

CLAIMS

What is claimed is:

1. A method of treating a patient having asthma, the method comprising administering to a patient having asthma an anti-tryptase beta antibody in a dosing regimen comprising a dosing cycle, wherein the dosing cycle comprises a first dose (C1D1) of the anti-tryptase beta antibody selected from 300 mg intravenously (IV), 450 mg IV, 750 mg SC, 900 mg IV, 1350 mg IV, 1800 mg IV, or 3600 mg IV, wherein the anti-tryptase beta antibody comprises the following six complementarity determining regions (CDRs):

- (a) an CDR-H1 comprising the amino acid sequence of DYGMV (SEQ ID NO: 1);
- (b) an CDR-H2 comprising the amino acid sequence of FISSGSSTVYYADTMKG (SEQ ID NO: 2);
- (c) an CDR-H3 comprising the amino acid sequence of RNYDDWYFDV (SEQ ID NO: 3);
- (d) an CDR-L1 comprising the amino acid sequence of SASSSVTYMY (SEQ ID NO: 4);
- (e) an CDR-L2 comprising the amino acid sequence of RTSDLAS (SEQ ID NO: 5); and
- (f) an CDR-L3 comprising the amino acid sequence of QHYHSYPLT (SEQ ID NO: 6).

2. The method of claim 1, wherein the antibody comprises (a) a heavy chain variable (VH) domain comprising an amino acid sequence having at least 90%, at least 95%, or at least 99% sequence identity to the amino acid sequence of SEQ ID NO: 7; (b) a light chain variable (VL) domain comprising an amino acid sequence having at least 90%, at least 95%, or at least 99% identity to the amino acid sequence of SEQ ID NO: 8; or (c) a VH domain as in (a) and a VL domain as in (b).

3. The method of claim 2, wherein the VH domain comprises the amino acid sequence of SEQ ID NO: 7.

4. The method of claim 2, wherein the VL domain comprises the amino acid sequence of SEQ ID NO: 8.

5. The method of claim 2, wherein the VH domain comprises the amino acid sequence of SEQ ID NO: 7 and the VL domain comprises the amino acid sequence of SEQ ID NO: 8.

6. The method of any one of claims 1-5, wherein the antibody comprises (a) a heavy chain comprising the amino acid sequence of SEQ ID NO: 9 and (b) a light chain comprising the amino acid sequence of SEQ ID NO: 10.

7. The method of any one of claims 1-5, wherein the antibody comprises (a) a heavy chain comprising the amino acid sequence of SEQ ID NO: 11 and (b) a light chain comprising the amino acid sequence of SEQ ID NO: 10.

8. The method of any one of claims 1-7, wherein the C1D1 is 300 mg IV.

9. The method of any one of claims 1-7, wherein the C1D1 is 450 mg IV.

10. The method of any one of claims 1-7, wherein the C1D1 is 750 mg SC.
11. The method of any one of claims 1-7, wherein the C1D1 is 900 mg IV.
12. The method of any one of claims 1-7, wherein the C1D1 is 1350 mg IV.
13. The method of any one of claims 1-7, wherein the C1D1 is 1800 mg IV.
14. The method of any one of claims 1-7, wherein the C1D1 is 3600 mg IV.
15. The method of any one of claims 1-14, wherein the dosing cycle further comprises a second dose (C1D2) and a third dose (C1D3) of the anti-tryptase beta antibody, wherein the C1D2 and the C1D3 are each equal to the C1D1.
16. The method of claim 15, wherein the doses of the dosing cycle are administered to the subject every four weeks (q4w).
17. The method of claim 15 or 16, wherein the dosing cycle has a length of about 57 days.
18. The method of claim 17, wherein the C1D1 is administered on Day 1 of the dosing cycle, the C1D2 is administered on Day 29 of the dosing cycle, and the C1D3 is administered on Day 57 of the dosing cycle.
19. The method of any one of claims 15-18, wherein the dosing regimen consists of one dosing cycle.
20. A method of treating a patient having asthma, the method comprising administering to a patient having asthma an anti-tryptase beta antibody in a dosing regimen comprising a dosing cycle, wherein the dosing cycle comprises administering 1800 mg IV of the anti-tryptase beta antibody to the patient every four weeks (q4w), wherein the anti-tryptase beta antibody comprises the following six CDRs:
 - (a) an CDR-H1 comprising the amino acid sequence of DYGMV (SEQ ID NO: 1);
 - (b) an CDR-H2 comprising the amino acid sequence of FISSGSSTVYYADTMKG (SEQ ID NO: 2);
 - (c) an CDR-H3 comprising the amino acid sequence of RNYDDWYFDV (SEQ ID NO: 3);
 - (d) an CDR-L1 comprising the amino acid sequence of SASSSVTYMY (SEQ ID NO: 4);
 - (e) an CDR-L2 comprising the amino acid sequence of RTSDLAS (SEQ ID NO: 5); and
 - (f) an CDR-L3 comprising the amino acid sequence of QHYHSYPLT (SEQ ID NO: 6).
21. The method of any one of claims 1-20, wherein the asthma is moderate asthma, severe asthma, allergic asthma, or atopic asthma.

