

CLAIMS

1. A method for treating osteogenesis imperfecta (OI) in a human patient comprising administering to the human patient a therapeutically effective amount of an anti-sclerostin antibody.
2. The method according to claim 1, wherein the OI is type I OI, type III OI or type IV OI.
3. The method according to claim 1 or claim 2, wherein the human patient has one or more mutations in the COL1A1 and/ or COL1A2 genes.
4. The method according to any preceding claim, wherein the anti-sclerostin antibody comprises:
 - (a) a heavy chain variable region CDR1 comprising an amino acid sequence set forth in SEQ ID NO:4;
 - (b) a heavy chain variable region CDR2 comprising an amino acid sequence set forth in SEQ ID NO:15;
 - (c) a heavy chain variable region CDR3 comprising an amino acid sequence set forth in SEQ ID NO:26;
 - (d) a light chain variable region CDR1 comprising an amino acid sequence set forth in SEQ ID NO:37;
 - (e) a light chain variable region CDR2 comprising an amino acid sequence set forth in SEQ ID NO:48; and
 - (f) a light chain variable region CDR3 comprising an amino acid sequence set forth in SEQ ID NO:59;or an anti-sclerostin antibody that binds to the same epitope as an anti-sclerostin antibody comprising:
 - (a) a heavy chain variable region CDR1 comprising an amino acid sequence set forth in SEQ ID NO:4;
 - (b) a heavy chain variable region CDR2 comprising an amino acid sequence set forth in SEQ ID NO:15;

- (c) a heavy chain variable region CDR3 comprising an amino acid sequence set forth in SEQ ID NO:26;
 - (d) a light chain variable region CDR1 comprising an amino acid sequence set forth in SEQ ID NO:37;
 - (e) a light chain variable region CDR2 comprising an amino acid sequence set forth in SEQ ID NO:48; and
 - (f) a light chain variable region CDR3 comprising an amino acid sequence set forth in SEQ ID NO:59.
5. The method according to claim 4, wherein the anti-sclerostin antibody binds to the same epitope as an anti-sclerostin antibody comprising a VL polypeptide sequence having the amino acid sequences set forth as SEQ ID NO:81 and a VH polypeptide sequence having the amino acid sequences set forth SEQ ID NO:70.
6. The method according to claim 5, wherein the anti-sclerostin antibody binds to the same epitope as an anti-sclerostin antibody comprising a full length light chain amino acid sequence having the amino acid sequence set forth as SEQ ID NO:173 and a full length heavy chain amino acid sequence having the amino acid sequence set forth as SEQ ID NO:172.
7. The method according to any one of claims 1-3, wherein the anti-sclerostin antibody comprises at least one complementarity determining region (CDR) sequence selected from the group consisting of:
- (a) heavy chain variable region CDR1 comprising an amino acid sequence set forth in SEQ ID NO:4;
 - (b) heavy chain variable region CDR2 comprising an amino acid sequence set forth in SEQ ID NO:15;
 - (c) heavy chain variable region CDR3 comprising an amino acid sequence set forth in SEQ ID NO:26;

- (d) light chain variable region CDR1 comprising an amino acid sequence set forth in SEQ ID NO:37;
 - (e) light chain variable region CDR2 comprising an amino acid sequence set forth in SEQ ID NO:48; and
 - (f) light chain variable region CDR3 comprising an amino acid sequence set forth in SEQ ID NO:59.
8. The method according to claim 7, wherein the anti-sclerostin antibody comprises at least the heavy chain variable region CDR3 comprising an amino acid sequence as set forth in SEQ ID NO: 26.
9. The method according to claim 7 or claim 8, wherein the anti-sclerostin antibody comprises:
- (a) a heavy chain variable region CDR1 comprising an amino acid sequence set forth in SEQ ID NO:4;
 - (b) a heavy chain variable region CDR2 comprising an amino acid sequence set forth in SEQ ID NO:15;
 - (c) a heavy chain variable region CDR3 comprising an amino acid sequence set forth in SEQ ID NO:26;
 - (d) a light chain variable region CDR1 comprising an amino acid sequence set forth in SEQ ID NO:37;
 - (e) a light chain variable region CDR2 comprising an amino acid sequence set forth in SEQ ID NO:48; and
 - (f) a light chain variable region CDR3 comprising an amino acid sequence set forth in SEQ ID NO:59.
10. The method according to any one of claims 7-9, wherein the anti-sclerostin antibody comprises:
- a) a VH polypeptide sequence having at least 90 percent sequence identity to the amino acid sequences set forth as SEQ ID NO:70; and/ or

- b) a VL polypeptide sequence having at least 90 percent sequence identity to the amino acid sequences set forth as SEQ ID NO:81.
11. The method according to claim 10, wherein the anti-sclerostin antibody comprises a VL polypeptide sequence comprising the amino acid sequence set forth as SEQ ID NO:81 and a VH polypeptide sequence comprising the amino acid sequence set forth as SEQ ID NO:70.
12. The method according to any one of claims 7-11, wherein the anti-sclerostin antibody comprises:
- a) a full length heavy chain amino acid sequence having at least 90 percent sequence identity to the amino acid sequence set forth as SEQ ID NO:172; and/ or
 - b) a full length light chain amino acid sequence having at least 90 percent sequence identity to the amino acid sequence set forth as SEQ ID NO:173.
13. The method according to claim 12, wherein the anti-sclerostin antibody comprises a full length light chain amino acid sequence comprising the amino acid sequence set forth as SEQ ID NO: 173 and a full length heavy chain amino acid sequence comprising the amino acid sequence set forth as SEQ ID NO: 172.
14. The method according to any one of claims 1-3, wherein the anti-sclerostin antibody binds to a sequence selected from SEQ ID NO: 174 and/ or SEQ ID NO: 175.
15. The method according to any one of claims 1-3 or 14, wherein the anti-sclerostin antibody binds to the same epitope as an anti-sclerostin antibody comprising a VL polypeptide sequence having the amino acid sequences set forth as SEQ ID NO:176 and a VH polypeptide sequence having the amino acid sequences set forth SEQ ID NO:177.
16. The method according to any one of claims 1-3, wherein the anti-sclerostin antibody is blosozumab.

