However, PTL 2 did not contemplate administering anti-OX40 antibody for a longer time period than 16 weeks, and did not report any results of administering the anti-OX40 antibody to human subjects.

[0007] Accordingly, there remain a need for an administration method for delivering anti-OX40 antibody for treating an OX40-mediated disease such as AD in a subject in need thereof that is proven to be safe and effective.

Citation List

Patent Literature

[0008] PTL 1: US 2010/0196359

PTL 2: WO 2019/229155

Non Patent Literature

[0009] NPL 1: Nakagawa et al. J. of Dermatological Science, 99: 82-89, 2020

Summary

[0009a] In one aspect, the present disclosure refers to use of an anti-OX40 antibody in the manufacture of a composition for the treatment of an OX40-related immune- or allergy-related disease, wherein the anti-OX40 antibody is to be subcutaneously administered to a patient at a dose of 150 mg to 600 mg once in two weeks to four weeks for at least 16 weeks. In another aspect, the present disclosure refers to use of an anti-OX40 antibody in the manufacture of a medicament for the treatments of an OX40-related immune- or allergy-related disease, wherein an anti-OX40 antibody is to be subcutaneously administered to a patient at a dose of 150 mg to 600 mg once in two weeks to four weeks continuously at the same dose.

[0009b] In one aspect, the present disclosure refers to use of an anti-OX40 antibody in the manufacture of a medicament for the treatments of an OX40-related immune- or allergy-related disease, wherein an anti-OX40 antibody is to be subcutaneously administered to a patient at a dose of 150 mg to 600 mg once in two weeks to four weeks continuously at the same dose.

[0010] One example of the present disclosure relates to a therapeutic method for an OX40-related immune- or allergy-related disease including subcutaneously administering an anti-OX40 antibody to a patient at a dose of 150 mg to 600 mg once in two weeks to four weeks for at least 16 weeks. In another example, the present disclosure relates to a composition for use in the treatments of an OX40-related immune- or allergy-related disease, wherein an anti-OX40 antibody is subcutaneously administering to a patient at a dose of 150 mg to 600 mg once in two weeks to four weeks continuously at the same dose.

[0011] In some examples, the anti-OX40 antibody is a monoclonal antibody containing a heavy chain variable region (also called VH) containing the amino acid sequence of SEQ ID NO: 1 and a light chain variable region (also called VL) containing the amino acid sequence of SEQ ID NO: 2.

[0012] In some examples, the administration is continued for at least 20 weeks, 22 weeks, 24 weeks or 34 weeks after starting the administration.

[0013] In some examples, the OX40-related immune- or allergy-related disease is atopic dermatitis.

[0014] In some examples, the anti-OX40 antibody is subcutaneously administered once in two weeks, three weeks or four weeks.

[0015] In some examples, the dose is selected from 150 mg, 300 mg, 450 mg and 600 mg.

[0016] In some examples, the OX40-related immune- or allergy-related disease is moderate to severe atopic dermatitis.

[0017] In some examples, the OX40-related immune- or allergy-related disease is moderate to severe atopic dermatitis which is poorly controllable using a topical agent

or moderate to severe atopic dermatitis for which a topical therapy is not medically recommended.

[0018] In some examples, the present disclosure relates to a therapeutic method or a composition for use in treating an OX40-related immune- or allergy-related disease, wherein the anti-OX40 antibody is combined with a known topical agent such as a steroid.

[0019] In some examples, the anti-OX40 antibody is KHK4083.

In some examples, the present disclosure relates to a therapeutic method for an OX40-related immune- or allergy-related disease including subcutaneously administering an anti-OX40 antibody to a patient at a dose of 150 mg to 600 mg once in two weeks to four weeks continuously at the same dose. In some examples, the present disclosure relates to a composition for use in a method for treating an OX40-related immune- or allergy-related disease including subcutaneously administering an anti-OX40 antibody to a patient at a dose of 150 mg to 600 mg once in two weeks to four weeks continuously at the same dose. In some examples, the anti-OX40 antibody is a monoclonal antibody containing a heavy chain variable region (also called VH) containing the amino acid sequence of SEQ ID NO: 1 and a light chain variable region (also called VL) containing the amino acid sequence of SEQ ID NO: 2. In some examples, the administration is continued for at least 16 weeks, 20 weeks, 22 weeks, 24 weeks or 34 weeks after starting the administration. In some examples, the OX40-related immune- or allergy-related disease is atopic dermatitis. In some examples, the anti-OX40 antibody is subcutaneously administered once in two weeks, three weeks or four weeks. In some examples, the dose is selected from 150 mg, 300 mg, 450 mg and 600 mg. In some examples, the anti-OX40 antibody is KHK4083. In some examples, 300 mg of the anti-OX40 antibody is administered once in 2 weeks for 24 weeks, and then administered once in 4 weeks. In some examples, 300 mg of the anti-OX40 antibody is administered once in 2 weeks for 24 weeks, and then administered once in 8 weeks. In some examples, 300 mg of the anti-OX40 antibody is administered once in 2 weeks for 16 weeks and then administered once in 4 weeks. In some examples, 300 mg of the anti-OX40 antibody is administered once in 2 weeks for 16 weeks and then administered once in 8 weeks. In some examples, 150 mg of the anti-OX40 antibody is administered once in 2 weeks for 24 weeks, and then administered once in 4 weeks. In some examples, 150 mg of the anti-OX40 antibody is administered once in 2 weeks for 24 weeks, and then administered once in 8 weeks. In some

examples, 150 mg of the anti-OX40 antibody is administered once in 2 weeks for 16 weeks and then administered once in 4 weeks. In some examples, 150 mg of the anti-OX40 antibody is administered once in 2 weeks for 16 weeks and then administered once in 8 weeks.