**CLINICAL STUDY AGREEMENT**

THIS AGREEMENT is made this \_\_\_\_\_\_ day of \_\_\_\_\_, 19 , between The University of Texas ("INSTITUTION"), a component of The University of Texas System ("SYSTEM"), and ICI Americas Pharmaceuticals Group, a business unit of ICI Americas Inc., Wilmington, DE, 19897, ("SPONSOR"). INSTITUTION and SPONSOR agree as follows:

**1. PROTOCOL**

1.1 INSTITUTION agrees to use its best efforts to conduct the STUDY, as an independent contractor, in accordance with INSTITUTIONAL policy, applicable laws and regulations and the Protocol "                          ", ("STUDY"), described in Exhibit I as attached hereto and incorporated herein. The STUDY will be supervised by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, at INSTITUTION with assistance from associates and colleagues as required.

1.2 SPONSOR agrees to engage the services of INSTITUTION to conduct the STUDY and further agrees to provide the drug at no cost to INSTITUTION for the conduct of the STUDY.

**2. AWARD**

2.1 SPONSOR shall pay INSTITUTION \_\_\_\_\_\_\_\_\_\_\_and NO/100 DOLLARS ($ \_\_\_ ) for STUDY expenses for the clinical study of approximately \_\_\_\_\_ (\_\_\_ ) patients and other related costs. This amount, shown by approximate category of expense in Exhibit II attached hereto for information only, is payable in \_\_\_\_\_\_ (\_\_\_ ) installments of \_\_\_\_\_\_\_\_\_ and NO/100 DOLLARS ($\_\_\_ ) each by SPONSOR to INSTITUTION. The first installment is \_\_\_\_\_ ($\_\_\_ ) payable within thirty (30) days of the date set forth herein above, and subsequent installments are payable on a quarterly basis upon receipt by SPONSOR of interim case reports for: (a) one-third (1/3) of the final patient enrollment; (b) two-thirds (2/3) of the final patient enrollment; and (c) the remaining patient enrollment and STUDY close out (i.e., all patient case report forms have been completed, all missing and/or erroneous data points have been resolved, the study summary has been submitted to the INSTITUTION's IRB and all clinical trial materials have been returned to SPONSOR or otherwise accounted for).

**3. TERM**

3.1 This Agreement shall continue in force until the earlier of completion of the STUDY as mutually agreed upon by the parties, or Twelve (12) month(s) from the date herein above; provided, that either party may terminate the STUDY by giving thirty (30) days advance notice of termination to the other.

3.2 Upon early termination of this Agreement, SPONSOR shall be liable for all reasonable costs incurred or obligated by INSTITUTION at the time of such termination, which costs cannot be canceled, subject to the maximum amount specified in Article 2. Within ninety (90) days of completion or earlier termination of the STUDY, the INVESTIGATOR will submit a final written report to SPONSOR, as required by federal regulations. Upon receipt of this report, SPONSOR shall pay INSTITUTION for such costs within thirty (30) days of receipt of an invoice for same.

3.3 Upon termination of this Agreement, INSTITUTION shall return SPONSOR'S material and equipment to SPONSOR.

**4. INDEMNIFICATION**

4.1 INSTITUTION shall, to the extent authorized under the Constitution and laws of the State of Texas, hold SPONSOR harmless from liability resulting from the negligent acts or omissions of INSTITUTION, its agents or employees pertaining to the activities to be carried out pursuant to the obligations of this Agreement; provided, however, that INSTITUTION shall not hold SPONSOR harmless from claims arising out of the negligence of SPONSOR, its officers, agents, or any person or entity not subject to INSTITUTION supervision or control.

4.2 SPONSOR shall indemnify and hold SYSTEM, INSTITUTION, and INVESTIGATOR harmless against liability for damages for personal injury to a patient, resulting from the use of drug provided by ICI for the conduct of the STUDY ("Study Drug"), as well as for personal injury arising from the performance of the protocol, if Study Drug is administered in accordance with the Protocol and if INSTITUTION and INVESTIGATOR shall have administered Study Drug and otherwise acted in conformity with the generally accepted standards in the medical community in which they practice, and SYSTEM, INSTITUTION, and INVESTIGATOR have not violated any local, state or federal laws giving rise to the subject matter of the claim, including, but not limited to, the Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated pursuant thereto and have not otherwise been negligent in any respect, so as to give rise to the subject matter of the claim; provided, however, that SYSTEM, INSTITUTION, and INVESTIGATOR (subject to the statutory duties of the Texas Attorney-General) shall permit SPONSOR's attorneys, at SPONSOR's discretion and cost, to handle and control the defense and settlement of any claim or suits.

This indemnity provision is further conditioned upon the SYSTEM, INSTITUTION, and INVESTIGATOR giving SPONSOR prompt written notice of any claim involving Study Drug and cooperating fully with SPONSOR in the defense thereof, affording SPONSOR complete access to all relevant records.

This agreement to indemnify under the circumstances set forth above, shall continue until the termination of the Study on or until five days' prior written notice of termination given by SPONSOR; but any such termination shall not affect SPONSOR's obligations with respect to any claim or lawsuit indemnified under the provisions of this section 4.2, including but not limited to claims arising prior to INSTITUTION'S receipt of such notice.

**5. OWNERSHIP, CONFIDENTIALITY AND PUBLICATION**

5.1 All rights to all data, inventions or discoveries INSTITUTION may make or conceive in the course of performance of work for SPONSOR under this Agreement using the [study drug] in accordance with the detailed Protocol provided by SPONSOR for this STUDY will be the property of SPONSOR and will be assigned to SPONSOR. INSTITUTION will cooperate with SPONSOR, including assisting SPONSOR in the execution of rightful papers, at SPONSOR'S expense, in obtaining proper patent protection in such Inventions in any country which SPONSOR at SPONSOR'S option, desires to obtain patent protection. All control of and decisions regarding such patent filings and prosecution, whether U.S. or foreign, and all costs and fees associated therewith, shall be exercised and/or borne by SPONSOR.

