

# Material Transfer Agreement

For MSC(s) to be used for Research Purpose Only

Messrs. **Summit Pharmaceutical International Corporation** at 1-2-2, Hitotsubashi, Chiyoda-ku, Tokyo 100-0003, Japan (hereafter referred to as "SPI")

In connection with the use of MSC(s) (as such terms are hereinafter defined), we, \_\_\_\_\_

\_\_\_\_\_

at \_\_\_\_\_

(hereafter referred to as "Purchaser"), hereby agree to comply with the following Material Transfer Agreement ("MTA").

## Material Transfer Agreement

This MTA is effective as of the date of signature by the Purchaser and governs the purchase and use of all MSC(s) under the terms and conditions set forth below.

### 1. Definitions

**"Commercial Use"** means the sale, license, lease, export, transfer or other distribution of the MSC(s), Modification(s), Progeny and Unmodified Derivative(s) to a person, organization or entity not party to this MTA for financial gain or other commercial purposes and/or the use of the MSC(s).

- a. to provide a service to a person, organization or entity not party to this MTA for financial gain;
- b. to produce or manufacture products for general sale or products for use in the manufacture of products ultimately intended for general sale;
- c. to use MSC(s), Progeny, Modification(s) or Unmodified Derivative(s) in (1) human subjects for human clinical use for therapeutic, diagnostic or prophylactic purposes or (2) in animals for veterinary use for therapeutic, diagnostic or prophylactic purposes, including but not limited to clinical applications, cell therapy, transplantation, and/or regenerative medicines;
- d. in connection with proficiency testing service(s), including but not limited to, providing the service of determining laboratory performance by means of comparing and evaluating calibrations or tests on the same or similar items or materials in accordance with predetermined conditions; or
- e. In addition, Commercial Use means the sale, license, lease, export, transfer or other distribution of any research result(s) developed in Purchaser's laboratory by the use of MSC(s), Modification(s), Progeny and Unmodified Derivative(s) for financial gain or other commercial purposes.

**"MSC(s)"** means the mesenchymal stem cell(s) provided by CellSource Co., Ltd. and distributed by SPI.

**"Purchase Order"** means an order submitted for MSC(s) in a form and format as determined by SPI from time to time.

**"Modification(s)"** means substances created by Purchaser, which contain and/or incorporate a significant or substantial portion of MSC(s), its (their) Progeny or Unmodified Derivative(s), and cells which are created by Purchaser through the use of MSC(s), its (their) Progeny or Unmodified Derivative(s) but which (i) do not differentiate into cell types from all three germ layers and (ii) are in a partially or terminally differentiated state.

**“Progeny”** means cells created by Purchaser from MSC(s) which (i) retain the ability to self-replicate, retain ability to differentiate into cell types from all three germ layers, and (ii) remain in an undifferentiated state whether genetically modified or cloned. .

**“Unmodified Derivative(s)”** mean substances created by Purchaser that constitute an unmodified functional sub-unit or product not changed in form or character and expressed by MSC(s). Unmodified Derivative(s) include, but are not limited to, subclones of unmodified cell lines, purified or fractionated subsets of MSC(s), proteins expressed by DNA/RNA, extracellular vesicles secreted from MSC(s), antibodies or any fragments thereof.

**“Purchaser(s)”** means the organization or entity purchasing and using the MSC(s) pursuant to this MTA.

**“Provider”** means CellSource Co., Ltd. that provides MSC(s) to Purchaser through SPI.

## **2. Term of this MTA**

- 2.1. This MTA shall remain effective from the date of signature by Purchaser until or unless earlier terminated under the provisions hereof.
- 2.2. This MTA shall end if SPI terminates this MTA by giving written notice to Purchaser within 7 days in case of Purchaser's breach of this MTA. In addition, SPI may immediately cease without notice to Purchaser further shipments of MSCs and shall be entitled to seek temporary restraining orders and other preliminary or permanent injunctive relief.

