

IL-13 ANTIBODIES FOR THE TREATMENT OF PERENNIAL ALLERGIC RHINITIS

SEQUENCE LISTING

[0001] The present application is being filed along with a Sequence Listing in ST.26 XML format. The Sequence Listing is provided as a file titled “30944_WO_000 Sequence Listing ST26” created December 11, 2024, and is 20 kilobytes in size. The Sequence Listing information in the ST.26 XML format is incorporated herein by reference in its entirety.

FIELD

[0002] The present invention relates to methods and uses of antibodies that specifically bind human interleukin (IL)-13 (“anti-IL-13 antibodies”) for treating perennial allergic rhinitis (PAR).

BACKGROUND

[0003] Perennial allergic rhinitis (PAR) is a type 2 inflammation-mediated disease (Giavina-Bianchi P, et al., United airway disease: current perspectives. J Asthma Allergy. 2016;9:93-100). Studies using samples collected from patients with allergic rhinitis (AR) showed that levels of IL-13 in the nasal mucosa and nasal secretions are increased following allergen challenge (Baumann, R., et al., The release of IL-31 and IL-13 after nasal allergen challenge and their relation to nasal symptoms. Clin Transl Allergy. 2012;2(1):13). Another study found that levels of serum Th2 cytokine transcripts, especially for IL-13 and IL13RA1, were higher in AR patients compared with non-allergic controls (Nur Husna S.M., et al., IL-4/IL-13 axis in allergic rhinitis: elevated serum cytokines levels and inverse association with tight junction molecules expression. Front Mol Biosci. (2022); 9:819772).

[0004] Symptoms of PAR include nasal congestion, nasal itch, and sleep disturbances. Diagnosis is usually made based on the presence of characteristic PAR symptoms, risk factors, and physical exam, and may be supported by skin testing for aeroallergen specific IgE (Dykewicz, M.S., et al., Rhinitis 2020: a practice parameter update. J Allergy Clin Immunol. (2020); 146(4):721-67).

[0005] The leading options for PAR treatment are intranasal corticosteroids (INCS), as well as additional therapy options including antihistamines (oral and intranasal), mast cell stabilizers, leukotriene modifiers, and allergen immunotherapy (AIT) (Dykewicz, et al., 2020). However,

these therapies have limitations and may not adequately treat daily symptoms in some patients. Although INCS are the most effective treatments available for most patients with PAR, they commonly cause burdensome local side effects such as epistaxis, raise potential growth limitation concerns when used in children, and cause unpleasant aftertaste and throat rundown that can influence patient preference and adherence (Seidman, M.D., et al., Clinical practice guideline: allergic rhinitis. *Otolaryngol Head Neck Surg.* (2015); 152(1 Suppl):S1-43; Mener, D.J., et al., Topical intranasal corticosteroids and growth velocity in children: a meta-analysis. *Int Forum Allergy Rhinol.* (2015); 5(2):95-103; Meltzer, E.O., Formulation considerations of intranasal corticosteroids for the treatment of allergic rhinitis. *Ann Allergy Asthma Immunol.* (2007); 98(1):12-21). While AIT is an option for patients with refractory symptoms, not all patients are indicated for AIT and non-adherence rates are reportedly as high as 90% with most patients only completing one year of the recommended three to five years needed for long-term efficacy (Roberts, G., et al., EAACI guidelines on allergen immunotherapy: allergic rhinoconjunctivitis. *Allergy.* (2018); 73(4):765-98; Mao J, et al., Cost of subcutaneous immunotherapy in a large insured population in the United States. *Curr Med Res Opin.* (2019); 35(2):351-8.). Though existing treatments are available, many patients with PAR are inadequately controlled by standard of care treatments resulting in significant remaining economic burden (Hellings, P.W., et al., A common language to assess allergic rhinitis control: results from a survey conducted during EAACI 2013 Congress. *Clin Transl Allergy.* (2015); 5:36; Dykewicz, et al., 2020).

[0006] There remains a need for alternative effective therapies for treating PAR. There is also a need for therapeutic treatments and dosing regimens that provide higher tolerability and convenience and lower risk for patients, thereby improving patient compliance and satisfaction.

SUMMARY OF INVENTION

[0007] Provided herein are methods and uses of an anti-IL-13 antibody (i.e., an antibody that specifically binds human IL-13), such as lebrikizumab, or pharmaceutical compositions comprising an anti-IL-13 antibody, for treating perennial allergic rhinitis.

[0008] In one aspect, provided herein are methods of treating perennial allergic rhinitis in a patient in need thereof, the methods comprising administering to the patient a therapeutically effective amount of an anti-IL-13 antibody. In some embodiments, provided herein are methods

of treating perennial allergic rhinitis, the methods comprising: selecting a patient who has perennial allergic rhinitis, and administering to the patient a therapeutically effective amount of an anti-IL-13 antibody.

[0009] In another aspect, provided herein are an anti-IL-13 antibody or pharmaceutical composition comprising an anti-IL-13 antibody for use in the treatment of perennial allergic rhinitis. Also provided herein are uses of an anti-IL-13 antibody in the manufacture of a medicament for the treatment of perennial allergic rhinitis.

[0010] In some embodiments, the anti-IL-13 antibody comprises a heavy chain variable region (VH) and a light chain variable region (VL), wherein the VH comprises a HCDR1 comprising SEQ ID NO: 1, a HCDR2 comprising SEQ ID NO: 2, and a HCDR3 comprising SEQ ID NO: 3, and the VL comprises a LCDR1 comprising SEQ ID NO: 4, a LCDR2 comprising SEQ ID NO: 5, and a LCDR3 comprising SEQ ID NO: 6. In some embodiments, the anti-IL-13 antibody comprises a VH comprising SEQ ID NO: 7, and a VL comprising SEQ ID NO: 8. In some embodiments, the anti-IL-13 antibody comprises a VH comprising SEQ ID NO: 11, and a VL comprising SEQ ID NO: 12. In some embodiments, the anti-IL-13 antibody comprises a heavy chain comprising SEQ ID NO: 9, and a light chain comprising SEQ ID NO: 10. In some embodiments, the anti-IL-13 antibody comprises a heavy chain comprising SEQ ID NO: 13, and a light chain comprising SEQ ID NO: 14. In some embodiments, the anti-IL-13 antibody is lebrikizumab. In certain embodiments, the anti-IL-13 antibody comprises a VH sequence set forth in SEQ ID NO: 11, a VL sequence set forth in SEQ ID NO: 12, and the human IgG sequence set forth in SEQ ID NO: 15. In certain embodiments, the anti-IL-13 antibody comprises a VH sequence set forth in SEQ ID NO: 11, a VL sequence set forth in SEQ ID NO: 12, the human IgG sequence set forth in SEQ ID NO: 15, and the constant light chain sequence set forth by SEQ ID NO: 16.

[0011] In some embodiments, the anti-IL-13 antibody is administered subcutaneously to the patient. In some embodiments, the anti-IL-13 antibody is administered at a dose of 250 mg to 500 mg. In some embodiments, the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 250 mg once every two weeks. In some embodiments, the patient is further treated with a loading dose of 500 mg of the anti-IL-13 antibody. In some embodiments, the loading dose is administered once or twice to the patient. In some embodiments, the loading dose

is administered to the patient at week 0 (baseline) and week 2. In some embodiments, the patient is treated with the anti-IL-13 antibody for a period of about 16 weeks.

[0012] In some embodiments, the patient is further treated for a maintenance period of about 40 weeks. In some embodiments, the patient is treated with a maintenance dose of 250 mg of the anti-IL-13 antibody once every four weeks during the maintenance period. In some embodiments, the patient is treated with a maintenance dose of 250 mg of anti-IL-13 antibody once every eight weeks during the maintenance period.

[0013] In some embodiments, the patient is treated with a loading dose of 500 mg of the anti-IL-13 antibody at week 0 (baseline) and week 2, followed by a dose of 250 mg once every two weeks for 16 weeks, followed by a maintenance dose of 250 mg once every four weeks for 40 weeks. In some embodiments, the patient is treated with a loading dose of 500 mg of the anti-IL-13 antibody at week 0 (baseline) and week 2, followed by a dose of 250 mg once every two weeks for 16 weeks, followed by a maintenance dose of 250 mg once every eight weeks for 40 weeks.

[0014] In some embodiments, the methods and uses described herein further comprise determining the total nasal symptom score (TNSS) of the patient before, during, and after the treatment. In some embodiments, the methods and uses described herein further comprise determining the Rhinoconjunctivitis Quality of Life Questionnaire Standardized Version (RQLQ(S)) score of the patient before, during, and after the treatment. In some embodiments, the methods and uses described herein further comprise determining the postnasal drip score of the patient before, during, and after the treatment.

[0015] In some embodiments, the methods and uses described herein further comprise administering an intranasal corticosteroid to the patient. In some embodiments, the intranasal corticosteroid is mometasone furoate. In some embodiments, the intranasal corticosteroid is administered simultaneously, concurrently or sequentially with the anti-IL-13 antibody.

[0016] In some embodiments, the patient had a history of inadequate response to intranasal corticosteroid before the treatment. In some embodiments, the patient has moderate or severe nasal symptoms with a TNSS score ≥ 8 before the treatment. In some embodiments, the patient is aged 18 years or older. In some embodiments, the patient is 12-18 years old and weigh at least 40 kilograms (kg).