5.2 The sole and exclusive ownership to any patentable inventions or discoveries other than those provided for in Section 5.1 above, made solely by INSTITUTION resulting wholly or in part from the performance of work under this Agreement is hereby reserved to and shall be the property of INSTITUTION. Any invention or discovery other than those provided for in Section 5.1 above, resulting wholly or in part from work performed under this Agreement made jointly by SPONSOR and INSTITUTION shall be owned jointly by the parties. SPONSOR will have the first right to negotiate an exclusive worldwide license, with right to sublicense, at a reasonable royalty to be agreed upon for the life of any patent, whether owned jointly by the parties or solely by the INSTITUTION, resulting from said inventions under this section or such other term to which the parties agree if said inventions are not patented, to make, have made, use and sell compounds, products or processes coming within said inventions or patents. If INSTITUTION and SPONSOR are not able to agree upon reasonable terms for any such patent licenses, and INSTITUTION is prepared to offer a license, or sell or assign its sole or joint interest, to a third party on terms other than those previously offered SPONSOR, SPONSOR shall also have the one-time right of first refusal for such other terms. SPONSOR shall treat any inventions made solely by INSTITUTION and disclosed to SPONSOR as INSTITUTION's confidential information and shall not disclose or use same, except as may be authorized by the license agreement licensing said inventions and provided that SPONSOR shall not be required to bind any of its employees for longer than five (5) years after said employee leaves SPONSOR's employ. The parties agree to conduct good-faith discussions concerning the options for commercialization of said joint property.

5.3 Any invention or discovery resulting wholly or in part from work performed under this Agreement made solely by SPONSOR shall be owned by SPONSOR.

5.4 It may be necessary for SPONSOR to disclose to INSTITUTION certain information considered proprietary or confidential (hereinafter "Confidential Information") to aid INSTITUTION in effecting or completing its performance under this Agreement. INSTITUTION agrees to maintain in confidence all Confidential Information INSTITUTION obtains from SPONSOR relating to this Agreement and not to disclose any of said Confidential Information to a third party without the prior written consent of SPONSOR. Notwithstanding the foregoing, it is understood that Confidential Information shall not include the following: (a) information that is now publicly available; (b) information that later becomes publicly available, after it has become publicly available; (c) information which INSTITUTION obtains from some third party not under any obligation to SPONSOR with respect to such information; or (d) information which INSTITUTION already has in its possession, prior to any disclosure by SPONSOR, as evidenced by written records.

5.5 Subject to the provisions of confidentiality set forth in Section 5.4 above, SPONSOR agrees that INSTITUTION may publish its findings in the scientific literature, provided that SPONSOR shall have the right to review at least thirty (30) days prior to submission for publication, copies of any and all final draft manuscripts which are authored or coauthored by INSTITUTION or by anyone in its research group and which are based in whole or in party on research conducted under this Agreement. Upon request by SPONSOR, in order to protect intellectual property rights, INSTITUTION agrees to delay submission of such final draft manuscripts for publication for a period not exceeding six (6) months from the date on which SPONSOR receives such final draft manuscripts, INSTITUTION agrees to implement any reasonable suggestions made to preserve SPONSOR's right in its Confidential Information before any disclosure for publication or presentation; INSTITUTION agrees to take appropriate cognizance of any other suggestions by SPONSOR before any disclosure for publication or presentation.

**6. GENERAL**

6.1 This Agreement and its exhibits constitute the entire and only Agreement between the parties relating to the STUDY, and all prior negotiation, representations, agreements, and understandings are superseded hereby. No agreements altering or supplementing the terms hereof may be made except by a written document signed by the duly authorized representatives of the parties.

6.2 Any conflicts between the Protocol and this Agreement are controlled by this Agreement.

6.3 THIS AGREEMENT SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH THE LAWS OF THE STATE OF TEXAS.

6.4 This Agreement anticipates educational training and may involve health science postgraduates and other students of the INSTITUTION.

6.5 It is understood and agreed that in connection with their performance under this Agreement, SYSTEM, INSTITUTION, and INVESTIGATOR shall be acting as independent contractors and not as agents or employees of Sponsor.

6.6 Except as otherwise required by law or regulation, neither party shall issue any information or statement to the press or public concerning the name of the other party including, but not limited to, advertisements for the enrollment of study subjects, without the prior written permission of an authorized representative of the party whose name is sought to be used, which permission shall not be unreasonably withheld.

6.7 Whenever any notice is to be given hereunder, it should be in writing and sent to the following addresses:

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| --- | --- |
| SYSTEM: Intellectual Property SectionOffice of General CounselUniversity of Texas System201 W. 7th Street, 7th FloorAustin, TX 78701 | INSTITUTION: The University of Texas\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, TX \_\_\_\_\_ |
| INVESTIGATOR:   | SPONSOR: ICI PharmaceuticalsICI Americas, Inc.Wilmington, DE 19879  |

IN WITNESS WHEREOF, The parties hereto have executed this Agreement on the day, month, and year indicated below:

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| --- | --- |
| UNIVERSITY OF TEXAS \_\_\_\_\_\_\_\_\_\_\_\_ By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | ICI PHARMACEUTICALS GROUPA BUSINESS UNIT OF ICI AMERICAS INC. By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

I have read this Agreement and understand
my obligations hereunder.

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
                   (Principal Investigator)

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

**ICI
Revised 6/29/93**