Claims

1. A pharmaceutical composition comprising an anti-beta amyloid (Aβ) antibody or Aβ-binding fragment thereof at a concentration of 50 mg/ml to 250 mg/ml, arginine hydrochloride (Arg.HCl) at a concentration of 50 mM to 200 mM, and methionine at a concentration of 0.1 mM to 150 mM, wherein the anti-Aβ antibody or Aβ-binding fragment thereof comprises an immunoglobulin heavy chain variable domain (VH) and an immunoglobulin light chain variable domain (VL), the VH and VL, respectively, comprising:

(a) VH complementarity determining regions (CDRs), wherein VH-CDR1 consists of the amino acid sequence set forth in SEQ ID NO:1; VH-CDR2 consists of the amino acid sequence set forth in SEQ ID NO:2, and VH-CDR3 consists of the amino acid sequence set forth in SEQ ID NO:3; and

(b) VL CDRs, wherein VL-CDR1 consists of the amino acid sequence set forth in SEQ ID NO:4; VL-CDR2 consists of the amino acid sequence set forth in SEQ ID NO:5; and VL-CDR3 consists of the amino acid sequence set forth in SEQ ID NO:6, and

wherein the composition has a pH of 5.2 to 6.2.

2. A pharmaceutical composition comprising an anti-beta amyloid (Aβ) antibody or Aβ-binding fragment thereof at a concentration of 50 mg/ml to 250 mg/ml,, a thiol-containing antioxidant selected from the group consisting of GSH, GSSG, the combination of GSH and GSSG, cystine, cysteine, and the combination of cysteine and cystine, arginine hydrochloride (Arg.HCl) at a concentration of 50 mM to 200 mM, and methionine at a concentration of 0.1 mM to 150 mM, wherein the anti-Aβ antibody or Aβ-binding fragment thereof comprises an immunoglobulin heavy chain variable domain (VH) and an immunoglobulin light chain variable domain (VL), the VH and VL, respectively, comprising:

(a) VH complementarity determining regions (CDRs), wherein

VH-CDR1 consists of the amino acid sequence set forth in SEQ ID NO:1;

VH-CDR2 consists of the amino acid sequence set forth in SEQ ID NO:2; and VH-CDR3 consists of the amino acid sequence set forth in SEQ ID NO:3; and

(b) VL CDRs, wherein

VL-CDR1 consists of the amino acid sequence set forth in SEQ ID NO:4;

VL-CDR2 consists of the amino acid sequence set forth in SEQ ID NO:5; and

VL-CDR3 consists of the amino acid sequence set forth in SEQ ID NO:6, and wherein the composition has a pH of 5.2 to 6.2.

3. The pharmaceutical composition of claim 2, wherein the thiol-containing antioxidant is at a concentration of 0.02 mM to 4 mM.

4. The pharmaceutical composition of claim 2 or claim 3, wherein the thiol-containing antioxidant is at a concentration of:

(i) 0.2 mM;

(ii) 0.4 mM; or

(iii) 1 mM.

5. The pharmaceutical composition of claim 2 or claim 3, wherein the thiol-containing antioxidant is a combination of GSH and GSSG, wherein the GSH and GSSG together have a combined concentration of 0.4 mM.

6. The pharmaceutical composition of claim 2 or claim 3, wherein the thiol-containing antioxidant is a combination of cysteine and cystine, wherein the cysteine is at a concentration of 0.4 mM and the cystine is at a concentration of 0.2 mM.

7. The pharmaceutical composition of any one of claims 1 to 6, wherein the composition comprises the anti-Aβ antibody or Aβ-binding fragment thereof at a concentration of 75 mg/ml to 200 mg/ml.

8. The pharmaceutical composition of any one of claims 1 to 7, wherein the composition comprises Arg.HCl at a concentration of 75 mM to 175 mM.

9. The pharmaceutical composition of any one of claims 1 to 8, wherein the composition comprises Polysorbate-80 (PS80).

10. The pharmaceutical composition of claim 9, wherein the composition comprises PS80 at a concentration (w/v) of 0.01% to 0.1%.

11. The pharmaceutical composition of claim 10, wherein the composition comprises PS80 at a concentration (w/v) of 0.03% to 0.08%.

12. The pharmaceutical composition of any one of claims 1 to 11, wherein the composition comprises a buffer selected from the group consisting of histidine, acetate, succinate, and citrate.

13. The pharmaceutical composition of claim 12, wherein the buffer comprises histidine, acetate, succinate, or citrate at a concentration of 10 mM to 30 mM.

14. The pharmaceutical composition of claim 12 or claim 13, wherein the buffer is histidine.

15. The pharmaceutical composition of claim 14, wherein histidine is at a concentration of 10 mM to 30 mM.

16. The pharmaceutical composition of any one of claims 1 to 15, wherein the composition comprises methionine at a concentration of 5 mM to 15 mM.

17. The pharmaceutical composition of any one of claims 1 to 16, wherein the composition comprises sucrose.

18. The pharmaceutical composition of claim 17, wherein the composition comprises sucrose at a concentration (w/v) of 0.01% to 3%.