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Figure 1 is a schematic diagram of the Phase 3 study design described in Example 1. Abbreviations: TBSS= total nasal symptom score; CFBL = change from baseline; INCS = intranasal corticosteroids; Lebri = lebrikizumab; PBO = placebo; Q2W = every 2 weeks; Q4W = every 4 weeks; Q8W = every 8 weeks.

DETAILED DESCRIPTION

[0018] Provided herein are methods and uses of an anti-IL-13 antibody (e.g., lebrikizumab), or pharmaceutical compositions comprising an anti-IL-13 antibody (e.g., lebrikizumab), for treating perennial allergic rhinitis.

[0019] In one aspect, provided herein are methods of treating perennial allergic rhinitis in a patient in need thereof, the methods comprising administering to the patient a therapeutically effective amount of an anti-IL-13 antibody. In some embodiments, provided herein are methods of treating perennial allergic rhinitis, the methods comprising: selecting a patient who has perennial allergic rhinitis, and administering to the patient a therapeutically effective amount of an anti-IL-13 antibody.

[0020] In another aspect, provided herein are an anti-IL-13 antibody or pharmaceutical composition comprising an anti-IL-13 antibody for use in the treatment of perennial allergic rhinitis. Also provided herein are uses of an anti-IL-13 antibody in the manufacture of a medicament for the treatment of perennial allergic rhinitis.

[0021] In some embodiments, the methods and uses described herein further comprise determining the total nasal symptom score (TNSS) of the patient before, during, and after the treatment. In some embodiments, the methods and uses described herein further comprise determining the Rhinoconjunctivitis Quality of Life Questionnaire Standardized Version (RQLQ(S)) score of the patient before, during, and after the treatment. In some embodiments, the methods and uses described herein further comprise determining the postnasal drip score of the patient before, during, and after the treatment.

[0022] In some embodiments, the methods and uses described herein further comprise administering an intranasal corticosteroid to the patient. In some embodiments, the intranasal corticosteroid is mometasone furoate. In some embodiments, the intranasal corticosteroid is administered simultaneously, concurrently or sequentially with the anti-IL-13 antibody.

[0023] In some embodiments, the patient had a history of inadequate response to intranasal corticosteroid before the treatment. In some embodiments, the patient has moderate or severe nasal symptoms with a TNSS score ≥ 8 before the treatment. In some embodiments, the patient is aged 18 years or older. In some embodiments, the patient is 12-18 years old and weigh at least 40 kg.

[0024] Anti-IL-13 antibodies suitable for use in the methods and uses provided herein have been described previously, e.g., WO2005/062967. In some embodiments, the anti-IL-13 antibody comprises a heavy chain variable region (VH) and a light chain variable region (VL), wherein the VH comprises a HCDR1 comprising SEQ ID NO: 1, a HCDR2 comprising SEQ ID NO: 2, and a HCDR3 comprising SEQ ID NO: 3, and the VL comprises a LCDR1 comprising SEQ ID NO: 4, a LCDR2 comprising SEQ ID NO: 5, and a LCDR3 comprising SEQ ID NO: 6. In some embodiments, the anti-IL-13 antibody comprises a VH comprising SEQ ID NO: 7, and a VL comprising SEQ ID NO: 8. In some embodiments, the anti-IL-13 antibody comprises a VH comprising SEQ ID NO: 11, and a VL comprising SEQ ID NO: 12. In some embodiments, the anti-IL-13 antibody comprises a heavy chain comprising SEQ ID NO: 9, and a light chain comprising SEQ ID NO: 10. In certain embodiments, the anti-IL-13 antibody comprises a VH sequence set forth in SEQ ID NO: 11, a VL sequence set forth in SEQ ID NO: 12, and the human IgG sequence set forth in SEQ ID NO: 15. In certain embodiments, the anti-IL-13 antibody comprises a VH sequence set forth in SEQ ID NO: 11, a VL sequence set forth in SEQ ID NO: 12, a human Fc region comprising the human IgG sequence set forth in SEQ ID NO: 15, and a constant light chain sequence set forth by SEQ ID NO: 16. In some embodiments, the anti-IL-13 antibody is lebrikizumab (CAS No. 953400-68-5). Lebrikizumab is a humanized monoclonal IgG4 antibody that specifically binds IL-13 with high affinity and blocks signaling through the active IL-4R α /IL-13R α 1 heterodimer. The amino acid sequences of lebrikizumab are provided in Table 1. C-terminal clipping of IgG antibodies could occur when one or two C-terminal amino acids are removed from the heavy chain of the IgG antibodies. For example, if a C-terminal lysine (K) is present, it may be truncated or clipped off from the heavy chain. A penultimate glycine (G) may also be truncated or clipped off from the heavy chain as well. Modification of N-terminal amino acid of IgG could also occur. For example, the N-terminal glutamine (Q) or glutamic acid (E) can cyclize into pyro-glutamate (pE) spontaneously. SEQ ID NO: 9 reflects these potential modifications of lebrikizumab heavy chain. Similarly, SEQ ID

NO: 11, 13, and 15 reflect these potential modifications of lebrikizumab variant VH, lebrikizumab variant HC, and human IgG1 Fc region, respectively.

Table 1. Anti-IL-13 Antibody Sequences

SEQ ID NO:	Description	Sequence
1	Lebrikizumab HCDR1	AYSVN
2	Lebrikizumab HCDR2	MIWGDGKIVYNSALKS
3	Lebrikizumab HCDR3	DGYYPYAMDN
4	Lebrikizumab LCDR1	RASKSVDSYGNSFMH
5	lebrikizumab LCDR2	LASNLES
6	Lebrikizumab LCDR3	QQNNEDPRT
7	Lebrikizumab heavy chain variable region (VH)	VTLRESGPALVKPTQTLTLTCTVSGFSLSAYSVN WIRQPPGKALEWLAMIWGDGKIVYNSALKSRLTI SKDTSKNQVVLMTNMDPVDATATYYCAGDGY PYAMDNWGQGSLVTVSS
8	Lebrikizumab light chain variable region (VL)	DIVMTQSPDSLVSLSLGERATINCRASKSVDSYGN SFMHWYQQKPGQPPKLLIYLASNLESGVPDRFSG SGSGTDFTLTISSLQAEDVAVYYCQQNNEDPRTF GGGTKVEIK
9	Lebrikizumab heavy chain (HC)	Xaa1VTLRESGPALVKPTQTLTLTCTVSGFSLSAYS VNWIRQPPGKALEWLAMIWGDGKIVYNSALKSR LTISKDTSKNQVVLMTNMDPVDATATYYCAGDG YYPYAMDNWGQGSLVTVSSASTKGPSVFPLAPC SRSTSESTAALGCLVKDYFPEPVTVSWNSGALTS GVHTFPAVLQSSGLYSLSVVTVPSSSLGTKTYTC NVDHKPSNTKVDKRVESKYGPPCPPCPAPEFLGG PSVFLFPPKPKDTLMISRTPEVTCVVVDVSDQDE VQFNWYVDGVEVHNAKTKPREEQFNSTYRVVS VLTVLHQDWLNGKEYKCKVSNKGLPSSIEKTISK

		AKGQPREPQVYTLPPSQEEMTKNQVSLTCLVKG FYPSDIAVEWESNGQPENNYKTTPPVLDSDGSFF LYSRLTVDKSRWQEGNVFSCSVMHEALHNHYTQ KSLSLSLXaa2Xaa3 wherein Xaa1 is Q, pE, or absent; Xaa2 is G or absent; Xaa3 is K or absent.
10	Lebrikizumab light chain (LC)	DIVMTQSPDLSVSLGERATINCRASKSVDSYGN SFMHWYQQKPGQPPKLLIYLASNLESGVPDRFSG SGSGTDFLTISLQAEDVAVYYCQQNNEDPRTF GGGTKVEIKRTVAAPSVFIFPPSDEQLKSGTASVV CLLNFPYPREAKVQWKVDNALQSGNSQESVTEQ DSKDSTYLSSTLTLSKADYEKHKVYACEVTHQ GLSSPVTKSFNRGEC
11	Lebrikizumab variant heavy chain variable region (VH)	Xaa1VQLQESGPGLVKPSETLSLTCTVSGFSLNAY SVNWIRQPPGKGLEWLGMIWGDGKIVYNSALKS RLTISKDSSKNQVSLKLSSVTAADTAVYYCAGDG YYPYAMDNDWGQGTITVTVSS wherein Xaa1 is E, pE, or absent
12	Lebrikizumab variant light chain variable region (VL)	DIQLTQSPSSLSASVGDRVTITCRASKSVDSYGN FMHWYQQKPGKAPKLLIYLASNLESGVPSRFSGS GSGTDFLTISLQPEDFATYYCQQNNEDPRTFG GGTKEIK
13	Lebrikizumab variant heavy chain (HC)	Xaa1VQLQESGPGLVKPSETLSLTCTVSGFSLNAY SVNWIRQPPGKGLEWLGMIWGDGKIVYNSALKS RLTISKDSSKNQVSLKLSSVTAADTAVYYCAGDG YYPYAMDNDWGQGTITVTVSSASTKGPSVFPLAPS SKSTSGGTAALGCLVKDYFPEPVTUSWNSGALTS GVHTFPAVLQSSGLYSLSSVTVPSSSLGTQTYIC NVNHKPSNTKVDKKVEPKSCDKTHTCPPCPAPE AAGGPSVFLFPPKPKDTLYITREPEVTCVVVDVS HEDPEVKFNWYVDGVEVHNAKTKPREEQYNST YRVVSVLTVLHQDWLNGKEYKCKVSNKALPAPI EKTISKAKGQPREPQVYTLPPSRDELTKNQVSLTC LVKGFYPSDIAVEWESNGQPENNYKTTPPVLDSD GSFFLYSKLTVDKSRWQQGNVFSC SVMHEALHNHYTQKSLSLXaa2Xaa3 wherein Xaa1 is E, pE, or absent; Xaa2 is P or absent; Xaa3 is G or absent