22. The method of claim 21, wherein the severe asthma is uncontrolled despite standard-of-care therapy.

23. The method of any one of claims 1-20, wherein the asthma is moderate to severe asthma.

24. The method of any one of claims 1-23, wherein the patient is receiving daily inhaled corticosteroid therapy and at least one of the following controller medications: a long-acting β -agonist (LABA), a leukotriene modulator, a long-acting muscarinic antagonist (LAMA), or a long-acting theophylline preparation.

25. The method of claim 24, wherein the leukotriene modulator is a leukotriene modifier (LTM) or leukotriene receptor antagonist (LTRA).

26. A kit comprising an anti-tryptase beta antibody and instructions to administer the anti-tryptase beta antibody to a patient having asthma in accordance with the method of any one of claims 1-25.

27. An anti-tryptase beta antibody for use in treating a patient having asthma, wherein the anti-tryptase beta antibody is for administration to a patient having asthma in a dosing regimen comprising a dosing cycle, wherein the dosing cycle comprises a first dose (C1D1) of the anti-tryptase beta antibody selected from 300 mg IV, 450 mg IV, 750 mg SC, 900 mg IV, 1350 mg IV, 1800 mg IV, or 3600 mg IV, wherein the anti-tryptase beta antibody comprises the following six CDRs:

- (a) an CDR-H1 comprising the amino acid sequence of DYGMV (SEQ ID NO: 1);
- (b) an CDR-H2 comprising the amino acid sequence of FISSGSSTVYYADTMKG (SEQ ID NO: 2);
- (c) an CDR-H3 comprising the amino acid sequence of RNYDDWYFDV (SEQ ID NO: 3);
- (d) an CDR-L1 comprising the amino acid sequence of SASSSVTYMY (SEQ ID NO: 4);
- (e) an CDR-L2 comprising the amino acid sequence of RTSDLAS (SEQ ID NO: 5); and
- (f) an CDR-L3 comprising the amino acid sequence of QHYHSYPLT (SEQ ID NO: 6).

28. The anti-tryptase beta antibody for use of claim 27, wherein the antibody comprises (a) a heavy chain variable (VH) domain comprising an amino acid sequence having at least 90%, at least 95%, or at least 99% sequence identity to the amino acid sequence of SEQ ID NO: 7; (b) a light chain variable (VL) domain comprising an amino acid sequence having at least 90%, at least 95%, or at least 99% identity to the amino acid sequence of SEQ ID NO: 8; or (c) a VH domain as in (a) and a VL domain as in (b).

29. The anti-tryptase beta antibody for use of claim 28, wherein the VH domain comprises the amino acid sequence of SEQ ID NO: 7.

30. The anti-tryptase beta antibody for use of claim 28, wherein the VL domain comprises the amino acid sequence of SEQ ID NO: 8.

31. The anti-tryptase beta antibody for use of claim 28, wherein the VH domain comprises the amino acid sequence of SEQ ID NO: 7 and the VL domain comprises the amino acid sequence of SEQ ID NO: 8.

32. The anti-tryptase beta antibody for use of any one of claims 27-31, wherein the antibody comprises (a) a heavy chain comprising the amino acid sequence of SEQ ID NO: 9 and (b) a light chain comprising the amino acid sequence of SEQ ID NO: 10.

33. The anti-tryptase beta antibody for use of any one of claims 27-31, wherein the antibody comprises (a) a heavy chain comprising the amino acid sequence of SEQ ID NO: 11 and (b) a light chain comprising the amino acid sequence of SEQ ID NO: 10.

34. The anti-tryptase beta antibody for use of any one of claims 27-33, wherein the C1D1 is 300 mg IV.

35. The anti-tryptase beta antibody for use of any one of claims 27-33, wherein the C1D1 is 450 mg IV.

36. The anti-tryptase beta antibody for use of any one of claims 27-33, wherein the C1D1 is 750 mg SC.

37. The anti-tryptase beta antibody for use of any one of claims 27-33, wherein the C1D1 is 900 mg IV.

38. The anti-tryptase beta antibody for use of any one of claims 27-33, wherein the C1D1 is 1350 mg IV.

39. The anti-tryptase beta antibody for use of any one of claims 27-33, wherein the C1D1 is 1800 mg IV.

40. The anti-tryptase beta antibody for use of any one of claims 27-33, wherein the C1D1 is 3600 mg IV.

41. The anti-tryptase beta antibody for use of any one of claims 27-40, wherein the dosing cycle further comprises a second dose (C1D2) and a third dose (C1D3) of the anti-tryptase beta antibody, wherein the C1D2 and the C1D3 are each equal to the C1D1.