19. The pharmaceutical composition of any one of claims 1 to 18, wherein the composition has a pH of 5.2 to 6.0.

20. The pharmaceutical composition of claim 1 or claim 2, comprising:

the anti-Aβ antibody or the Aβ-binding fragment thereof at a concentration of 50 mg/ml to 250 mg/ml; Arg.HCl at a concentration of 75 mM to 175 mM; methionine at a concentration of 5 mM to 15 mM; histidine at a concentration of 10 mM to 30 mM; polysorbate-80 (PS80) at a concentration (w/v) of 0.01% to 0.1%; and wherein the composition has a pH of 5.2 to 6.0.

21. The pharmaceutical composition of any one of claims 1 to 20, wherein the composition comprises the anti-Aβ antibody or Aβ-binding fragment thereof at a concentration of 175 mg/ml.

22. The pharmaceutical composition of any one of claims 1 to 20, wherein the composition comprises the anti-Aβ antibody or Aβ-binding fragment thereof at a concentration of 100 mg/ml.

23. The pharmaceutical composition of any one of claims 1 to 22, wherein the composition has a pH of 5.3 to 5.7.

24. The pharmaceutical composition of claim 1, wherein the composition comprises the anti-Aβ antibody or the Aβ-binding fragment thereof at a concentration of 100 mg/ml; Arg.HCl at a concentration of 150 mM; methionine at a concentration of 10 mM; histidine at a concentration of 10 mM to 30 mM; polysorbate-80 (PS80) at a concentration (w/v) of 0.01% to 0.1%; and wherein the composition has a pH of 5.2 to 6.0.

25. The pharmaceutical composition of claim 1, comprising the anti-Aβ antibody or the Aβ-binding fragment thereof at a concentration of 100 mg/ml; Arg.HCl at a concentration of 150 mM; methionine at a concentration of 10 mM; histidine at a concentration of 20 mM; and polysorbate-80 (PS80) at a concentration (w/v) of 0.05%, wherein the composition has a pH of 5.5

26. The pharmaceutical composition of claim 2, comprising: the anti-Aβ antibody or the Aβ-binding fragment thereof at a concentration of 175 mg/ml; Arg.HCl at a concentration of 150 mM; methionine at a concentration of 10 mM; thiol-containing antioxidant is at a concentration of 0.02 mM to 4 mM; histidine at a concentration of 10 mM to 30 mM; polysorbate-80 (PS80) at a concentration (w/v) of 0.01% to 0.1%; and wherein the composition has a pH of 5.2 to 6.0.

27. The pharmaceutical composition of claim 2, comprising: the anti-Aβ antibody or the Aβ-binding fragment thereof at a concentration of 175 mg/ml; Arg.HCl at a concentration of

150 mM; methionine at a concentration of 10 mM; thiol-containing antioxidant is at a concentration of 0.02 mM to 4 mM; histidine at a concentration of 20 mM; and polysorbate-80 (PS80) at a concentration (w/v) of 0.05%, wherein the composition has a pH of 5.5.

28. The pharmaceutical composition of any one of claims 1 to 27, wherein:
the VH comprises a sequence at least 80% identical to SEQ ID NO:7 and the VL comprises a sequence at least 80% identical to SEQ ID NO:8.

29. The pharmaceutical composition of any one of claims 1 to 27, wherein:
the VH comprises a sequence at least 90% identical to SEQ ID NO:7 and the VL comprises a sequence at least 90% identical to SEQ ID NO:8.

30. The pharmaceutical composition of any one of claims 1 to 27, wherein:
the VH comprises the amino acid sequence set forth in SEQ ID NO:7 and the VL comprises the amino acid sequence set forth in SEQ ID NO:8.

31. The pharmaceutical composition of any one of claims 1 to 30, wherein the anti-Aβ antibody comprises an immunoglobulin heavy chain and an immunoglobulin light chain, wherein:
the heavy chain comprises a sequence at least 80% identical to SEQ ID NO:9 and the light chain comprises a sequence at least 80% identical to SEQ ID NO:10.

32. The pharmaceutical composition of any one of claims 1 to 30, wherein the anti-Aβ antibody comprises an immunoglobulin heavy chain and an immunoglobulin light chain, wherein:
the heavy chain comprises a sequence at least 90% identical to SEQ ID NO:9 and the light chain comprises a sequence at least 90% identical to SEQ ID NO:10.

33. The pharmaceutical composition of any one of claims 1 to 30, wherein the anti-Aβ antibody comprises an immunoglobulin heavy chain and an immunoglobulin light chain, wherein:
the heavy chain comprises the amino acid sequence set forth in SEQ ID NO:9 and the light chain comprises the amino acid sequence set forth in SEQ ID NO:10.

34. Use of the pharmaceutical composition of any one of claims 1 to 33 in the manufacture of a medicament for the treatment of (i) mild cognitive impairment; or (ii) Alzheimer's disease.

35. The use of claim 34, wherein the medicament is to be administered subcutaneously or intravenously to the human subject.

36. A pharmaceutical composition of any one of claims 1 to 33 for use in therapy.