14	Lebrikizumab variant light chain (LC)	DIQLTQSPSSLSASVGDRVTTITCRASKSVDSYGNS FMHWYQQKPGKAPKLLIYLASNLESGVPSRFSGS GSGTDFLTISSLQPEDFATYYCQQNNEDPRFTG GGTKVEIKRTVAAPSVFIFPPSDEQLKSGTASVVC LLNNFYPPREKAVQWKVDNALQSGNSQESVTEQD SKDSTYLSSTLTLSKADYEKHKVYACEVTHQGL SSPVTKSFNRGEC
15	hlgGI-LALA-YTE HC constant domain	ASTKGPSVFPLAPSSKSTSGGTAAALGCLVKDYFP EPVTUSWNSGALTSGVHTFPAVLQSSGLYSLSSV VTPSSSLGTQTYICNVNHKPSNTKVDKKVEPKS CDKTHCTCPPEAPEAAGGPSVFLFPPKPKDTLYIT REPEVTCVVVDVSHEDPEVKFNWYVDGVEVHN AKTKPREEQYNSTYRVVSVLTVLHQDWLNGKEY KCKVSNKALPAPIEKTISKAKGQPREPQVYTLPPS RDELTKNQVSLTCLVKGFYPSDIAVEWESNGQPE NNYKTTTPVLDSDGSFFLYSKLTVDKSRWQQGN VFSC SVMHEALHNYHTQKSLSLSXaa1Xaa2 wherein Xaa1 is P or absent; Xaa2 is G or absent
16	LC human kappa LC	RTVAAPSVFIFPPSDEQLKSGTASVVCLLNNFYPR EAKVQWKVDNALQSGNSQESVTEQDSKDSTYSL SSTLTLSKADYEKHKVYACEVTHQGLSSPVTKSF NRGEC

[0025] In some embodiments, the anti-IL-13 antibody is a lebrikizumab variant that comprises the same HCDR and LCDR sequences as lebrikizumab. In some embodiments, the anti-IL-13 antibody is a lebrikizumab variant described in WO2023245187, e.g., construct 133, 134, 136, 141. In some embodiments, the anti-IL-13 antibody is APG777. The amino acid sequences of a lebrikizumab variant are also provided in Table 1.

[0026] Other exemplary anti-IL-13 antibodies include, but not limited to, IMA-026, IMA-638 (also referred to as, anrukizumab, QAX-576, CAS No. 910649-32-0), tralokinumab (also referred to as CAT-354, CAS No. 1044515-88-9); cendakimab (also referred to as CC-93538, RPC4046, ABT-308, CAS No. 2151032-62-9), AER-001, ABT-308 (also referred to as humanized 13C5.5 antibody). Examples of such anti-IL-13 antibodies and other inhibitors of IL-13 are disclosed, for example, in WO2008/086395, WO2006/085938, US 7,615,213, US 7,501,121, US 7,935,343, US 7,829,090, US7,947,273, WO2007/036745, WO2010/073119,

WO2007/045477, and WO 2014/165771. In some embodiments, the anti-IL-13 antibody is tralokinumab. In some embodiments, the anti-IL-13 antibody is cendakimab.

[0027] The anti-IL-13 antibody can be formulated with suitable carriers or excipients into a pharmaceutical composition that is suitable for administration to patients. For example, the anti-IL-13 antibody, e.g., lebrikizumab, can be formulated in a pharmaceutical composition as described in WO 2013/066866. The pharmaceutical composition can comprise 100 mg, 150 mg, 200 mg, 250 mg, 300 mg, 350 mg, 400 mg, 450 mg, or 500 mg of the anti-IL-13 antibody. In some embodiments, the pharmaceutical composition comprises 250 mg to 500 mg of the anti-IL-13 antibody. In some embodiments, the pharmaceutical composition comprises 250 mg or 500 mg of the anti-IL-13 antibody. In some embodiments, the anti-IL-13 antibody concentration in the pharmaceutical composition is between 100 mg/mL and 150 mg/mL, e.g., 125 mg/mL. The pharmaceutical composition can also comprise a buffer, e.g., 5 mM - 40 mM histidine acetate buffer, pH 5.4 to 6.0. In some embodiments, the pharmaceutical composition further comprises a polyol (e.g., sugar) that has a concentration between 100 mM and 200 mM, and/or a surfactant (e.g., polysorbate 20) that has a concentration of 0.01% - 0.1%. In one embodiment, the pharmaceutical composition comprises 125 mg/mL of an anti-IL-13 antibody (e.g., lebrikizumab), 20 mM histidine acetate buffer, pH 5.7, 175 mM sucrose and 0.03% polysorbate 20. In some embodiments, provided herein are pharmaceutical composition comprising a means for inhibiting IL-13 and a pharmaceutically acceptable carrier or excipient.

[0028] In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered subcutaneously to the patient. The anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody can be administered to the patient at a dosing frequency of about once a week, once every two weeks, once every three weeks, once every four weeks, once every five weeks, once every six weeks, once every seven weeks, or once every eight weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered to the patient once every two weeks, once every four weeks or once every eight weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 250 mg once every two weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 250

mg once every four weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 250 mg once every eight weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered to the patient once every eight weeks, once every twelve weeks, once every twenty-four weeks, once every 36 weeks, or once every 52 weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered to the patient once about every eight weeks, once about every twelve weeks, once about every twenty-four weeks, once about every 36 weeks, or once about every 52 weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 360 mg once every eight weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 360 mg once every twelve weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 360 mg once every twenty-four weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 360 mg once every thirty-six weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 360 mg once every fifty-two weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 360 mg once about every eight weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 360 mg once about every twelve weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 360 mg once about every twenty-four weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 360 mg once about every thirty-six weeks. In some embodiments, the anti-IL-13 antibody or a pharmaceutical

composition comprising the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 360 mg once about every fifty-two weeks.

[0029] In some embodiments, the patient is treated with the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody for a period of about 16 weeks or more. In some embodiments, the patient is further treated for a maintenance period of about 40 weeks or more. In some embodiments, the patient is treated with the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody for about 16 weeks, about 18 weeks, about 20 weeks, about 22 weeks, about 24 weeks, about 26 weeks, about 28 weeks, about 30 weeks, about 32 weeks, about 34 weeks, about 36 weeks, about 38 weeks, about 40 weeks, about 42 weeks, about 44 weeks, about 46 weeks, about 48 weeks, about 50 weeks, about 52 weeks, about 54 weeks, about 56 weeks, about 58 weeks, or about 60 weeks. In some embodiments, the patient is treated with the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody for a period of about 16 weeks. In some embodiments, the patient is further treated with the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody for a maintenance period of about 40 weeks. In some embodiments, the patient is treated with the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody for a period of about 56 weeks.

[0030] In some embodiments, the patient is treated with a loading dose of the anti-IL-13 antibody, e.g., a loading dose of 500 mg of the anti-IL-13 antibody. The loading dose can be administered a few times to the patient at the beginning of the treatment. For example, a loading dose of 500 mg of the anti-IL-13 antibody can be administered at week 0 (baseline) and week 2. After the loading dose, the anti-IL-13 antibody can be administered to the patient at a dose of 250 mg once every two weeks, 250 mg once every four weeks, 250 mg once every eight weeks.

[0031] In some embodiments, the patient is treated with a loading dose of 500 mg of the anti-IL-13 antibody at week 0 (baseline) and week 2, followed by a dose of 250 mg once every two weeks for 16 weeks, followed by a maintenance dose of 250 mg once every four weeks for 40 weeks.

[0032] In some embodiments, the patient is treated with a loading dose of 500 mg of the anti-IL-13 antibody at week 0 (baseline) and week 2, followed by a dose of 250 mg once every two weeks for 16 weeks, followed by a maintenance dose of 250 mg once every eight weeks for 40 weeks.

[0033] In some embodiments, the patient is treated with a loading dose of 720 mg of the anti-IL-13 antibody at week 0 and week 2, followed by a dose of 360 mg of the anti-IL-13 antibody at week 4 and week 12, followed by a maintenance dose of 360 mg of the anti-IL-13 antibody once every twelve weeks for 40 weeks.

[0034] In some embodiments, the patient is treated with a loading dose of 720 mg of the anti-IL-13 antibody at week 0 and week 2, followed by a dose of 360 mg of the anti-IL-13 antibody at week 4 and week 12, followed by a maintenance dose of 360 mg of the anti-IL-13 antibody once every twenty-four weeks for 40 weeks.