## **3. Scope of Use**

- 3.1 Subject to the provisions of this MTA, Purchaser may use the MSC(s), Modification(s), Progeny and Unmodified Derivative(s) during the term of this MTA for non-exclusive research purposes in Purchaser's laboratory only. MSC(s), Modification(s), Progeny and Unmodified Derivative(s) are strictly prohibited to use in humans, including but not limited, any clinical research and any clinical trial. Purchaser agrees that the MSCs designated as biosafety greater than [1] constitute known pathogens and that MSCs not designated this way may be pathogenic under certain conditions (for further details see the Certificate of Analysis (“COA”) and the Product Sheet provided by SPI if any). Purchaser assumes all risk and responsibility in connection with the receipt, handling, storage, disposal, transfer and Purchaser's use of the MSC(s) including without limitation taking all appropriate safety and handling precautions to minimize health or environmental risk. Purchaser agrees that any activity undertaken with the MSC(s) will be conducted in compliance with all applicable guidelines, laws and regulations, and that Purchaser will obtain all permits, licenses or other approvals required by any governmental authority in connection with purchaser's receipt, handling, storage, disposal, transfer and use of the MSC(s).
- 3.2 Purchaser shall not distribute, sell, lend or otherwise transfer, to a person, organization or entity not party to this MTA, the MSC(s), Modification(s), Progeny and/or Unmodified Derivative(s) for any reason, without SPI's prior written consent. Purchaser agrees that any third party other than the Purchaser utilizing the MSC(s), Modification(s), Progeny and Unmodified Derivative(s) will be required to obtain a prior written agreement separately.
- 3.3 Purchaser and SPI shall have discussion separately and determine the specific terms and condition if Purchaser wishes to use MSC(s), Modification(s), Progeny and/or Unmodified Derivative(s) for Commercial Use. Provider and SPI make no representation or warranty that the use of the MSC(s), Modification(s), Progeny and/or Unmodified Derivative(s) will not infringe any patent or other proprietary right and regarding the existence or the validity of such rights. Purchaser shall have the sole responsibility for obtaining any intellectual property licenses necessitated by its possession and use of the MSC(s) Modification(s), Progeny and/or Unmodified Derivative(s).
- 3.4 Upon termination of this MTA, Purchaser shall stop to use MSC(s), Modification(s), Progeny and/or Unmodified Derivative(s).
- 3.5 SPI is providing Purchaser with MSC(s) pursuant to an agreement by and between Provider and SPI. Provider is an express third party beneficiary of this MTA.

#### **4. Compliance with Laws**

Purchaser agrees to acknowledge that MSC(s) is human mesenchymal stem cells and to be solely responsible for compliance with all foreign and domestic, federal, state and local statutes, ordinances, governmental regulations and guidelines and any other regulations or guidelines pertaining to research that are relevant in connection with the use of MSC(s) Modification(s), Progeny and Unmodified Derivative(s). Without limiting the generality of the foregoing, any shipment of MSC(s) to countries outside of Japan must comply with all applicable foreign and Japanese laws. If there is any conflict between the terms of this MTA and any applicable law or regulation with respect to MSC(s), Modification(s), Progeny and Unmodified Derivative(s) the terms of the applicable law or regulation shall govern.

#### **5. Warranty**

SPI warrants that:

- a. cells included in the MSC(s) shall be viable upon initiation of culture for a period of twenty-five (25) days after receipt of MSC(s) by Purchaser ("Warranty Period") and
- b. any MSC(s) shall meet the specifications on the applicable COA. Purchaser's exclusive remedy, and SPI's sole liability, for breach of the warranties set forth in this paragraph is for SPI to, at SPI's sole option, either (i) to grant a fair and reasonable price reduction for such MSC(s) (exclusive of shipping and handling charges), or (ii) replace the MSC(s). The warranties set forth in this paragraph apply only if Purchaser handles and stores the MSC(s) as described in the applicable COA or the Product Sheet provided by SPI.

To obtain the exclusive remedy, Purchaser must report the lack of viability or non-conformation to specifications on the applicable COA to SPI within the applicable Warranty Period. Except as expressly provided above, the MSC(s) and any technical information and assistance provided by SPI are provided as-is, without warranties of any kind, express or implied, including but not limited to any implied warranties of merchantability, fitness for a particular purpose, typicality, safety, accuracy and/or non-infringement.

