

CLAIMS

- ~~1. An anti-sclerostin antibody for use in treating osteogenesis imperfecta (OI) in a human patient, wherein a therapeutically effective amount of the anti-sclerostin antibody is to be administered to the human patient, and wherein the antisclerostin 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.~~

- ~~2.1. Use of an anti-sclerostin antibody in the manufacture of a medicament for the treatment of osteogenesis imperfecta (OI) in a human patient, wherein a therapeutically effective amount of the anti-sclerostin antibody is to be administered to the human patient, wherein the OI is type I OI, type III OI or type IV OI, wherein the human patient has one or more mutations in the COL1A1 and/ or COL1A2 genes, wherein the anti-sclerostin antibody is to be administered at a dose of 1-50 mg per kg body weight of the human patient on a monthly, bi-monthly or quarterly basis, and wherein the antisclerostin 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.

~~3. The anti-sclerostin antibody for use according to claim 1 or the use according to claim 2, wherein the OI is type I OI, type III OI or type IV OI.~~

~~4. The anti-sclerostin antibody for use according to claim 1 or 3, or the use according to claim 2 or 3, wherein the human patient has one or more mutations in the COL1A1 and/ or COL1A2 genes.~~

~~5.2. The anti-sclerostin antibody for use according to any one of claims 1, 3 or 4, or the use according to any one of claims 2-4 claim 1, 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.

~~6.3. The anti-sclerostin antibody for use according to any one of claims 1, 3, 4 or 5, or the use according to any one of claims 2-5 claim 1 or 2, 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.

~~7.4. The anti-sclerostin antibody for use according to any one of claims 1, 3-5 or 6, or the use according to any one of claims 2-6 1-3, 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.~~

~~8.5. The anti-sclerostin antibody for use according to any one of claims 1, 3-6 or 7, or the use according to any one of claims 2-7 1-4, 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.~~

~~9. The anti-sclerostin antibody for use according to any one of claims 1, 3-7 or 8, or the use according to any one of claims 2-8, wherein the anti-sclerostin antibody is to be administered at a dose of 1-50 mg per kg body weight of the human patient.~~

~~10. The anti-sclerostin antibody for use according to any one of claims 1, 3-8 or 9, or the use according to any one of claims 2-9, wherein the anti-sclerostin antibody is to be administered:~~

- ~~(a) at a dose of 1-30 mg per kg body weight of the human patient, for example at a dose of 1-20 mg per kg of body weight of the human patient; or~~
- ~~(b) at a dose of 10-30 mg per kg body weight of the human patient; and/or~~
- ~~(c) at a dose of 10-5000 mg, for example at a dose of 100-3000 mg; and/or~~
- ~~(d) to the human patient on a daily, weekly, bi-weekly, monthly, bi-monthly or quarterly basis.~~

6. The use according to any one of claims 1-5, wherein the anti-sclerostin antibody is to be administered at a dose of 2-45 mg per kg body weight of the human patient.

7. The use according to any one of claims 1-5, wherein the anti-sclerostin antibody is to be administered at a dose of 8-45 mg per kg body weight of the human patient.
8. The use according to any one of claims 1-5, wherein the anti-sclerostin antibody is to be administered at a dose of 10-40 mg per kg body weight of the human patient.
9. The use according to any one of claims 1-5, wherein the anti-sclerostin antibody is to be administered at a dose of 8-25 mg per kg body weight of the human patient.
10. The use according to any one of claims 1-5, wherein the anti-sclerostin antibody is to be administered at a dose of 5-20 mg per kg body weight of the human patient.
11. The use according to any one of claims 1-10, wherein the anti-sclerostin antibody is to be administered to the human patient on a monthly basis.
12. The use according to any one of claims 1-10, wherein the anti-sclerostin antibody is to be administered to the human patient on a quarterly basis
- ~~11.13.~~ The anti-sclerostin antibody for use according to any one of claims 1, 3-9 or 10, or the use according to any one of claims 2-10 1-12, wherein the treatment regimen comprises a first dosing regimen optionally followed by a second dosing regimen.
- ~~12.14.~~ The anti-sclerostin antibody for use according to claim 11, or the use according to claim 11, wherein:
- (a) the first dosing regimen is 1-50 mg per kg body weight of the human patient is to be administered on a monthly basis, ~~for example the first dosing regimen is 20 mg per kg body weight of the human patient is to be administered on a monthly basis;~~
 - (b) the second dosing regimen is 1-50 mg per kg body weight of the human patient is to be administered on a bi-monthly or quarterly basis, ~~for example the second dosing~~

~~regimen is 20 mg per kg body weight of the human patient is to be administered on a bi-monthly or quarterly basis; and/or~~

- (c) ~~the first dosing regimen is 20 mg per kg body weight of the human patient is to be administered on a monthly basis and the second dosing regimen is 20 mg per kg body weight of the human patient is to be administered on a bi-monthly or quarterly basis; for example the first dosing regimen is 20 mg per kg body weight of the human patient is to be 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 is to be administered on a bi-monthly or quarterly basis for a period of at least 1 year.~~

~~13. The anti-sclerostin antibody for use according to claim 11, or the use according to claim 11, wherein:~~

- ~~(a) the first dosing regimen is 10-5000 mg is to be administered on a monthly basis;~~
~~(b) the second dosing regimen is 10-5000 mg is to be administered on a bi-monthly or quarterly basis; and/or~~
~~(c) the first dosing regimen is 10-5000 mg is to be administered on a monthly basis and the second dosing regimen is 10-5000 mg is to be administered on a bi-monthly or quarterly basis, for example the first dosing regimen is 10-5000 mg is to be administered on a monthly basis for a period of 1 year, and the second dosing regimen is 10-5000 mg is to be administered on a bi-monthly or quarterly basis for a period of at least 1 year.~~

~~14.15. The anti-sclerostin antibody for use according to any one of claims 1, 3-12 or 13, or the use according to any one of claims 2-13 1-14, wherein the anti-sclerostin antibody is to be administered intravenously or subcutaneously.~~

~~15.16. The anti-sclerostin antibody for use according to any one of claims 1, 3-13 or 14, or the use according to any one of claims 2-14 1-15, wherein 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 is to be administered.

17. The use according to any one of claims 1-16, wherein the patient is an adult patient.

18. The use according to any one of claims 1-16, wherein the patient is a pediatric patient.

16.19. ~~The anti-sclerostin antibody for use according to any one of claims 1, 3-14 or 15, or the~~
use according to any one of claims ~~2-15~~ 1-18, wherein the antibody is formulated in a pharmaceutical composition.