[0035] In some embodiments, the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody is administered to the patient using a subcutaneous administration device. The subcutaneous administration device can be selected from a prefilled syringe, disposable pen injection device, microneedle device, microinfuser device, needle-free injection device, or autoinjector device. Various subcutaneous administration devices, including autoinjector devices, are known in the art and are commercially available. Exemplary devices include, but are not limited to, prefilled syringes (such as BD HYPAK SCF®, READYFILL™, and STERIFILL SCF™ from Becton Dickinson; CLEARSHOT™ copolymer prefilled syringes from Baxter; and Daikyo Seiko CRYSTAL ZENITH® prefilled syringes available from West Pharmaceutical Services); disposable pen injection devices such as BD Pen from Becton Dickinson; ultra-sharp and microneedle devices (such as INJECT-EASE™ and microinfuser devices from Becton Dickinson; and H-PATCH™ available from Valeritas) as well as needle-free injection devices (such as BIOJECTOR® and IJECT® available from Bioject; and SOF-SERTER® and patch devices available from Medtronic). In some embodiments, the subcutaneous administration device is an autoinjector device described in WO 2008/112472, WO 2011/109205, WO 2014/062488, or WO 2016/089864.

[0036] Before, during and after the treatment period, the patient can be assessed for one or more characteristics, which determine certain signs, symptoms, features, or parameters that have been associated with perennial allergic rhinitis and that can be quantitatively or qualitatively assessed. Such characteristics include, but are not limited to, TNSS, RQLQ(S), postnasal drip score, VAS for allergic rhinitis control, NPIF, FEV₁, TOSS, SNOT-22, ACQ-6, EQ-5D-5L, WPAI+CIQ:AS, PROMIS Anxiety Short Form v1.0 – Anxiety 8a, PROMIS Depression Short Form v1.0 – Depression 8a, PGI-S, PGI-C.

[0037] The total nasal symptom score (TNSS) is a clinical outcome assessment measuring participant-reported severity of 4 symptoms including the following (Downie, S.R., et al., Symptoms of persistent allergic rhinitis during a full calendar year in house dust mite-sensitive subjects. *Allergy*. (2004); 59(4):406-14): rhinorrhea (secretion/runny nose); nasal congestion (nasal obstruction); nasal pruritis (nasal itching), and sneezing. Participants assess the severity of each individual symptom daily (over the previous 24 hours), using a 0 to 3 scale (0=no symptom up to 3=severe symptom) and recording the results in an eDiary away from the study site. The individual scores for the 4 symptoms are then summed for a total score in the range of 0 to 12.

[0038] The subjective impact of PAR on a participant's health-related quality of life can be evaluated by the Rhinoconjunctivitis Quality of Life Questionnaire Standardized Version (RQLQ(S)) (Juniper, E.F., et al., Interpretation of rhinoconjunctivitis quality of life questionnaire data. *J Allergy Clin Immunol*. (1996); 98(4):843-5). The RQLQ(S) comprises 28 items that are grouped into 7 domains: Nasal symptoms (4 items); Eye symptoms (4 items); Activity limitations (3 items); Sleep impairment (3 items); Non-nose/eye symptoms (7 items); Practical problems (3 items), and Emotional function (4 items). Participants are asked to recall their experiences of health-related quality of life impairment during the previous week, responding to each question on a 7-point scale (0 to 6) and recording their responses on a tablet at the study site. RQLQ(S) total mean scores are calculated, with a maximum severity score of 6. A change in the total RQLQ(S) score of at least 0.5 points is considered a minimally clinically important change, and a score or at least 1.0 point is considered a moderately important change (Juniper et al., 1996). The RQLQ(S) 3-item sleep impairment domain is used to assess how troubled participants have been by each sleep problem as a result of nose/eye symptoms in the last week. The RQLQ(S) sleep impairment domain is composed of 3 items, replicated verbatim from the corresponding RQLQ(S) items asking about: difficulty getting to sleep, waking up during the night, and lacking a good night's sleep. Consistent with RQLQ(S) responses, options range from 0 (not troubled) to 6 (extremely troubled) with scores calculated in the same way as the total mean score.

[0039] Postnasal drip, which refers to mucus drainage down the throat, as part of their allergic rhinitis, is rated by participants using a 4-point scale, where 0 corresponds to no symptoms and 3 corresponds to severe symptoms. Participants are asked to record the severity of

their postnasal drip for the previous 24 hours. This assessment is collected on the participant eDiary.

[0040] Visual Analog Scale (VAS) for allergic rhinitis control can be assessed as follows. Allergic rhinitis control can be assessed using a single item 0-100 mm VAS scale, assessing how bothersome allergic symptoms are with the ends of the scale anchored by the terms not at all bothersome and extremely bothersome in response to the question “Over the past 7 days, how much are your allergic rhinitis symptoms bothering you?” Well-controlled AR has been defined as a VAS score of 20 or less on a 0 to 100 mm scale (Bousquet, J., et al., MACVIA clinical decision algorithm in adolescents and adults with allergic rhinitis. *J Allergy Clin Immunol.* 2016 Aug.;138(2):367-374.e2).

[0041] Nasal Peak Inspiratory Flow (NPIF) measures maximum inspiratory flow rate through both nostrils during inspiration with results expressed in L/min. Participants with NPIF results >120 L/min represents no nasal obstruction (Mo, S, et al. Nasal peak inspiratory flow in healthy and obstructed patients: systematic review and meta-analysis. *Laryngoscope.* (2021); 131(2):260-7). NPIF is performed at the identified time points, using the highest of 3 readings. Measurement of NPIF are conducted by trained and qualified personnel.

[0042] Spirometry is used to measure the physiologic air flow during forced expiratory volume in 1 second (FEV₁). Normal FEV₁ values are typically ≥80% (Barriero, T.J., An approach to interpreting spirometry. *Am Fam Physician.* (2004); 69(5):1107-14). Lower FEV₁ values can indicate more severe asthma or other causes of airway restriction or obstruction. Only participants entering the study with a current history of asthma have their FEV₁ measured at identified visits, and after withholding the last dose of short-acting bronchodilator for at least 6 hours, Spirometry is performed using study-supplied spirometer that meets the American Thoracic Society/European Respiratory Society recommendations. Percent predicted values is based on the Global Lung Function Initiative (Quanjer, P.H., et al., Multi-ethnic reference values for spirometry for the 3-95-yr age range: the global lung function 2012 equations. *Eur Respir J.* (2012); 40(6):1324-43). Spirometry is conducted by trained and qualified personnel, according to procedures specified in the study reference manual. A minimum of 3 and a maximum of 8 maneuvers must be performed at each timepoint. Spirometry is reviewed by a central over reader who confirms the highest FEV₁ and FVC value for each timepoint. Wherever possible study sites should conduct spirometry within ±1 hour of the baseline value.

[0043] The Total Ocular Symptom Score (TOSS) is a clinical outcome assessment measuring patient-reported severity of the following 2 eye symptoms: itchy/red eyes, and watery eyes. Participants assess the severity of each individual symptom daily (over the previous 24 hours) on an eDiary away from the study site, using a 0 to 3 integer scale (0=absent to 3=severe) (Pfaar, O., et al., Recommendations for the standardization of clinical outcomes used in allergen immunotherapy trials for allergic rhinoconjunctivitis: an EAACI position paper. *Allergy*. (2014); 69(7):854-67). The individual scores for the 2 symptoms are then summed for a total score in the range of 0 to 6.

[0044] The Sino-Nasal Outcome Test (SNOT-22) is a validated participant-reported questionnaire that assesses the impact on health-related quality of life. It consists of 22 questions assessing sino-nasal and auricular function, psychological impact, productivity, and sleep quality. Participants are asked to recall their experiences over the past 2 weeks and rate their symptoms on a scale ranging from 0, which corresponds to no problem, to 5, which corresponds to problem as bad as it can be. The scores of the individual questions are summed to create a total score that ranges from 0, which corresponds to no disease, to 110, which corresponds to worst disease. Lower scores indicate less impact, and the recall period is past 2 weeks. A change in a score of 8.9 points has been identified as the minimal clinically important difference (Hopkins, C., et al., Psychometric validity of the 22-item Sinonasal Outcome Test. *Clinical Otolaryngology*. (2009); <https://doi.org/10.1111/j.1749-4486.2009.01995.x>).

[0045] Asthma Control Questionnaire-6 (ACQ-6) is a 6-question validated participant-reported questionnaire that assess the most common asthma symptoms and is collected on a tablet at the study site only for participants with asthma. The questions include the following: Woken by asthma; Symptoms on waking; Activity limitation; Shortness of breath; Wheezing; and Puffs/inhalation use. Participants with a history of asthma are asked to recall how their asthma had been during the previous week and to respond to the questions on a 7-point scale where 0 corresponds to no impairment and 6 corresponds to maximum impairment. An ACQ-6 score is calculated from the mean of the scores and expresses a total control value out of 6, where 0 corresponds to totally controlled asthma and 6 corresponds to severely uncontrolled asthma. A minimal clinically important difference value for the ACQ-6 has been defined as a 0.5 point change (Juniper, E.F., et al., Development and validation of a questionnaire to measure asthma control. *Eur Respir J*. (1999); 14(4):902-7; Juniper, E.F., et al., Measurement properties

and interpretation of three shortened versions of the asthma control questionnaire. *Respir Med.* (2005); 99(5):553-8).

[0046] The European Quality of Life–5 Dimensions–5 Levels (EQ-5D-5L) is a generic questionnaire that assesses health status, and is collected on a tablet at the study site. It includes a descriptive system comprised of 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with each dimension having 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The questionnaire also includes a VAS scale where the respondent self-rates their health on a vertical VAS, with endpoints of “the best health you can imagine” and “the worst health you can imagine” (EuroQol Group. *EuroQol--a new facility for the measurement of health-related quality of life. Health Policy.* 1990;16(3):199-208; Herdman, M., et al., Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res.* (2011); 20(10):1727-36; Remenschneider, A.K., et al., The EQ-5D: a new tool for studying clinical outcomes in chronic rhinosinusitis. *Laryngoscope.* (2015); 125(1):7-15).