42. The anti-tryptase beta antibody for use of claim 41, wherein the doses of the dosing cycle are administered to the subject every four weeks (q4w).

43. The anti-tryptase beta antibody for use of claim 41 or 42, wherein the dosing cycle has a length of about 57 days.

44. The anti-tryptase beta antibody for use of claim 43, wherein the C1D1 is administered on Day 1 of the dosing cycle, the C1D2 is administered on Day 29 of the dosing cycle, and the C1D3 is administered on Day 57 of the dosing cycle.

45. The anti-tryptase beta antibody for use of any one of claims 41-44, wherein the dosing regimen consists of one dosing cycle.

46. An anti-tryptase beta antibody for use in treating a patient having asthma, wherein the anti-tryptase beta antibody is for administration to a patient having asthma in a dosing regimen comprising a dosing cycle, wherein the dosing cycle comprises administering 1800 mg IV of the anti-tryptase beta antibody to the patient every four weeks (q4w), wherein the anti-tryptase beta antibody comprises the following six CDRs:

- (a) an CDR-H1 comprising the amino acid sequence of DYGMV (SEQ ID NO: 1);
- (b) an CDR-H2 comprising the amino acid sequence of FISSGSSTVYYADTMKG (SEQ ID NO: 2);
- (c) an CDR-H3 comprising the amino acid sequence of RNYDDWYFDV (SEQ ID NO: 3);
- (d) an CDR-L1 comprising the amino acid sequence of SASSSVTYMY (SEQ ID NO: 4);
- (e) an CDR-L2 comprising the amino acid sequence of RTSDLAS (SEQ ID NO: 5); and
- (f) an CDR-L3 comprising the amino acid sequence of QHYHSYPLT (SEQ ID NO: 6).

47. The anti-tryptase beta antibody for use of any one of claims 27-46, wherein the asthma is moderate asthma, severe asthma, allergic asthma, or atopic asthma.

48. The anti-tryptase beta antibody for use of claim 47, wherein the severe asthma is uncontrolled despite standard-of-care therapy.

49. The anti-tryptase beta antibody for use of any one of claims 27-48, wherein the asthma is moderate to severe asthma.

50. The anti-tryptase beta antibody for use of any one of one of claims 27-49, wherein the patient is receiving daily inhaled corticosteroid therapy and at least one of the following controller medications: an LABA, a leukotriene modulator, an LAMA, or a long-acting theophylline preparation.

51. The anti-tryptase beta antibody for use of claim 50, wherein the leukotriene modulator is an LTM or an LTRA.

52. Use of an anti-tryptase beta antibody in the manufacture of a medicament for treating a patient having asthma, wherein the medicament is for administration to a patient having asthma in a dosing regimen comprising a dosing cycle, wherein the dosing cycle comprises a first dose (C1D1) of the

anti-tryptase beta antibody selected from 300 mg IV, 450 mg IV, 750 mg SC, 900 mg IV, 1350 mg IV, 1800 mg IV, or 3600 mg IV, wherein the anti-tryptase beta antibody comprises the following six CDRs:

- (a) an CDR-H1 comprising the amino acid sequence of DYGMV (SEQ ID NO: 1);
- (b) an CDR-H2 comprising the amino acid sequence of FISSGSSTVYYADTMKG (SEQ ID NO: 2);
- (c) an CDR-H3 comprising the amino acid sequence of RNYDDWYFDV (SEQ ID NO: 3);
- (d) an CDR-L1 comprising the amino acid sequence of SASSSVTYMY (SEQ ID NO: 4);
- (e) an CDR-L2 comprising the amino acid sequence of RTSDLAS (SEQ ID NO: 5); and
- (f) an CDR-L3 comprising the amino acid sequence of QHYHSYPLT (SEQ ID NO: 6).

53. Use of an anti-tryptase beta antibody in the manufacture of a medicament for treating a patient having asthma, wherein the medicament is for administration to a patient having asthma in a dosing regimen comprising a dosing cycle, wherein the dosing cycle comprises administering 1800 mg IV of the anti-tryptase beta antibody to the patient every four weeks (q4w), wherein the anti-tryptase beta antibody comprises the following six CDRs:

- (a) an CDR-H1 comprising the amino acid sequence of DYGMV (SEQ ID NO: 1);
- (b) an CDR-H2 comprising the amino acid sequence of FISSGSSTVYYADTMKG (SEQ ID NO: 2);
- (c) an CDR-H3 comprising the amino acid sequence of RNYDDWYFDV (SEQ ID NO: 3);
- (d) an CDR-L1 comprising the amino acid sequence of SASSSVTYMY (SEQ ID NO: 4);
- (e) an CDR-L2 comprising the amino acid sequence of RTSDLAS (SEQ ID NO: 5); and
- (f) an CDR-L3 comprising the amino acid sequence of QHYHSYPLT (SEQ ID NO: 6).