#### **6. Indemnification**

Purchaser shall, at all times during the term of this MTA and thereafter, indemnify, defend and hold harmless SPI, Provider and their affiliates from and against all claims, proceedings, demands and liabilities of any kind whatsoever, including legal expenses and reasonable attorneys' fees (collectively "Claims"), resulting from Purchaser's use, handling, storage or disposition of the MSC(s), Modification(s), Progeny and Unmodified Derivative(s) and other activities relating to MSC(s), Modification(s), Progeny and/or Unmodified Derivative(s), provided that Purchaser's liability shall be limited to the extent that any such Claim arises out of SPI and/or Provider's gross negligence or willful misconduct.

#### **7. Limitation of Liability**

In no event will SPI and/or Provider be liable for any use of the MSC(s), Modification(s), Progeny and/or Unmodified Derivative(s) by Purchaser, or for any loss, claim, damage or liability of any kind or nature, that may arise from or in connection with the MTA or with the use, handling, storage or disposition of the MSC, Modification(s), Progeny and/or Unmodified Derivative(s). In addition, in no event shall SPI and/or Provider be liable for any indirect, special, incidental or consequential damages of any kind in connection with or arising out of the MTA or MSC(s), Modification(s), Progeny and/or Unmodified Derivative(s) even if SPI and/or Provider has been advised of the possibility of such damages.

#### **8. Intellectual Property; Identification**

- 8.1 As between the parties, Provider shall retain ownership of all right, title and interest in the MSC(s), Progeny, Unmodified Derivatives and MSC(s) contained or incorporated in Modifications.

- 8.2 Purchaser retains ownership of:
- a. Modifications (except of MSC(s) included therein), and
  - b. those substances created through the use of MSC(s), but which do not contain MSC(s).
- 8.3 Notwithstanding the foregoing, Purchaser acknowledges and agrees that the MSC(s), Modification(s), Progeny and Unmodified Derivative(s) are subject to the restrictions noted in the "Scope of Use" section above. Purchaser agrees to acknowledge Provider as the source of the MSC(s) in all research, academic or scholarly publications and in patent applications that reference the MSC(s). Purchaser explicitly acknowledges that Provider retains all right, title and interest in the Provider trademarks, trade-names, logos and Provider specific designations of MSC(s). Purchaser expressly agrees not to use the Provider trademarks, trade-names, logos or Provider specific designations of MSC(s) in any way without Provider's prior written agreement.

## 9. Miscellaneous

- 9.1 Any disputes, claims or controversies arising out of, relating to, or in connection with this MTA shall be exclusively and finally settled by the Tokyo District Court, Japan and Purchaser hereby expressly consents to, submits to and waives any objection to the jurisdiction of this court. This MTA shall be governed by Japanese Law.
- 9.2 Purchaser may not assign or otherwise transfer this MTA or any rights or obligations under this MTA, whether by operation of law or otherwise. Any such attempted assignment or transfer will be void and of no force or effect.
- 9.3 This MTA, including all documents incorporated herein by reference, constitutes the entire agreement between SPI and Purchaser with respect to the MSC (s) and supersedes all previous agreements or representations (whether written or oral) between SPI and Purchaser relating to the same subject matter.
- 9.4 This MTA may not be modified, waived or terminated except in writing and signed by the parties hereto. No term or provision contained herein shall be deemed waived and no breach excused unless such waiver or consent shall be in writing and signed by the parties.
- 9.5 If any provision of this MTA is for any reason found to be unenforceable, the remainder of this MTA will continue in full force and effect.
- 9.6 None of the provisions of this MTA are intended to create, nor shall be deemed or construed to create, any relationship between SPI and Purchaser other than that of independent entities contracting with each other hereunder solely for the purpose of effecting the provisions of this MTA.
- 9.7 The Purchase Order shall prevail over the provisions of this MTA.

Purchaser acknowledges that they have read, understand and agree to the terms of this MTA:

Purchaser: \_\_\_\_\_  
(Organization/Entity)

Signature: \_\_\_\_\_

Authorized Person: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_