[0047] The Work Productivity and Activity Impairment plus Classroom Impairment Questions: Allergy Specific (WPAI+CIQ:AS) is a patient-reported instrument used to assess impairments in work, classroom, and regular activities in patients with AR; it is also collected on a tablet at the study site. It contains 9 items that measure the following: employment status; hours actually worked; hours missed from work due to allergies; degree allergies affected productivity while working; status of attending classes in an academic setting; hours attended school/class; hours missed from class due to allergies; degree allergies affected productivity in classroom setting; degree allergies affected regular daily activities. The WPAI+CIS:AS yields 4 sub-scores: absenteeism (work or classroom time missed); presenteeism (impairment at work or classroom / reduced on-the-job effectiveness); work productivity loss (overall work or classroom impairment/absenteeism plus presenteeism), and activity impairment. Scores are calculated as impairment percentages (Reilly, M.C., Zbrozek, A.S., Dukes, E.M. The validity and reproducibility of a work productivity and activity impairment instrument. *Pharmacoeconomics.* (1993); 4(5):353-65), with higher numbers indicating greater impairment and less productivity, i.e., worse outcomes.

[0048] The PROMIS Anxiety Short Form v1.0 – Anxiety 8a can be used with the general population and with individuals living with chronic conditions. The PROMIS Anxiety item bank

assesses self-reported fear (fearfulness, panic), anxious misery (worry, dread), hyperarousal (tension, nervousness, restlessness), and somatic symptoms related to arousal (racing heart, dizziness). The PROMIS Anxiety Short Form 8a (v1.0) includes 8 questions which assess participants' symptoms over the previous 7 days. Response options range from 1=Never; 2=Rarely; 3=Sometimes; 4=Often; 5=Always. Total raw scores are converted to T-Scores with higher scores representing greater anxiety (PROMIS Anxiety 2019, Published March 01, 2019. Accessed March 8, 2021. Available at https://www.healthmeasures.net/images/PROMIS/manuals/PROMIS_Anxiety_Scoring_Manual.pdf).

[0049] The PROMIS Depression Short Form v1.0 – Depression 8a can be used with the general population and with individuals living with chronic conditions. The PROMIS Depression item bank assesses self-reported negative mood (sadness, guilt), views on self (self-criticism, worthlessness), and social cognition (loneliness, interpersonal alienation), as well as decreased positive affect and engagement (loss of interest, meaning, and purpose). The PROMIS Depression Short Form 8a (v1.0) includes 8 questions which assess participants' symptoms over the previous 7 days. Response options range from 1=Never; 2=Rarely; 3=Sometimes; 4=Often; 5=Always. Total raw scores are converted to T-Scores with higher scores representing greater depression (PROMIS Depression 2019, Published February 28, 2019. Accessed March 8, 2021. Available at https://www.healthmeasures.net/images/PROMIS/manuals/PROMIS_Depression_Scoring_Manual.pdf).

[0050] Patient Global Impression of Severity (PGI-S) and Patient Global Impression of Change (PGI-C) scales are used to facilitate assessment of clinically meaningful within patient change for the TNSS, postnasal drip, and RQLQ(S).

[0051] The PGI-S: TNSS asks the participant to rate the overall severity of their nasal symptoms due to AR (nasal obstruction, nasal itching, sneezing, runny nose) over the past 14 days with response options of: no symptoms, mild, moderate, severe, and very severe.

[0052] The PGI-S: postnasal drip asks the participant to rate the overall severity of their postnasal drip due to AR over the past 14 days with response options of: no symptoms, mild, moderate, severe, and very severe.

[0053] The PGI-S: RQLQ(S) asks the participant to rate the overall severity of their activity limitations due to AR (regular activities at home, work or school, social, or outdoor activities) over the past 7 days with response options of: no symptoms, mild, moderate, severe, and very severe.

[0054] The PGI-C: TNSS asks the participant to describe the overall change in their nasal symptoms due to AR (nasal obstruction, nasal itching, sneezing, runny nose) since they started taking the new medication with response options of: very much better, much better, a little better, no change, a little worse, much worse, and very much worse.

[0055] The PGI-C: Postnasal drip asks the participant to describe the overall change in their postnasal drip due to AR since they started taking the new medication with response options of: very much better, much better, a little better, no change, a little worse, much worse, and very much worse.

[0056] The PGI-C: RQLQ(S) asks the participants to describe the overall change in their activity limitations due to AR since they started taking the new medication with response options of: very much better, much better, a little better, no change, a little worse, much worse, and very much worse.

[0057] The described characteristics can be measured at baseline and at one or more time points after administration of the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody. For example, they may be measured at the end of week 1, week 2, week 3, week 4, week 5, week 6, week 7, week 8, week 9, week 10, week 11, week 12, week 13, week 14, week 15, week 16, week 17, week 18, week 19, week 20, week 21, week 22, week 23, week 24, or longer after the initial treatment with the anti-IL-13 antibody or a pharmaceutical composition comprising the anti-IL-13 antibody. The difference between the value at a particular time point following initiation of treatment and the value at baseline is used to establish whether there has been an improvement (e.g., a reduction) in the characteristics.

[0058] In another aspect, provided herein are an anti-IL-13 antibody or pharmaceutical composition comprising an anti-IL-13 antibody for use in the treatment of perennial allergic rhinitis. Also provided herein are uses of an anti-IL-13 antibody in the manufacture of a medicament for the treatment of perennial allergic rhinitis.

[0059] As used herein, the term “a,” “an,” “the” and similar terms used in the context of the present disclosure (especially in the context of the claims) are to be construed to cover both the singular and plural unless otherwise indicated herein or clearly contradicted by the context.

[0060] The term “about” as used herein, means in reasonable vicinity of the stated numerical value, such as plus or minus 10% of the stated numerical value.

[0061] The term “antibody,” as used herein, refers to an immunoglobulin molecule that binds an antigen. Embodiments of an antibody include a monoclonal antibody, polyclonal antibody, human antibody, humanized antibody, chimeric antibody, or conjugated antibody. The antibodies can be of any class (e.g., IgG, IgE, IgM, IgD, IgA) and any subclass (e.g., IgG1, IgG2, IgG3, IgG4).

[0062] An exemplary antibody is an immunoglobulin G (IgG) type antibody comprised of four polypeptide chains: two heavy chains (HC) and two light chains (LC) that are cross-linked via inter-chain disulfide bonds. The amino-terminal portion of each of the four polypeptide chains includes a variable region of about 100-125 or more amino acids primarily responsible for antigen recognition. The carboxyl-terminal portion of each of the four polypeptide chains contains a constant region primarily responsible for effector function. Each heavy chain is comprised of a heavy chain variable region (VH) and a heavy chain constant region. Each light chain is comprised of a light chain variable region (VL) and a light chain constant region. The IgG isotype may be further divided into subclasses (e.g., IgG1, IgG2, IgG3, and IgG4).

[0063] The VH and VL regions can be further subdivided into regions of hyper-variability, termed complementarity determining regions (CDRs), interspersed with regions that are more conserved, termed framework regions (FR). The CDRs are exposed on the surface of the protein and are important regions of the antibody for antigen binding specificity. Each VH and VL is composed of three CDRs and four FRs, arranged from amino-terminus to carboxyl-terminus in the following order: FR1, CDR1, FR2, CDR2, FR3, CDR3, FR4. Herein, the three CDRs of the heavy chain are referred to as “HCDR1, HCDR2, and HCDR3” and the three CDRs of the light chain are referred to as “LCDR1, LCDR2 and LCDR3”. The CDRs contain most of the residues that form specific interactions with the antigen. Assignment of amino acid residues to the CDRs may be done according to the well-known schemes, including those described in Kabat (Kabat et al., Sequences of Proteins of Immunological Interest, National Institutes of Health, Bethesda, Md. (1991)), Chothia (Chothia, et al., Canonical structures for the hypervariable regions of

immunoglobulins, *Journal of Molecular Biology*, 196, 901-917 (1987); Al-Lazikani, et al., Standard conformations for the canonical structures of immunoglobulins, *Journal of Molecular Biology*, 273, 927-948 (1997)), North (North, et al., A New Clustering of Antibody CDR Loop Conformations, *Journal of Molecular Biology*, 406, 228-256 (2011)), or IMGT (the international ImMunoGeneTics database available on at www.imgt.org; see, Lefranc, et al., *Nucleic Acids Res.* 1999; 27:209-212).

[0064] Exemplary embodiments of antibodies of the present disclosure also include antibody fragments or antigen-binding fragments, which comprise at least a portion of an antibody retaining the ability to specifically interact with an antigen such as Fab, Fab', F(ab')₂, Fv fragments, scFv, scFab, disulfide-linked Fvs (sdFv), a Fd fragment and linear antibodies.

[0065] The term “anti-IL-13 antibody”, as used herein, refers to an antibody that specifically binds human IL-13. In some embodiments, an anti-IL-13 antibody binds human IL-13 with a dissociation constant (K_D) of $\leq 1\mu\text{M}$, $\leq 100\text{ nM}$, $\leq 10\text{ nM}$, $\leq 1\text{ nM}$, $\leq 0.1\text{ nM}$, or $\leq 0.01\text{ nM}$, (e.g., 10^{-8} M or less, or 10^{-9} M or less).