17. The method according to any preceding claim, wherein the anti-sclerostin antibody is administered at a dose of 1-50 mg per kg body weight of the human patient.
18. The method according to any preceding claim, wherein the anti-sclerostin antibody is administered at a dose of 10-30 mg per kg body weight of the human patient.
19. The method according to any one of claims 1-16, wherein the anti-sclerostin antibody is administered at a dose of 10-5000 mg.
20. The method according to any one of claims 1-16 or 19, wherein the anti-sclerostin antibody is administered at a dose of 100-3000 mg.
21. The method according to any preceding claim, wherein the anti-sclerostin antibody is administered to the human patient on a daily, weekly, bi-weekly, monthly, bi-monthly or quarterly basis.
22. The method according to any preceding claim, wherein the anti-sclerostin antibody is administered to the human patient on a monthly basis.
23. The method according to any preceding claim, wherein the anti-sclerostin antibody is administered to the human patient on a bi-monthly or quarterly basis.
24. The method according to any preceding claim, wherein the treatment regimen comprises a first dosing regimen optionally followed by a second dosing regimen.
25. The method according to claim 24, wherein the first dosing regimen is 1-50 mg per kg body weight of the human patient administered on a monthly basis.
26. The method according to claim 25, wherein the first dosing regimen is 20 mg per kg body weight of the human patient administered on a monthly basis.

27. The method according to any one of claims 24-26, wherein the second dosing regimen is 1-50 mg per kg body weight of the human patient administered on a bi-monthly or quarterly basis.
28. The method according to any one of claims 24-27, wherein the second dosing regimen is 20 mg per kg body weight of the human patient administered on a bi-monthly or quarterly basis.
29. The method according to any one of claims 24-28, wherein the first dosing regimen is 20 mg per kg body weight of the human patient administered on a monthly basis and the second dosing regimen is 20 mg per kg body weight of the human patient administered on a bi-monthly or quarterly basis.
30. The method according to claim 29, wherein the first dosing regimen is 20 mg per kg body weight of the human patient administered on a monthly basis for a period of 1 year, and the second dosing regimen is 20 mg per kg body weight of the human patient administered on a bi-monthly or quarterly basis for a period of at least 1 year.
31. The method according to claim 24, wherein the first dosing regimen is 10-5000 mg administered on a monthly basis.
32. The method according to claim 24 or claim 31, wherein the second dosing regimen is 10-5000 mg administered on a bi-monthly or quarterly basis.
33. The method according to claim 24, wherein the first dosing regimen is 10-5000 mg administered on a monthly basis and the second dosing regimen is 10-5000 mg administered on a bi-monthly or quarterly basis.

34. The method according to claim 33, wherein the first dosing regimen is 10-5000 mg administered on a monthly basis for a period of 1 year, and the second dosing regimen is 10-5000 mg administered on a bi-monthly or quarterly basis for a period of at least 1 year.
35. The method according to any preceding claim, wherein the anti-sclerostin antibody is administered intravenously.
36. The method according to any preceding claim, comprising administering a further therapeutic agent, such as bisphosphonate, parathyroid hormone, calcilytics, calcimimetics (e.g., cinacalcet), statins, anabolic steroids, lanthanum and strontium salts, and/or sodium fluoride.
37. A lyophilizate comprising an anti-sclerostin antibody as defined in any one of claims 1-16.
38. The lyophilizate according to claim 37, further comprising sucrose, arginine hydrochloride, L-histidine, polysorbate 80, and hydrochloric acid.
39. A dosage unit form comprising an anti-sclerostin antibody as defined in any one of claims 1-16, or a lyophilizate according to claim 37 or claim 38.
40. The dosage unit form according to claim 39, comprising 10-5000 mg of the anti-sclerostin antibody.
41. A kit comprising an anti-sclerostin antibody as defined in any one of claims 1-16, a lyophilizate according to claim 37 or claim 38, or a dosage unit form according to claim 39 or claim 40.
42. The kit according to claim 41 comprising a further therapeutic agent, such as a combination therapy agent e.g bisphosphonate, parathyroid hormone, calcilytics, calcimimetics (e.g.,

cinacalcet), statins, anabolic steroids, lanthanum and strontium salts, and/or sodium fluoride.

43. The anti-sclerostin antibody as defined in any one of claims 1-16, the lyophilizate according to claim 37 or claim 38, the dosage unit form according to claim 39 or claim 40, or the kit according to claim 41 or claim 42, for use in a method according to any one of claims 1-36.
44. The method, anti-sclerostin antibody, lyophilizate, dosage unit form, kit, and/or use substantially as described herein with reference to the drawings.