

CLAIMS

1. A chimeric anti-GD2 antibody dinutuximab beta for use in a method of treating a newly diagnosed neuroblastoma in a patient by administering chimeric anti-GD2 antibody dinutuximab beta to the patient in combination with induction chemotherapy, wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during the induction chemotherapy at a cumulative dose of up to 500 mg/m², such as wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during the induction chemotherapy at a cumulative dose of at least 100 mg/m², such as from 100 to 200 mg/m², from 200 to 300 mg/m², from 300 to 400 mg/m², or from 400 to 500 mg/m².
2. A chimeric anti-GD2 antibody dinutuximab beta for use in a method of treating a newly diagnosed neuroblastoma in a patient by administering chimeric anti-GD2 antibody dinutuximab beta to the patient in combination with induction chemotherapy, wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient in a dose of up to 100 mg/m² per cycle during one or more cycles of induction chemotherapy, such as wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during all but the first 2 cycles, or all but the first cycle, or all cycles of the induction chemotherapy.
3. The chimeric anti-GD2 antibody dinutuximab beta for use of Claim 2, wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during the induction chemotherapy in a dose per cycle that is equal for all cycles during which the chimeric anti-GD2 antibody dinutuximab beta is administered, such as wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during the induction chemotherapy in a dose per cycle that is at least 10 mg/m² per cycle, such as from 10 to 30 mg/m² per cycle, from 20 to 40 mg/m² per cycle, from 30 to 50 mg/m² per cycle, from 40 to 60 mg/m² per cycle, from 50 to 70 mg/m² per cycle or from 60 to 80 mg/m² per cycle.
4. The chimeric anti-GD2 antibody dinutuximab beta for use of Claim 2, wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during the induction chemotherapy in a dose per cycle that varies by up to 20 mg/m² such as up to 10 mg/m² between different cycles during which the chimeric anti-GD2 antibody dinutuximab beta is administered, such as wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during the induction chemotherapy in a dose per cycle of at least 10 mg/m² per cycle for all cycles, such as from 10 to 30 mg/m² per cycle for one or more cycles and from 20 to 40 mg/m² per cycle for the other cycles

during which the chimeric anti-GD2 antibody dinutuximab beta is administered; or from 20 to 40 mg/m² per cycle for one or more cycles and from 30 to 50 mg/m² per cycle for the other cycles during which the chimeric anti-GD2 antibody dinutuximab beta is administered; or from 20 to 40 mg/m² per cycle for one or more cycles and from 40 to 60 mg/m² per cycle for the other cycles during which the chimeric anti-GD2 antibody dinutuximab beta is administered; or from 40 to 60 mg/m² per cycle for one or more cycles and from 60 to 80 mg/m² per cycle for the other cycles during which the chimeric anti-GD2 antibody dinutuximab beta is administered.

5. The chimeric anti-GD2 antibody dinutuximab beta for use of any one of Claims 2 to 4, wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during the induction chemotherapy in a dose per cycle of 20 mg/m², 30 mg/m², 40 mg/m², 50 mg/m², 60 mg/m², or 70 mg/m² during one or more cycles of induction chemotherapy.

6. The chimeric anti-GD2 antibody dinutuximab beta for use of Claim 1, wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during the induction chemotherapy in a dosing regimen as defined in any one of Claims 2 to 5.

7. The chimeric anti-GD2 antibody dinutuximab beta for use of any one of Claims 2 to 5, wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during the induction chemotherapy at a cumulative dose as defined in Claim 1.

8. A chimeric anti-GD2 antibody dinutuximab beta for use in a method of treating a newly diagnosed neuroblastoma in a patient by administering chimeric anti-GD2 antibody dinutuximab beta to the patient in combination with induction chemotherapy, wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during the induction chemotherapy at a treatment density of up to 5 mg/m²/day, wherein a newly diagnosed neuroblastoma is treated in the patient.

9. The chimeric anti-GD2 antibody dinutuximab beta for use of Claim 8, wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during the induction chemotherapy at a treatment density of at least 1 mg/m²/day, such as from 1 to 2 mg/m²/day, from 2 to 3 mg/m²/day, or from 3 to 4 mg/m²/day.

10. The chimeric anti-GD2 antibody dinutuximab beta for use of Claim 1 or 7, wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during the induction chemotherapy at a treatment density as defined in Claim 8 or 9.

11. The chimeric anti-GD2 antibody dinutuximab beta for use any one of Claims 2 to 5 or 7, wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during the induction chemotherapy at a treatment density as defined in Claim 8 or 9.

12. The chimeric anti-GD2 antibody dinutuximab beta for use of Claim 8 or 9, wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient during the induction chemotherapy at a cumulative dose as defined in Claim 1, or in a dosing regimen as defined in any one of Claims 2 to 5.

13. The chimeric anti-GD2 antibody dinutuximab beta for use of any one of the preceding claims, wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient as a continuous intravenous infusion over 24 hours per day, in a daily dose of 10 mg/m^2 ; and/or wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient on consecutive days of a cycle until all of the dose per cycle of the chimeric anti-GD2 antibody dinutuximab beta has been administered; and/or wherein the administration of the chimeric anti-GD2 antibody dinutuximab beta improves one or more clinical parameters compared to the induction chemotherapy administered without the chimeric anti-GD2 antibody dinutuximab beta, such as wherein the one of more clinical parameters are selected from complete response rate, partial response rate, primary tumour volume reduction, Curie score, event free survival and overall survival.

14. The chimeric anti-GD2 antibody dinutuximab beta for use of any one of the preceding claims wherein the induction chemotherapy comprises 6 alternating chemotherapy cycles of N5 (cisplatin, etoposide, and vindesine) and N6 (ifosfamide, vincristine, dacarbazine, and doxorubicin), wherein the cycles are of at least 21 days, such as wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient at a cumulative dose of from 160 to 220 mg/m^2 and/or a treatment density of from 1.52 to $2.10 \text{ mg/m}^2/\text{day}$; or at a cumulative dose of from 220 to 280 mg/m^2 and/or a treatment density of from 2.10 to $2.67 \text{ mg/m}^2/\text{day}$; or at a cumulative dose of from 280 to 340 mg/m^2 and/or a treatment density of from 2.67 to $3.24 \text{ mg/m}^2/\text{day}$; or at a cumulative dose of from 320 to 380 mg/m^2 and/or a treatment density of from 3.05 to $3.62 \text{ mg/m}^2/\text{day}$.

15. The chimeric anti-GD2 antibody dinutuximab beta for use of Claims 1 to 13 wherein the induction chemotherapy comprises consecutive chemotherapy cycles of A (vincristine, carboplatin and etoposide), B (vincristine and cisplatin), C (vincristine, cyclophosphamide

and etoposide), B, A, B, C and B, wherein the cycles are of at least 10 days, such as wherein the chimeric anti-GD2 antibody dinutuximab beta is administered to the patient at a cumulative dose of from 120 to 160 mg/m² and/or a treatment density of from 2.00 to 2.67 mg/m²/day; or at a cumulative dose of from 160 to 200 mg/m² and/or a treatment density of from 2.67 to 3.33 mg/m²/day; or at a cumulative dose of from 190 to 230 mg/m² and/or a treatment density of from 3.17 to 3.83 mg/m²/day; or at a cumulative dose of from 220 to 260 mg/m² and/or a treatment density of from 3.67 to 4.30 mg/m²/day.