

CLAIMS

We claim:

1. A method of treating a patient having or suspected of having an autism spectrum disorder, the method comprising administering a therapeutically effective amount of human allogeneic cord tissue-derived mesenchymal stromal cells (hCT-MSCs) to the patient.
2. The method of claim 1, wherein the hCT-MSCs are administered systemically.
3. The method of claim 1 or 2, wherein the hCT-MSCs are administered intravenously.
4. The method of any of claims 1-3, wherein the patient is from about 1 year old to about 45 years old.
5. The method of claim 4, wherein the patient is from about 2 years old to about 11 years old.
6. The method of claim 4, wherein the patient is from about 4 years old to about 8 years old.
7. The method of any of claims 1-6, wherein the hCT-MSCs are administered in one dose, two doses, three doses, or 4 or more doses.
8. The method of any of claims 1-7, wherein each dose is administered from about 1 month to about 6 months apart.
9. The method claim 8, wherein each dose is administered about two months apart.
10. The method of any of claims 1-9, wherein the therapeutically effective dose of hCT-MSCs comprises about 1.0×10^6 cells/kg to about 6.0×10^6 cells/kg per dose.
11. The method of claim 10, wherein the dose comprises about 2.0×10^6 cells/kg.
12. The method of claim 10, wherein the dose comprises about 3.0×10^6 cells/kg.
13. The method of claim 10, wherein the dose comprises about 6.0×10^6 cells/kg.

14. The method of any of claims 1-6, wherein the therapeutically effective dose of hCT-MSCs comprises a total of about 6.0×10^6 cells/kg, and is administered in 2 to 3 doses within about 6 months.
15. The method of any of claims 1-14, wherein the therapeutically effective dose of hCT-MSCs is greater than 90% CD73+ and CD90+.
16. The method of any of claims 1-14, wherein the therapeutically effective dose of hCT-MSCs is less than 10% CD45+, CD3+, or CD31+.
17. A method of assessing the therapeutic effectiveness of treatment with hCT-MSCs on a patient suffering from an autism spectrum disorder comprising:
- (a) performing one or more appropriate tests on the patient to establish behavioral and/or biomarker baseline score(s);
 - (b) administering an effective amount of hCT-MSCs to the patient;
 - (c) reevaluating the patient at one or more time points post-administration of hCT-MSCs for the same one or more behavioral and/or biomarker tests set forth in (a); and
 - (d) comparing the results in (c) with the baseline score(s) established in (a).
18. The method of claim 17, wherein the behavioral test(s) performed in (a) and (c) comprise one or more of: Vineland Adaptive Behavior Scales-II (VABS-II), Vineland Adaptive Behavior Scales-III (VABS-III), Clinical Global Impression Scale (CGI), Pervasive Developmental Disorder Behavior Inventory (PDDBI), Expressive One-Word Picture Vocabulary Test-4 (EOWPVT-4), Aberrant Behavior Checklist, Sensory Experiences Questionnaire, Repetitive Behavior Scale, Intelligence Scales (Mullen Scales of Early Learning or Stanford-Binet), Language Environment Analysis, ATN GI Symptoms Inventory, and Parenting Stress Index.
19. The method of any of claims 17-18, wherein reevaluation of the patient in (c) is performed at one or more time points comprising: 2 months, 4 months, 6 months, 9 months, 12 months, 18 months, 24 months, 2 years, 3 years, 4 years, 5 years, 10 years, 15 years, 20 years or indefinitely post-administration.