

Judge Pechman

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U.S. DISTRICT COURT
BY WESTERN DISTRICT OF WASHINGTON
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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA,
ex rel. JAMES MARCHESE,

Plaintiff,

v.

CELL THERAPEUTICS, INC.,
MEDCOMM SOLUTIONS,
ENVISION PHARMA, INC., and
AMERISOURCEBERGEN CORP.,

Defendants.

NO. 06-0168-MJP

FILED IN CAMERA
and
UNDER SEAL

EXHIBIT 1 TO STIPULATION OF DISMISSAL
AND MOTION TO LIFT SEAL

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (“Agreement”) is entered into between the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”) (collectively the “United States”); James Marchese (“Relator”); and Cell Therapeutics, Inc. (“CTI”) (hereafter referred to as “the Parties”), through their authorized representatives.

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. WHEREAS, CTI is a corporation with its principal place of business located at 501 Elliott Avenue West, Seattle, Washington, and is principally engaged in the development, manufacture and sale of pharmaceuticals, including prescription pharmaceuticals subject to regulation by the United States Food and Drug Administration (“FDA”).

B. WHEREAS, from 2000 until June 30, 2005, CTI owned, manufactured, and sold the prescription drug Arsenic Trioxide, which CTI sold under the trade name Trisenox® (“Trisenox”).

C. WHEREAS, Relator is a former employee of CTI and is a resident of the State of New Jersey. On February 1, 2006, Relator filed a qui tam action in the United States District Court for the Western District of Washington, captioned United States ex rel. James Marchese v. Cell Therapeutics, et al., Civil Action Number 06-168-MJP (hereinafter “the Civil Action”).

D. WHEREAS, the United States contends that CTI caused to be submitted claims for payment for Trisenox to the Medicare Program (Medicare), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg.

E. WHEREAS, the United States contends that it has certain civil claims against CTI, as specified in subparagraphs 1 - 5 below, for engaging in the following conduct during the period from September 25, 2000 to June 30, 2005 with respect to the marketing, promotion and sale of Trisenox:

1. The United States contends that CTI knowingly and willfully promoted the sale and use of Trisenox for the treatment of Acute Myelocytic Leukemia, Chronic Lymphocytic Leukemia, Chronic Myeloid Leukemia, Liver Cancer, Multiple Myeloma and Myelodysplastic Syndromes, when CTI knew that the use of Trisenox for such indications had not been approved as safe and effective by the FDA ("off-label indications"), and knowingly caused the submission of claims to the Medicare program as described below. Trisenox has only been approved by the FDA for the treatment of refractory or relapsed Acute Promyelocytic Leukemia.

2. The United States contends that CTI made false and misleading statements to treating doctors to the effect that Trisenox was medically accepted for its off-label indications, and therefore eligible for Medicare reimbursement; thereby causing treating physicians to mistakenly administer Trisenox off-label to their patients, and causing them to present false or fraudulent claims for payment to Medicare.

3. The United States contends that CTI caused a series of false statements to be made to medical directors of Medicare program intermediaries and carriers, to the effect that Trisenox's off-label indications were medically accepted and therefore eligible for Medicare

reimbursement, when CTI knew that Trisenox's off-label indications were not medically accepted, thereby causing Medicare medical directors to mistakenly approve Medicare reimbursement for off-label indications of Trisenox.

4. The United States contends that CTI provided doctors and other medical professionals with money, free travel, food and entertainment, grants, and other valuable goods and services, with the intent to induce such physicians and medical professionals to prescribe or recommend Trisenox for its off-label indications, thus causing them to submit false claims for payment to Medicare for the administration of Trisenox off-label.

5. The United States contends that, in the context of CTI funded clinical studies of off-label indications of Trisenox, CTI knowingly and willfully failed to provide to investigators the study drug at no cost or at CTI's production cost, as required by law, but instead required investigators conducting such studies to purchase Trisenox from commercial sources, and directed such investigators to submit what CTI knew to be false claims for the administration of Trisenox to Medicare.

CTI's conduct as described in subparagraphs E(1) – E(5) above is hereinafter referred to as the "Covered Conduct".

F. WHEREAS, the United States also contends that it has certain administrative claims against CTI for engaging in the Covered Conduct, as specified in Paragraph 3 below.