[0066] The term “baseline”, as used herein, means prior to or at the time of administration of the first dose of the anti-IL-13 antibody (week 0) or a pharmaceutical composition comprising the anti-IL-13 antibody.

[0067] The terms “bind” and “binds” as used herein are intended to mean, unless indicated otherwise, the ability of a protein or molecule to form a chemical bond or attractive interaction with another protein or molecule, which results in proximity of the two proteins or molecules as determined by common methods known in the art.

[0068] An “effective amount” of an agent refers to an amount effective, at dosages and for periods of time necessary, to achieve the desired treatment result.

[0069] The term “IL-13”, as used herein, refers to any interleukin-13 isoform from human, unless otherwise indicated. The term encompasses “full-length”, unprocessed IL-13 as well as any form of IL-13 that results from processing in the cell. The term also encompasses naturally occurring variants of IL-13, e.g., splice variants or allelic variants. The amino acid sequences of exemplary human IL-13 are known, e.g., NCBI Accession Nos. NP_002179.2, NP_001341920.1, NP_001341921.1, NP_001341922.1; UniProtKB Accession No. P35225.

[0070] The term “loading dose” means a dose of a drug given at the beginning of a course of treatment that is higher than the dose given subsequently, and each dose given for the remainder of the treatment.

[0071] The term “maintenance dose” refers to a subsequent dose of a drug administered to a patient to maintain or continue a desired therapeutic effect.

[0072] The term “patient”, as used herein, refers to a human patient.

[0073] The term "Perennial Allergic Rhinitis (PAR)" is well-known in the art and is generally considered a type 2 inflammation-mediated disease (Giavina-Bianchi P, et al., United airway disease: current perspectives. J Asthma Allergy. (2016); 9:93-100). As used herein, PAR is intended to refer to the same or essentially the same disease or condition known in the art as allergic rhinitis triggered by perennial allergens.

[0074] As used herein, “treatment” or “treating” refers to all processes wherein there may be a slowing, controlling, delaying, or stopping of the progression of the disorders or disease disclosed herein, or ameliorating disorder or disease symptoms, but does not necessarily indicate a total elimination of all disorder or disease symptoms. Treatment includes administration of a protein or nucleic acid or vector or composition for treatment of a disease or condition in a patient, particularly in a human.

EXAMPLES

Example 1. A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Lebrikizumab in Adult Participants with Perennial Allergic Rhinitis.

[0075] This is a Phase 3, multinational, multicenter, double-blinded, PBO-controlled, parallel group, randomized clinical study to assess the efficacy and safety of lebrikizumab in approximately 450 adult (>18 years of age) participants with PAR whose disease is not adequately controlled with standard-of-care treatment (INCS with or without OAH, INAH, or combination eye drops of AHs, and/or mast cell stabilizers, or have both of these properties for the treatment of allergic symptoms).

[0076] This study has four study periods: Screening (up to 30 days), Run-in (4 weeks), Randomized treatment (56 weeks), which includes an induction period (16 weeks; Week 0 to Week 16) and maintenance period (40 weeks; Week 16 to Week 56), and Safety follow-up

(SFU) (8 weeks), starting after the study site visit at Week 56. The maximum planned duration of study participation for each participant is up to approximately 72 weeks.

[0077] Objectives and Endpoints:

[0078] The primary, secondary and exploratory objectives and endpoints of this study are shown in Table 2.

Table 2. Objectives and Endpoints

Objectives	Endpoints
Primary Objective: To evaluate the efficacy of lebrikizumab 250 mg Q2W up to Week 16 on total nasal symptoms compared with PBO	Primary Endpoint: Total Nasal Symptom Score (TNSS) mean change from baseline (CFBL) to Week 16
Key Secondary Objectives: - To evaluate the efficacy of lebrikizumab 250 mg Q2W up to Week 16 compared with PBO - To evaluate the long-term efficacy of lebrikizumab 250 mg Q4W and Q8W up to Week 56, after 250 mg Q2W through Week 16, compared with PBO	Key Secondary Endpoints: - RQLQ(S) mean CFBL to Week 16 - RQLQ(S) mean CFBL to Week 56 - TNSS score mean CFBL to Week 4 - TNSS score mean CFBL to Week 56 - Postnasal drip score mean CFBL to Week 16

Other Secondary Objectives: To compare the efficacy of lebrikizumab to PBO as measured by clinician assessments, and as assessed by participant-reported outcomes and quality of life measures	Other Secondary Endpoints: - Proportion of participants requiring use of rescue medication by visit - Sleep domain of RQLQ(S) mean CFBL by visit - Mean CFBL in TNSS and its 4 components by visit - Proportion of participants with 50% reduction in TNSS by visit - Proportion of participants with ≥ 1.0-point improvement in the RQLQ(S) by visit - Mean CFBL in RQLQ(S) by visit - Mean CFBL in postnasal drip score by visit - Mean CFBL in NPIF by visit - Mean CFBL in FEV₁ by visit - Mean CFBL in TOSS by visit - Mean CFBL in SNOT-22 by visit - Mean CFBL in VAS for AR Control by visit - Mean CFBL in PROMIS Anxiety Short Form by visit - Mean CFBL in PROMIS Depression Short Form by visit - Mean CFBL in ACQ-6 by visit - Mean CFBL in WPAI+CIQ:AS by visit - Mean CFBL in EQ-5D-5L by visit - Mean CFBL in PGI-S by scale by visit - Mean PGI-C by scale by visit
Safety Objectives: To describe the safety and tolerability of lebrikizumab	Safety Endpoints: - Incidence of adverse events and serious adverse events - Postbaseline values and changes over time of clinical laboratory evaluations - Postbaseline values and changes over time of vital signs

Exploratory Objectives: • To characterize the pharmacokinetics of lebrikizumab over the course of the study • To characterize immunogenicity and changes in exploratory biomarkers over the course of the study • To characterize change in reaction to the SPT and/or antigen-specific IgE as a function of treatment • To analyze genetic variation in relation to drug response (optional)	Exploratory Endpoints • Serum concentration of lebrikizumab at identified visits • Immunogenicity (antidrug antibodies), total immunoglobulin E (IgE), and nasal and blood biomarkers at identified visits • Change from screening in reaction to the SPT/antigen-specific IgE at Week 56 • Pharmacogenomic analysis
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Patient Population

The inclusion and exclusion criteria for enrolling participants in this study are described in the following sections.

[0079] Inclusion Criteria: Each participant must meet all of the following criteria to be enrolled in this study:

1. Adult participants ≥ 18 years of age at time of signing the informed consent form (ICF).
2. Physician-diagnosed PAR, requiring treatment to control persistent symptoms on most days for more than 12 weeks per year for at least 2 consecutive years. The participant must have a history of inadequate response to INCS, with or without background therapy despite its regular or consistent use, i.e., presence of moderate or severe nasal symptoms with a TNSS score ≥ 8 both at screening (Visit 1) and at randomization (Visit 3) (averaged over 2 weeks prior to randomization [Visit 3], measured at least 4 days per week).
3. At screening, have a positive skin prick test (SPT) with indoor allergens (mean wheal diameter at least 5 mm greater than the negative control) and/or positive antigen-specific serum IgE for indoor allergens (eg, pet, mold, dust mites, cockroach, horse) ≥ 0.70 kU/L, utilizing a validated assay (central laboratory) where in addition, one of the following is true:
 - a. The participant must be allergic to at least 1 of the dust mite species, **or**

- b. The participant must be exposed for the duration of the study to at least 1 of the other (not dust mite) perennial allergens that elicited a positive SPT and/or a positive antigen-specific serum IgE. (Note: Participants positive to mold only are not eligible), **or**
 - c. The participant must have clinical symptoms associated with positive perennial allergen as tested by the SPT or a positive antigen-specific serum test.
- 4. A dermatographic participant who has a known history of dermatographism or identified during the SPT may participate in this study with a positive serum IgE test.
 - 5. Participants who have concomitant asthma must be stable in the 3 months prior to screening using permitted regular asthma treatment.
 - 6. For women of childbearing potential (WOCBP), highly effective contraceptive use should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. WOCBP and women not of childbearing potential (WNOCBP) may participate in this study.
 - 7. The participant must understand the investigational nature of this study and sign an Institutional Ethics Committee (IEC)/Institutional Review Board (IRB)-approved written informed consent prior to receiving any study-related procedure.
 - 8. Is willing and able to comply with all clinic visits, study-related procedures, and questionnaires, importantly including taking required background medication and completing a daily eDiary.
 - 9. Participants must complete their eDiaries 4 out of 7 days every week in the 2 weeks prior to randomization visit (Visit 3 [baseline]).

[0080] Exclusion Criteria: Participants meeting any of the following criteria are excluded from the study:

- 1. Has received a dose of lebrikizumab.
- 2. Is currently enrolled in any other clinical study involving an investigational drug or any other type of medical research judged not to be scientifically or medically compatible with this study.
- 3. Has received treatment with an investigational drug within 8 weeks or within 5 half-lives (if known), whichever is longer, prior to randomization.
- 4. Has a known hypersensitivity to any component of lebrikizumab or its excipients.

