

## CLAIMS

What is claimed:

1. A composition comprising erenumab and one or more erenumab variants, wherein the one or more erenumab variants comprises an isomerization variant and a deamidation variant, and wherein the amount of the isomerization variant and deamidation variant in the composition is less than about 30%.
2. The composition of claim 1, wherein the amount of the isomerization variant and deamidation variant in the composition is less than about 15%.
3. The composition of claim 1, wherein the amount of the isomerization variant and deamidation variant in the composition is less than about 8%.
4. The composition of claim 1, wherein the amount of the isomerization variant and deamidation variant in the composition is less than about 4%.
5. The composition of claim 1, wherein the amount of the isomerization variant and deamidation variant in the composition is from about 1% to about 10%.
6. The composition of claim 1, wherein the amount of the isomerization variant and deamidation variant in the composition is from about 1% to about 4%.
7. The composition of any one of claims 1 to 6, wherein the isomerization variant has an isoaspartic acid residue or a succinimide at amino acid position 105 in either or both heavy chains (SEQ ID NO: 1 or SEQ ID NO: 3) of erenumab.
8. The composition of any one of claims 1 to 7, wherein the deamidation variant has the asparagine residue at amino acid position 102 in either or both heavy chains (SEQ ID NO: 1 or SEQ ID NO: 3) of erenumab converted to an aspartic acid residue, a succinimide, or an isoaspartic acid residue.

9. The composition of any one of claims 1 to 8, wherein the amount of the isomerization variant and deamidation variant in the composition is determined by hydrophobic interaction chromatography high performance liquid chromatography (HIC-HPLC).
10. A composition comprising erenumab and one or more erenumab acidic variants, wherein the amount of acidic variants in the composition is less than about 40%.
11. The composition of claim 10, wherein the amount of acidic variants in the composition is less than about 35%.
12. The composition of claim 10, wherein the amount of acidic variants in the composition is from about 25% to about 38%.
13. The composition of claim 10, wherein the amount of acidic variants in the composition is from about 26% to about 34%.
14. The composition of any one of claims 10 to 13, wherein one or more acidic variants comprise disulfide isoform variants, fragmentation variants, or combinations thereof.
15. The composition of any one of claims 10 to 14, wherein the amount of acidic variants in the composition is determined by cation exchange high performance liquid chromatography (CEX-HPLC).
16. A composition comprising erenumab and one or more disulfide isoform variants thereof, wherein the one or more disulfide isoform variants comprise an IgG2-B isoform, and wherein the amount of the IgG2-B isoform in the composition is less than about 20%.
17. The composition of claim 16, wherein the amount of the IgG2-B isoform in the composition is less than about 10%.

18. The composition of claim 16, wherein the amount of the IgG2-B isoform in the composition is from about 4% to about 6%.
19. The composition of any one of claims 16 to 18, wherein the one or more disulfide isoform variants further comprise an IgG2-A/B isoform.
20. The composition of claim 19, wherein the amount of the IgG2-A/B isoform in the composition is from about 34% to about 37%.
21. The composition of any one of claims 16 to 20, wherein the amount of disulfide isoform variants in the composition is determined by non-reduced reversed phase high performance liquid chromatography (RP-HPLC).
22. A composition comprising erenumab and a high molecular weight (HMW) species of erenumab, wherein the amount of the HMW species in the composition is less than about 2.5%.
23. The composition of claim 22, wherein the amount of the HMW species in the composition is about 1.8% or less.
24. The composition of claim 22, wherein the amount of the HMW species in the composition is about 1.2% or less.
25. The composition of any one of claims 22 to 24, wherein the HMW species comprises a covalently-linked dimer of erenumab.
26. The composition of any one of claims 22 to 25, wherein the amount of the HMW species in the composition is determined by size exclusion ultra-high performance liquid chromatography (SE-UHPLC).
27. A composition comprising erenumab and one or more erenumab variants, wherein the erenumab variants comprise isomerization variants, deamidation variants, acidic variants, HMW

species, or combinations thereof, wherein the composition has one or more of the following characteristics:

(a) the amount of acidic variants in the composition is from about 25% to about 38% as measured by CEX-HPLC;

(b) the amount of HMW species in the composition is about 2.1% or less as measured by SE-UHPLC; and

(c) the amount of isomerization variants and deamidation variants in the composition is about 8% or less as measured by the pre-peaks in HIC-HPLC.

28. The composition of claim 27, wherein the composition has one or more of the following characteristics:

(a) the amount of acidic variants in the composition is from about 26.5% to about 33.6% as measured by CEX-HPLC;

(b) the amount of HMW species in the composition is about 1.2% or less as measured by SE-UHPLC; and

(c) the amount of isomerization variants and deamidation variants in the composition is about 3.2% or less as measured by the pre-peaks in HIC-HPLC.

29. The composition of any one of claims 1 to 28, wherein erenumab comprises a heavy chain of SEQ ID NO: 1 and a light chain of SEQ ID NO: 2.

30. The composition of any one of claims 1 to 28, wherein erenumab comprises a heavy chain of SEQ ID NO: 3 and a light chain of SEQ ID NO: 4.

31. A pharmaceutical formulation comprising the composition of any one of claims 1 to 30 and one or more pharmaceutically acceptable excipients.

32. A method for treating, preventing, or reducing the occurrence of headache in a patient in need thereof comprising administering to the patient the pharmaceutical formulation of claim 31.

33. The method of claim 32, wherein the headache is migraine.

34. The method of claim 33, wherein the migraine is episodic migraine or chronic migraine.
35. An erenumab composition of any one of claims 1 to 30 for use in a method for treating, preventing, or reducing the occurrence of headache in a patient in need thereof.
36. The erenumab composition of claim 35, wherein the headache is migraine.
37. The erenumab composition of claim 36, wherein the migraine is episodic migraine or chronic migraine.
38. Use of an erenumab composition of any one of claims 1 to 30 in the preparation of a medicament for treating, preventing, or reducing the occurrence of headache in a patient in need thereof.
39. The use of claim 38, wherein the headache is migraine.
40. The use of claim 39, wherein the migraine is episodic migraine or chronic migraine.
41. A method for assessing the quality of an erenumab composition, comprising:  
obtaining an erenumab composition that contains erenumab and one or more erenumab variants;  
measuring the amount of one or more erenumab variants in the composition, wherein the erenumab variants comprise isomerization variants, deamidation variants, acidic variants, HMW species, or combinations thereof;  
comparing the measured amount of the one or more erenumab variants to a pre-determined reference criterion; and  
preparing a pharmaceutical formulation or pharmaceutical product of the erenumab composition if the comparison indicates that the pre-determined reference criterion is met.

42. The method of claim 41, wherein the amount of isomerization variants and deamidation variants is measured and the pre-determined reference criterion is about 10% or less.

43. The method of claim 42, wherein the amount of isomerization variants and deamidation variants in the erenumab composition is measured by HIC-HPLC.

44. The method of claim 41, wherein the amount of acidic variants is measured and the pre-determined reference criterion is about 38% or less.

45. The method of claim 44, wherein the amount of acidic variants in the erenumab composition is measured by CEX-HPLC.

46. The method of claim 41, wherein the amount of HMW species is measured and the pre-determined reference criterion is about 2.5% or less.

47. The method of claim 46, wherein the amount of HMW species is measured by SE-UHPLC.

48. The method of any one of claims 41 to 47, wherein the erenumab composition is obtained from a Chinese Hamster Ovary (CHO) cell line that expresses a nucleic acid encoding a heavy chain of SEQ ID NO: 1 and a nucleic acid encoding a light chain of SEQ ID NO: 2.