, ~~which comprises emicizumab,~~ wherein emicizumab is to be administered at an antibody dose of 6 mg/kg on Day 1, at an antibody dose of 3 to 6 mg/kg on Day 2, at an antibody dose of 1.5 to 3 mg/kg on Day 8, and at an antibody dose of 3 to 4 mg/kg every 2 weeks from Day 15, or at an antibody dose of 6 mg/kg every 4 weeks from Day 15, wherein the administration every 2 weeks or every 4 weeks from Day 15 is to be repeated one or more times.