5. Has a contraindication or intolerance to mometasone furoate or any background medication that is taken during the study.
6. Is currently on allergen immunotherapy (subcutaneous or sublingual immunotherapy [SCIT/SLIT]). However, individuals who discontinued SCIT/SLIT for ≥ 3 years prior to randomization are eligible, if they were not on maintenance AIT regimen.
7. Has received treatment with any rescue medication during the screening and run-in period.
8. Has received treatment with any biologic or systemic immunosuppressants for inflammatory disease or autoimmune disease (e.g., rheumatoid arthritis, inflammatory bowel disease, primary biliary cirrhosis, systemic lupus erythematosus, multiple sclerosis) prior to the baseline (Visit 3; randomization), including the following:
 - B Cell-depleting biologics, including rituximab, within 6 months.
 - Other biologics within 5 half-lives (if known) or 8 weeks, whichever is longer.
 - Systemic immunosuppressants within 4 weeks prior to baseline (Visit 3).
9. A participant with a history of seasonal worsening of AR is excluded if the seasonal worsening is expected during the 4-week run-in period, the first 16 weeks after randomization (induction period), or during the last 4 weeks of the maintenance period (Week 52 through Week 56).
10. Anticipates significant changes in their daily environmental exposure for >2 consecutive weeks within the 2 weeks preceding Week 16 or within the 4 weeks preceding Week 56.
11. Has a known history of recurrent acute or chronic sinusitis defined as requiring treatment with systemic antibiotics within the 3 months preceding screening or more than 4 times within the 2 years preceding screening.
12. Has a known history of ≥ 2 severe asthma exacerbations in the previous year, with severe asthma exacerbation defined as any asthma worsening that requires systemic corticosteroids for at least 3 days and/or a need for hospitalization. A single parenteral dose of corticosteroids for asthma worsening would also be considered a severe exacerbation.
13. Has a history of nasal polyps or nasal polyps present at screening (Visit 1).
14. Has a moderate-to-severe nasal septum deviation.

15. Has had any sinus/nasal surgery within 12 months prior to screening (Visit 1) or has a planned surgery during the study.
16. Has a known history of rhinitis secondary to other causes (e.g. rhinitis medicamentosa, vasomotor rhinitis).
17. Has received any live or live-attenuated vaccine (including Bacillus Calmette-Guerin vaccine or treatment) within 4 weeks of the baseline (Visit 3) or intend to receive a live or live-attenuated vaccine (or Bacillus Calmette-Guerin treatment) during the study, or within 4 weeks after receiving the last dose of IP. NOTE: The following are not considered live vaccines: messenger RNA vaccines, vaccines with inactive viral elements, and/or non-replicating viral vector vaccines.
18. Has a known history of HIV infection or positive HIV serology.
19. Has a current infection or chronic infection with hepatitis B virus (HBV) (that is, positive for hepatitis B surface antigen (HBsAg) and/or polymerase chain reaction positive).
20. Has a current infection with hepatitis C virus (HCV) (positive for HCV RNA).
21. Has known liver cirrhosis and/or chronic hepatitis of any etiology.
22. Is diagnosed with active endoparasitic infections or at high risk of these infections.
23. Has a known or suspected history of immunosuppression, including history of invasive opportunistic infections (e.g., tuberculosis [TB], histoplasmosis, listeriosis, coccidioidomycosis, pneumocystosis, and aspergillosis) despite infection resolution; or unusually frequent, recurrent, or prolonged infections, in the opinion of the investigator.
24. Has had any of the following types of infection within 3 months of screening or develop any of these infections during screening or the run-in period:
 - a. Serious (requiring hospitalization, and/or IV or equivalent oral antibiotic treatment).
 - b. Opportunistic [as defined in Winthrop KL, Novosad SA, Baddley JW, et al. Opportunistic infections and biologic therapies in immune-mediated inflammatory diseases: consensus recommendations for infection reporting during clinical trials and postmarketing surveillance. *Ann Rheum Dis*. 2015; 74(12):2107-16].
 - c. Symptomatic herpes zoster infection not resolved at the time of screening. NOTE: Herpes zoster is considered active and ongoing until all vesicles are dry and crusted over.
 - d. Chronic (duration of symptoms, signs, and/or treatment of 6 weeks or longer).

- e. Recurring (including, but not limited to recurring cellulitis, chronic osteomyelitis)
Participants with only recurrent, mild, and uncomplicated orolabial and/or genital herpes may be permitted at the medical monitor's discretion.
25. Has an active or acute infection requiring treatment with systemic antibiotics, antivirals, antiparasitics, antiprotozoals, or antifungals within 2 weeks before the baseline (Visit 3).
NOTE: Participants may be rescreened after infections resolves. A participant who has a vaginal candida infection, or an oral candida infection and who are being treated only symptomatically and not requiring systemic anti-infectives may be considered for enrollment if other study eligibility criteria are met. Enrollment of participants with other uncomplicated local infections should be discussed with the sponsor's designated medical monitor.
26. Has a history of malignancy within 5 years before screening (Visit 1; exceptions include adequately treated basal cell or squamous cell skin cancer, carcinoma in situ of the cervix).
27. Has any other medical or psychological condition that, in the opinion of the investigator, may suggest a new and/or insufficiently understood disease, may present an unreasonable risk to the study participant because of their participation in this clinical study, may make the participant's participation unreliable, or may interfere with study assessments.
28. Has a severe concomitant illness(es) that, in the opinion of the investigator, would adversely affect participation in the study.
29. In the opinion of the investigator, has clinically significant laboratory results from the chemistry or hematology tests obtained at screening (Visit 1) or at baseline (Visit 3).
30. Female participant who is pregnant or breastfeeding or are planning to become pregnant or to breastfeed during the study.
31. Has a recent nose piercing that has not completely healed and could lead to nasal symptoms at the time of screening (Visit 1) or planning a new nose piercing during study participation.
32. Is a Lilly employee, family of a Lilly employee, or is an employee of any third party involved in the study who require exclusion of their employees.

33. Is an investigator study site staff directly affiliated with this study and/or their immediate families where immediate family is defined as a spouse, parent, child, or sibling, whether biological or legally adopted.
34. Is a participant or caregiver unable or unwilling to make themselves available for the duration of the study or are unwilling to follow study restrictions and procedures, including subcutaneous administration of study medication.
35. Has a history of chronic alcohol abuse, intravenous drug abuse, or other illicit drug abuse within the 2 years prior to screening.
36. Is otherwise unsuitable for inclusion in the study in the opinion of the investigator.

Study Drug:

[0081] Pharmaceutical compositions containing 125 mg/mL lebrikizumab or placebo are supplied as sterile pre-filled syringes with a pre-assembled needle safety device (PFS-NSD) for subcutaneous administration to the patients. Lebrikizumab sequences are provided in Table 1. The placebo solution is identical in appearance and volume to the active solution except that it does not contain lebrikizumab.

[0082] INCS mometasone furoate nasal spray is administered at 100 µg (2 sprays, 50 µg in each nostril) daily.

Study Design:

[0083] The study design of this trial is shown in Figure 1.

[0084] Individuals meeting the inclusion and exclusion criteria are randomly assigned 1:1:1 using an interactive web response system to the following treatment arms after the screening and run-in periods, at baseline (Visit 3):

- Lebrikizumab Q2W/Q4W arm: lebrikizumab 500 mg loading dose at Week 0 and Week 2, followed by lebrikizumab 250 mg Q2W through Week 16 (induction period) and then lebrikizumab 250 mg Q4W to Week 56 (maintenance period).
- Lebrikizumab Q2W/Q8W arm: lebrikizumab 500 mg loading dose at Week 0 and Week 2, followed by lebrikizumab 250 mg Q2W through Week 16 (induction period) and then lebrikizumab 250 mg Q8W to Week 56 (maintenance period). To maintain the blind,

participants receive doses of PBO at 8-week intervals, starting 4 weeks after the dose at Week 16.

- PBO arm: PBO Q2W through Week 16 (induction period) and PBO Q4W to Week 56 (maintenance period).

[0085] Randomization is stratified by the following factors:

- Allergic rhinitis classification (PAR, PAR + seasonal AR [defined as positive to 1 perennial allergen and 1 seasonal allergen]). Allergic rhinitis classification is based on the SPT and/or serum IgE at study entry. PAR: participants with sensitization of indoor allergen(s) and no sensitization with seasonal allergens; PAR + seasonal AR: participants with sensitization of indoor allergen(s) and sensitization to at least 1 seasonal allergen;
- Region (North America, Europe, rest of world); and
- Baseline use of oral antihistamine (OAH)/ intranasal antihistamine (INAH) (INAH use, OAH but no INAH, no OAH or INAH).

[0086] Participants, investigators, and study site staff are fully blinded to treatment arm.

[0087] Intranasal mometasone furoate is required as background medication during the 4-week run-in period as well as throughout the randomized treatment period (Week 0 to Week 56).

Additional background medication may also be provided throughout the study, starting at the beginning of the run-in period. Participants may continue background medication (including mometasone furoate) during the safety follow-up period at the discretion of the investigator.

[0088] Statistical analyses are performed for the primary, secondary and exploratory endpoints.