G. WHEREAS, Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement, but Relator and the United States have not agreed on the entitlement or amount of that award, if any.

H. WHEREAS, CTI denies each and every one of these allegations and all allegations described in any pleading filed in the Civil Action.

I. WHEREAS, CTI contends that to the extent that any false or misleading statements were made by CTI or its agents pertaining to the availability of Medicare reimbursement for Trisenox, such statements were a consequence of negligent advice provided to CTI by a third party, which advice is the subject of Cell Therapeutics, Inc. V. The Lash Group et al., U.S. District Court for the Western District of Washington, No. 07-310-JLR.

J. WHEREAS, to avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. CTI agrees to pay to the United States the sum of ten million, five hundred thousand dollars (\$10,500,000.00), plus any interest that may have accrued between December 18, 2006 and the Effective Date of this Agreement at a rate of 4.75% per annum (the "Settlement Amount") in full, to the United States by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the Western District of Washington. CTI agrees to make this electronic funds transfer no later than three days from the Effective Date of this Agreement.

2. Subject to the exceptions in Paragraph 5 below, in consideration of the obligations of CTI in this Agreement, conditioned upon CTI's full payment of the Settlement Amount and subject to Paragraph 17 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under the Agreement), and subject to the provisions of Paragraph 3 below, the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release CTI from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, negligent misrepresentation and fraud. No individuals are released by this Agreement.

3. In consideration of the obligations of CTI set forth in this Agreement, conditioned upon CTI's full payment of the Settlement Amount and compliance with the Notice and Integrity Requirements (defined below), and subject to Paragraph 17 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against CTI under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 5, below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude CTI from Medicare,

Medicaid, or other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 5, below. Furthermore, in connection with this Paragraph 3:

a. CTI represents that, as of the Effective Date, it is not engaged in the manufacturing, marketing, sales, or distribution of any products that are reimbursed by Federal health care programs (“Covered Products”). If, during the five-year period beginning on the Effective Date of this Agreement, CTI intends to engage in the manufacture, marketing, sales, or distribution of any Covered Products or if it intends to acquire either a Covered Product or another entity with a Covered Product, it shall notify the OIG-HHS, in writing, of that intention 90 days prior to commencing the manufacture, marketing, sales, or distribution of the Covered Product. This notice shall be provided to the Assistant Inspector General for Legal Affairs, Office of Counsel to the Inspector General, Room 5527, Cohen Building, 330 Independence Avenue, S.W., Washington, DC 20201. CTI further agrees to negotiate and enter into a Corporate Integrity Agreement (CIA) with the OIG-HHS prior to manufacturing, marketing, selling, or distributing any Covered Product. If CTI acquires a company with a Covered Product or acquires a Covered Product, CTI may continue to manufacture, market, sell or distribute the acquired Covered Product so long as not more than 90 days lapses from the date CTI notifies OIG of its intentions, as required above, and the date CTI executes a CIA with the OIG. (These obligations to provide notice and to negotiate and enter a CIA shall be referred to collectively as the “Notice and Integrity Requirements.”) The CIA shall address CTI’s compliance with Federal health care program requirements and the requirements of the FDA. The CIA shall contain terms

appropriate to the operations of CTI's business, as determined at the sole discretion of the OIG-HHS after considering, among other things, information and documentation provided by CTI and after consultation with the FDA.

b. If CTI fails to comply with the Notice and Integrity Requirements set forth in this Paragraph 3, the OIG-HHS may rescind the releases provided in this Paragraph. In the event that the OIG-HHS, opts to rescind the releases provided in this Paragraph 3, CTI agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any administrative claims that (a) are filed by the OIG-HHS within 180 calendar days of written notification to CTI that the administrative releases provided in this Paragraph 3 have been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of this Agreement.

