37(4-5):349-62). In prior studies the inventors have reported outcomes of infants enrolled in a CTSI- supported phase I trial of autologous cells. In that study, and in a phase II study, cord blood is collected, red blood cell- and volume-reduced. In the phase II, two doses of cells or placebo are infused in the first 48 postnatal hours. In the phase I, fifty-one infants received cells. Two infants died (after hospital discharge). Twenty-five (64%) of 39 infants with known outcomes survived with one year developmental scores > 85, which compares favorably with the hypothermia trials in which approximately 50% of cooled infants survived without moderate or severe impairment (Higgins et al., *J Pediatr*. 2011, 159(5):851-858). A challenge to generalizability of clinical trials, and potential future use of autologous cord blood cells for newborns with HIE has become apparent however: collecting cord blood cells at difficult deliveries. Collecting cord blood is not routine in most institutions. Having an 'off – the – shelf,' allogeneic cell-based product would allow for a readily available cellular intervention for newborn infants with moderate to severe HIE who did not have cord blood collected.

SUMMARY

[0010] The present disclosure offers a method of treating patients with cerebral palsy or HIE through the administration of allogeneic human umbilical cord tissue-derived mesenchymal stromal cells (hCT-MSCs). The present disclosure provides the benefit of eliminating the restriction of having an autologous CB unit.

[0011] In one example, the present disclosure comprises a method of treating a patient with cerebral palsy comprising administering a therapeutically effective amount of human allogeneic umbilical cord-derived mesenchymal stromal cells (hCT-MSCs) to the patient. In certain examples of the disclosure, the hCT-MSCs are administered systemically. In certain examples, they are administered intravenously. In some examples of the disclosure, the patient is administered hCT-MSCs three times in a six month period. In certain examples, the administration is at baseline, at three months, and at six months. In other examples of the disclosure, the patient is administered hCT-MSCs at a dose of at least about $2x10^6$ cells/kg.

[0011a] In one aspect, the present disclosure refers to use of human allogeneic umbilical cord-derived mesenchymal stromal cells (hCT-MSCs) in the manufacture of a pharmaceutical composition for treating cerebral palsy, wherein the pharmaceutical composition is to be administered at a dose of at least $2x10^6$ hCT-MSCs/kg of body weight, to be administered three times in a six-month period.

[0012] In a further example, the present disclosure comprises a method of treating a patient with HIE comprising administering a therapeutically effective amount of human allogeneic umbilical cord-derived mesenchymal stromal cells (hCT-MSCs) to the patient. In certain examples of the disclosure, the hCT-MSCs are administered systemically. In certain examples, they are administered intravenously. In some examples

of the disclosure, the patient is administered hCT-MSCs three times in a six month period. In certain examples, the administration is at baseline, at three months, and at six months. In other examples of the disclosure, the patient is administered hCT-MSCs at a dose of at least about $2x10^6$ cells/kg.

[0012a] In one ~~aspect~~example, the present disclosure refers to use of human allogeneic umbilical cord-derived mesenchymal stromal cells (hCT-MSCs) in the manufacture of a pharmaceutical composition for treating hypoxic- ischemic encephalopathy (HIE).

[0013] In yet a further example, the present disclosure comprises a method of treating a patient with HIE comprising administering a therapeutically effective amount of human allogeneic umbilical cord-derived mesenchymal stromal cells (hCT-MSCs) to the patient. In certain examples of the disclosure, the patient with HIE is a newborn 36 weeks gestation or later, who suffers from moderate to severe hypoxic-ischemic neonatal encephalopathy. In certain examples of the disclosure, the hCT-MSCs are administered systemically. In certain examples, they are administered intravenously. In some examples of the disclosure, the patient is administered hCT-MSCs in a single dose in the first 48 postnatal hours. In some examples of the disclosure, the patient is administered two doses of hCT-MSCs. In certain examples where the patient is administered two doses, the first dose is given in the first 48 postnatal hours, and the second dose is given approximately two months after the first dose. In other examples of the disclosure, the patient is administered hCT-MSCs at a dose of at least about $2x10^6$ cells/kg. In certain examples of the disclosure, the hCT-MSCs are administered in conjunction with therapeutic hypothermia.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] **Figure 1** is a flow chart summarizing the Phase I/II trial to determine the effect size of change in GMFM-66 score in subjects treated with hCT-MSC compared to allogeneic CB.

[0015] **Figure 2** is a flow chart summarizing the Phase I Study of hCT-MSC, an Umbilical Cord-Derived Mesenchymal Stromal Cell Product, in newborn infants with moderate or severe hypoxic- ischemic neonatal encephalopathy.

DETAILED DESCRIPTION OF THE INVENTION

[0016] Before the disclosed processes and materials are described, it is to be understood that the aspects described herein are not limited to specific embodiments, apparati, or configurations, and as such can, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular aspects only and, unless specifically defined herein, is not intended to be limiting.

We claim:

1. Use of human allogeneic umbilical cord-derived mesenchymal stromal cells (hCT-MSCs) in the manufacture of a pharmaceutical composition for treating cerebral palsy, wherein the pharmaceutical composition is to be administered at a dose of at least $2x10^6$ hCT-MSCs/kg of body weight, to be administered three times in a six-month period.

2. The use of claim 1, wherein the pharmaceutical composition is to be administered systemically.

3. The use of claim 2, wherein the pharmaceutical composition is to be administered intravenously.

~~4. The use of claim 1, wherein the pharmaceutical composition is to be administered three times in a six-month period.~~

~~4~~5. The use of claim 1~~4~~, wherein the pharmaceutical composition is to be administered at baseline, at three months, and at six months.

~~6. The use of claim 1, wherein the pharmaceutical composition is to be administered at a dose of at least about $2x10^6$ hCT-MSCs/kg of body weight.~~

~~7. Use of human allogeneic umbilical cord-derived mesenchymal stromal cells (hCT-MSCs) in the manufacture of a pharmaceutical composition for treating hypoxic- ischemic encephalopathy (HIE).~~

~~8. The use of claim 7, wherein the pharmaceutical composition is to be administered systemically.~~

~~9. The use of claim 8, wherein the pharmaceutical composition is to be administered intravenously.~~

~~10. The use of claim 7, wherein the pharmaceutical composition is to be administered three times in a six-month period.~~

~~11. The use of claim 10, wherein the pharmaceutical composition is to be administered at baseline, at three months, and at six months.~~

~~12. The use of claim 7, wherein the pharmaceutical composition is to be administered at a dose of at least about $2x10^6$ hCT-MSCs/kg of body weight.~~

~~13. The use of claim 7, wherein the pharmaceutical composition is to be administered to a newborn of 36 weeks gestation or later, who suffers from moderate to severe hypoxic-ischemic neonatal encephalopathy.~~

~~14. The use of claim 13, wherein the pharmaceutical composition is to be administered in a single dose in the first 48 postnatal hours.~~

~~15. The use of claim 14, wherein a second dose of the pharmaceutical composition is to be administered approximately two months after the first dose.~~

~~16. The use of claim 13, wherein the pharmaceutical composition is to be administered systemically.~~

~~17. The use of claim 16, wherein the pharmaceutical composition is to be administered intravenously.~~

~~18. The use of claim 13, wherein the pharmaceutical composition is to be administered at a dose of at least about $2x10^6$ hCT-MSCs/kg of body weight.~~