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

an~~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.

2. A pharmaceutical composition comprising:

an anti-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, and cysteine; 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.~~3. The pharmaceutical composition of ~~any one of~~ claim~~s~~ 1 ~~to 20~~ or 2, wherein the composition comprises the anti-Aβ antibody or Aβ-binding fragment thereof at a concentration of 175 mg/ml.

~~22.~~4. The pharmaceutical composition of any one of claims 1 to 3~~20~~, wherein the composition comprises the anti-Aβ antibody or Aβ-binding fragment thereof at a concentration of 100 mg/ml.

~~23.~~5. The pharmaceutical composition of any one of claims 1 to 4~~22~~, wherein the composition has a pH of 5.3 to 5.7.

~~24.~~6. 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.~~7. 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.~~8. 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.~~9. 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.

10. The pharmaceutical composition of any one of claims 2, 8, and 9, 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.

~~28.~~11. The pharmaceutical composition of any one of claims 1 to ~~27~~10, 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.~~12. The pharmaceutical composition of any one of claims 1 to ~~27~~10, 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.~~13. The pharmaceutical composition of any one of claims 1 to ~~27~~10, 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.

14. The pharmaceutical composition of any one of claims 1 to 13, wherein the anti-Aβ antibody comprises a human IgG1 constant region.

~~31.~~15. The pharmaceutical composition of any one of claims 1 to ~~30~~14, 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.~~16. The pharmaceutical composition of any one of claims 1 to ~~30~~14, 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.~~17. The pharmaceutical composition of any one of claims 1 to 14~~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.~~18. Use of the pharmaceutical composition of any one of claims 1 to 17~~33~~ in the manufacture of a medicament for the treatment of (i) mild cognitive impairment; or (ii) Alzheimer's disease.

~~35.~~19. The use of claim 18~~34~~, wherein the medicament is to be administered subcutaneously or intravenously to the human subject.

~~36.~~20. A pharmaceutical composition of any one of claims 1 to 17~~33~~ for use in therapy.