4. Subject to the exceptions in Paragraph 5, below, in consideration of the obligations of CTI in this Agreement, conditioned upon CTI's full payment of the Settlement Amount, and subject to Paragraph 17 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, agrees to release CTI from any civil monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

5. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including CTI and Relator) are the following claims of the United States:

- a. Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
 - b. Any criminal liability;
 - c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
 - d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
 - e. Any liability based upon such obligations as are created by this Agreement;
 - f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
 - g. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and
 - h. Any liability of individuals, including officers and employees.
6. Relator and his heirs, successors, attorneys, agents, and assigns agree not to object to this Agreement and agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). In connection with this Agreement and this Civil Action, Relator and his heirs, successors, attorneys, agents, and assigns agree that neither this Agreement, any intervention by the United States in the Civil Action in order to dismiss the Civil Action, nor any dismissal of the Civil Action, shall waive or otherwise affect the ability of the United States to contend that provisions in the False Claims Act, including 31 U.S.C. §§ 3730(d)(3) and 3730(e), bar Relator from sharing in the proceeds of this

Agreement. Moreover, the United States and Relator and his heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the False Claims Act on the issue of the percentage, if any, that Relator should receive of any proceeds of the settlement of his claim(s), and that no agreements concerning Relator share have been reached to date.

7. Conditioned upon receipt of the payment described in Paragraph 1, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, agrees to release CTI, its officers, agents, and employees, from any liability to Relator arising from the filing of the Civil Action. Notwithstanding the foregoing, this Agreement does not release, resolve or in any manner affect any claims Relator may have against CTI or their officers, agents or employees arising under 31 U.S.C. § 3730(h), and/or any claims Relator may have against Medcomm Solutions, Envision Pharma, Inc., Amerisourcebergen Corp. and/or Documedics or their officers, agents or employees. Furthermore, notwithstanding the foregoing, this Agreement does not abrogate or in any manner affect Relator's right to recover attorney's fees, costs and expenses pursuant to 31 U.S.C. §§ 3730(d)(1), and (2) which he incurred in connection with his prosecution of the Civil Action.

8. CTI has provided financial disclosure statements ("Financial Statements") to the United States and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Agreement. If the United States learns that CTI's financial statements as of December 31, 2006 as filed with the SEC on Form 10-K dated March 16, 2007, and any other financial statements filed with SEC through the Effective Date of this Settlement Agreement, contained any knowing misrepresentation or omission that caused a material understatement of CTI's ability to pay (a "Knowing Material Misrepresentation"), the United

States may at its option pursue relief under this Paragraph 8 as follows: (a) the United States shall provide CTI with written notice of the nature of the Knowing Material Misrepresentation; (b) within ten (10) calendar days of the date of the written notice, CTI shall provide the United States, in writing, with any explanation it may have regarding the the Knowing Material Misrepresentation referenced in the written notice; (c) if unsatisfied with CTI's explanation, as determined in its sole and absolute discretion, the United States may file an action seeking relief under this Paragraph 8 in which the United States shall bear the burden of establishing by a preponderance of the evidence the Knowing Material Misrepresentation; (d) if the court finds a Knowing Material Misrepresentation, then the court may enter judgment in favor of the United States and award the following relief: (i) the Settlement Amount shall be increased by one hundred percent (100%) of the amount of the Knowing Material Misrepresentation; (ii) any remaining unpaid principal portion of the Settlement Amount (including the increase specified in subparagraph (d)(i) above) shall become accelerated and immediately due and payable, with interest at a simple rate of 5% from the Effective Date of this Agreement to the date of the Court finding, and at the Medicare interest rate (per 42 C.F.R. part 405.378) from the date of the court finding until the date of payment; (iii) the United States may offset the remaining unpaid balance of the Settlement Agreement (inclusive of interest and the increase specified in subparagraph d(i) above) from any amounts due and owing to CTI by any department, agency, or agent of the United States; and (iv) CTI shall immediately pay the United States all reasonable attorney's fees and expenses incurred in the action seeking relief under this Paragraph 8.

9. CTI waives and shall not assert any defenses CTI may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole

or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

10. CTI fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that CTI has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

11. This Agreement is neither intended by the parties to be, nor should be, interpreted as an admission of liability by CTI. In addition, the parties agree that no representation, term or condition of this Settlement Agreement or any draft thereof shall be admissible as an admission of, or evidence of, any fault or omission of CTI in any proceeding in any court or before any administrative body.

12. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary or any state payer, related to the Covered Conduct; and CTI shall not cause others to resubmit to any Medicare carrier or intermediary or any state payer any previously denied claims related to the Covered Conduct, and shall not appeal or support the appeal any such denials of claims.

13. CTI agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, CTI shall make reasonable efforts to facilitate access to, and encourage the cooperation of, its directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals, and shall furnish to the United States, upon reasonable request, all nonprivileged documents and records in its possession, custody, or control relating to the Covered Conduct.

14. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 15 below.

15. CTI agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

16. CTI warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to CTI within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set

forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which CTI was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

17. If within 91 days of the Effective Date of this Agreement or of any payment made under this Agreement, CTI commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of CTI's debts, or seeking to adjudicate CTI as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for CTI or for all or any substantial part of CTI's assets, CTI agrees as follows:

a. CTI's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and CTI shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) CTI's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) CTI was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to CTI.

b. If CTI's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action, or proceeding against CTI for the claims that would otherwise be covered by the releases provided in Paragraphs 2 and 3 above. CTI agrees that (i) any such claims, actions, or proceedings brought by the United States

(including any proceedings to exclude CTI from participation in Medicare, Medicaid, or other Federal health care programs) are not subject to an “automatic stay” pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceedings described in the first clause of this Paragraph, and CTI shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) CTI shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding that are brought by the United States within 120 calendar days of written notification to CTI that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date; and (iii) the United States has a valid claim against CTI in the amount of \$214,965,945.03 and the United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

c. CTI acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

18. Upon receipt of the payments described in Paragraph 1, above, the United States shall promptly file in the Civil Action a Notice of Partial Intervention, together with the United States' Complaint in Intervention, and, together with the Relator, file a Joint Stipulation of Dismissal with prejudice of the Civil Action as to CTI, pursuant to the terms of the Agreement.

19. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

20. CTI represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

21. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement is the United States District Court for the Western District of Washington.

22. Relator represents that this Agreement is freely and voluntarily entered into without any duress or compulsion whatsoever.

23. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

24. The individuals signing this Agreement on behalf of CTI represent and warrant that they are authorized by CTI to execute this Agreement. The individual(s) signing this Agreement on behalf of the Relator represent and warrant that they are authorized by Relator to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

25. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

26. This Agreement is binding on CTI's successors, transferees, heirs, and assigns.


27. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

28. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

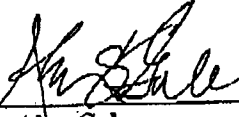
29. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA


DATED: 4-13-07

BY: 
Peter A. Winn
Assistant United States Attorney
Western District of Washington

DATED: 4-13-07

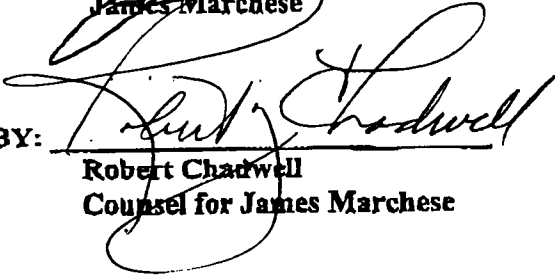
BY: 
Alan Gale
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 4/16/07

BY: 
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the
Inspector General
Office of Inspector General
United States Department of
Health and Human Services

JAMES MARCHESE - RELATOR

DATED: 4/13/07 BY: 
James Marchese

DATED: 4/13/07 BY: 
Robert Chatwell
Counsel for James Marchese

CELL THERAPEUTICS, INC. - DEFENDANT

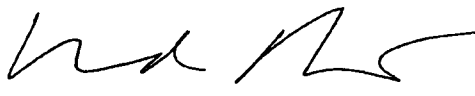
DATED: 04-13-07 BY: James Blanco
James Blanco
Chief Executive Officer

DATED: _____ BY: _____
Harold Malkin
Counsel for Cell Therapeutics, Inc.

DATED: _____ BY: _____
Stuart Gerson
Counsel for Cell Therapeutics, Inc.

CELL THERAPEUTICS, INC. – DEFENDANT

DATED: _____ BY: _____
James Bianco
Chief Executive Officer

DATED: 4/13/07 BY: 
Harold Malkin
Counsel for Cell Therapeutics, Inc.

DATED: _____ BY: _____
Stuart Gerson
Counsel for Cell Therapeutics, Inc.

CELL THERAPEUTICS, INC. -- DEFENDANT

DATED: _____ BY: _____
James Bianco
Chief Executive Officer

DATED: _____ BY: _____
Harold Malkin
Counsel for Cell Therapeutics, Inc.

DATED: April 13
2007 BY: [Signature]
Stuart Gerson
Counsel for Cell Therapeutics, Inc.