CLAIMS

1. A method of treating perennial allergic rhinitis in a patient in need thereof, the method comprising administering to the patient a therapeutically effective amount of an anti-IL-13 antibody, wherein the anti-IL-13 antibody comprises a heavy chain variable region (VH) and a light chain variable region (VL), wherein the VH comprises a HCDR1 comprising SEQ ID NO: 1, a HCDR2 comprising SEQ ID NO: 2, and a HCDR3 comprising SEQ ID NO: 3, and the VL comprises a LCDR1 comprising SEQ ID NO: 4, a LCDR2 comprising SEQ ID NO: 5, and a LCDR3 comprising SEQ ID NO: 6.
2. A method of treating perennial allergic rhinitis, the method comprising:
selecting a patient who has perennial allergic rhinitis, and administering to the patient a therapeutically effective amount of an anti-IL-13 antibody, wherein the anti-IL-13 antibody comprises a heavy chain variable region (VH) and a light chain variable region (VL), wherein the VH comprises a HCDR1 comprising SEQ ID NO: 1, a HCDR2 comprising SEQ ID NO: 2, and a HCDR3 comprising SEQ ID NO: 3, and the VL comprises a LCDR1 comprising SEQ ID NO: 4, a LCDR2 comprising SEQ ID NO: 5, and a LCDR3 comprising SEQ ID NO: 6.
3. The method of claim 1 or 2, wherein the anti-IL-13 antibody comprises a VH comprising SEQ ID NO: 7, and a VL comprising SEQ ID NO: 8.
4. The method of any one of claims 1-3, wherein the anti-IL-13 antibody comprises a heavy chain comprising SEQ ID NO: 9, and a light chain comprising SEQ ID NO: 10.
5. The method of any one of claims 1-4, wherein the anti-IL-13 antibody is lebrikizumab.
6. The method of any one of claims 1-5, wherein the anti-IL-13 antibody is administered subcutaneously to the patient.
7. The method of any one of claims 1-6, wherein the anti-IL-13 antibody is administered at a dose of 250 mg to 500 mg.
8. The method of any one of claims 1-7, wherein the anti-IL-13 antibody is administered subcutaneously to the patient at a dose of 250 mg once every two weeks.
9. The method of claim 8, wherein the patient is further treated with a loading dose of 500 mg of the anti-IL-13 antibody.

10. The method of claim 9, wherein the loading dose is administered to the patient at week 0 and week 2.
11. The method of any one of claims 1-10, wherein the patient is treated with the anti-IL-13 antibody for a period of about 16 weeks.
12. The method of any one of claims 1-11, wherein the patient is further treated for a maintenance period of about 40 weeks.
13. The method of claim 12, wherein the patient is treated with a maintenance dose of 250 mg of the anti-IL-13 antibody once every four weeks during the maintenance period.
14. The method of claim 12, wherein the patient is treated with a maintenance dose of 250 mg of anti-IL-13 antibody once every eight weeks during the maintenance period.
15. The method of any one of claims 1-14, further comprising determining the total nasal symptom score (TNSS) of the patient before, during, and after the treatment.
16. The method of any one of claims 1-14, further comprising determining the Rhinoconjunctivitis Quality of Life Questionnaire Standardized Version (RQLQ(S)) score of the patient before, during, and after the treatment.
17. The method of any one of claims 1-14, further comprising determining the postnasal drip score of the patient before, during, and after the treatment.
18. The method of any one of claims 1-17, wherein the anti-IL-13 antibody is administered to the patient using a subcutaneous administration device.
19. The method of claim 18, wherein the subcutaneous administration device is selected from a prefilled syringe, disposable pen injection device, microneedle device, microinfuser device, needle-free injection device, or autoinjector device.
20. The method of any one of claims 1-19, further comprising administering an intranasal corticosteroid to the patient.
21. The method of claim 20, wherein the intranasal corticosteroid is mometasone furoate.
22. The method of claim 20 or 21, wherein the intranasal corticosteroid is administered simultaneously, concurrently, or sequentially with the anti-IL-13 antibody.

23. The method of any one of claims 1-22, wherein the patient had a history of inadequate response to intranasal corticosteroid before the treatment.
24. The method of any one of claims 1-23, wherein the patient has moderate or severe nasal symptoms with a TNSS score ≥ 8 before the treatment.
25. The method of any one of claims 1-24, wherein the patient is aged 18 years or older.
26. An anti-IL-13 antibody for use in the treatment of perennial allergic rhinitis, wherein the anti-IL-13 antibody comprises a heavy chain variable region (VH) and a light chain variable region (VL), wherein the VH comprises a HCDR1 comprising SEQ ID NO: 1, a HCDR2 comprising SEQ ID NO: 2, and a HCDR3 comprising SEQ ID NO: 3, and the VL comprises a LCDR1 comprising SEQ ID NO: 4, a LCDR2 comprising SEQ ID NO: 5, and a LCDR3 comprising SEQ ID NO: 6.
27. A pharmaceutical composition comprising an anti-IL-13 antibody for use in the treatment of perennial allergic rhinitis, wherein the anti-IL-13 antibody comprises a heavy chain variable region (VH) and a light chain variable region (VL), wherein the VH comprises a HCDR1 comprising SEQ ID NO: 1, a HCDR2 comprising SEQ ID NO: 2, and a HCDR3 comprising SEQ ID NO: 3, and the VL comprises a LCDR1 comprising SEQ ID NO: 4, a LCDR2 comprising SEQ ID NO: 5, and a LCDR3 comprising SEQ ID NO: 6.
28. Use of an anti-IL-13 antibody in the manufacture of a medicament for the treatment of perennial allergic rhinitis, wherein the anti-IL-13 antibody comprises a heavy chain variable region (VH) and a light chain variable region (VL), wherein the VH comprises a HCDR1 comprising SEQ ID NO: 1, a HCDR2 comprising SEQ ID NO: 2, and a HCDR3 comprising SEQ ID NO: 3, and the VL comprises a LCDR1 comprising SEQ ID NO: 4, a LCDR2 comprising SEQ ID NO: 5, and a LCDR3 comprising SEQ ID NO: 6.
29. The anti-IL-13 antibody for use of claim 26, wherein the anti-IL-13 antibody comprises a VH comprising SEQ ID NO: 7, and a VL comprising SEQ ID NO: 8.
30. The anti-IL-13 antibody for use of claim 26 or 29, wherein the anti-IL-13 antibody comprises a heavy chain comprising SEQ ID NO: 9, and a light chain comprising SEQ ID NO: 10.
31. The anti-IL-13 antibody for use of any one of claims 26, 29 or 30, wherein the anti-IL-13 antibody is lebrikizumab.

32. The anti-IL-13 antibody for use of any one of claims 26 or 29-31, wherein the anti-IL-13 antibody is administered subcutaneously to the patient.
33. The anti-IL-13 antibody for use of any one of claims 26 or 29-32, wherein the anti-IL-13 antibody is administered at a dose of 250 mg to 500 mg.
34. The anti-IL-13 antibody for use of any one of claims 26 or 29-33, wherein the anti-IL-13 antibody is administered subcutaneously at a dose of 250 mg once every two weeks.
35. The anti-IL-13 antibody for use of any one of claims 34, wherein the anti-IL-13 antibody is further administered at a loading dose of 500 mg.
36. The anti-IL-13 antibody for use of claim 35, wherein the loading dose is administered at week 0 and week 2.
37. The anti-IL-13 antibody for use of any one of claims 26 or 29-36, wherein the anti-IL-13 antibody is administered for a period of about 16 weeks.
38. The anti-IL-13 antibody for use of any one of claims 26 or 29-37, wherein the anti-IL-13 antibody is further administered for a maintenance period of about 40 weeks.
39. The anti-IL-13 antibody for use of claim 38, wherein the anti-IL-13 antibody is administered at a dose of 250 mg of the anti-IL-13 antibody once every four weeks during the maintenance period.
40. The anti-IL-13 antibody for use of claim 38, wherein the anti-IL-13 antibody is administered at a dose of 250 mg of the anti-IL-13 antibody once every eight weeks during the maintenance period.
41. The anti-IL-13 antibody for use of any one of claims 26 or 29-40, further comprising determining the total nasal symptom score (TNSS) of the patient before, during, and after the treatment.
42. The anti-IL-13 antibody for use of any one of claims 26 or 29-41, further comprising determining the Rhinoconjunctivitis Quality of Life Questionnaire Standardized Version (RQLQ(S)) score of the patient before, during, and after the treatment.
43. The anti-IL-13 antibody for use of any one of claims 26 or 29-41, further comprising determining the postnasal drip score of the patient before, during, and after the treatment.

44. The anti-IL-13 antibody for use of any one of claims 26 or 29-43, wherein the anti-IL-13 antibody is administered using a subcutaneous administration device.
45. The anti-IL-13 antibody for use of claim 44, wherein the subcutaneous administration device is selected from a prefilled syringe, disposable pen injection device, microneedle device, microinfuser device, needle-free injection device, or autoinjector device.
46. The anti-IL-13 antibody for use of any one of claims 26 or 29-45, further comprising administering an intranasal corticosteroid.
47. The anti-IL-13 antibody for use of any one of claim 46, wherein the intranasal corticosteroid is mometasone furoate.
48. The anti-IL-13 antibody for use of claim 46 or 47, wherein the intranasal corticosteroid is administered simultaneously, concurrently, or sequentially with the anti-IL-13 antibody.
49. The anti-IL-13 antibody for use of any one of claims 26 or 29-48, wherein the patient had a history of inadequate response to intranasal corticosteroid before the treatment.
50. The anti-IL-13 antibody for use of any one of claims 26 or 29-49, wherein the patient has moderate or severe nasal symptoms with a TNSS score ≥ 8 before the treatment.
51. The anti-IL-13 antibody for use of any one of claims 26 or 29-50, wherein the patient is aged 18 years or older.