

## CLINICAL TRIAL AGREEMENT

This Clinical Trial Research Agreement (the “**Agreement**”), entered into as of this 19th day of June (the “**Effective Date**”), is by and between San Mateo Medical Center, Clinical Trials and Research Unit, having its principal office and place of business located at 222 West. 39<sup>th</sup> Avenue, San Mateo, CA 94403 (“**Institution**”), and SciClone Pharmaceuticals, Inc., a corporation organized under the laws of the State of California, having its principal offices located at 901 Mariner’s Island Blvd., Suite 205, San Mateo, California 94404 (“**Sponsor**”).

WHEREAS, the Sponsor would like to enlist the assistance of the Institution to conduct a clinical study, and such clinical study is of mutual interest and benefit to the Institution and the Sponsor and will further the instructional and research objectives of the Institution in a manner consistent with its status as a nonprofit, tax-exempt, research and educational institution.

NOW, THEREFORE, in consideration of the following mutual promises, covenants, and conditions and any sums to be paid by the Sponsor to the Institution, hereunder, the parties hereto agree as follows:

1. Statement of Work. The Institution and the Institution’s Principal Investigator (as defined below) agree to conduct a clinical study of ZADAXIN<sup>®</sup> (thymalfasin) Thymosin alpha 1, Injection (the “**Study Drug**”) on behalf of the Sponsor, entitled “A Multicenter Double-Blinded Study In Patients With Compensated Cirrhosis Due to Chronic Hepatitis C Who Are Non-Responders To Prior Interferon Alfa Or Interferon Alfa + Ribavirin Therapy, Comparing Treatment With Thymosin Alpha 1 + Peginterferon Alfa-2a With Peginterferon Alfa-2a + Placebo” Protocol Tα1-CHC-2K0804” (the “**Study**”) in accordance with the protocol attached and included as part of this Agreement as Exhibit A (the “**Study Protocol**”). The Institution will conduct the Study in accordance with all applicable laws, application Institution policies and the conditions specified in the Statement of Principal Investigator, FDA Form 1572, signed by the Institution’s Principal Investigator, including but not limited to compliance with the Sponsor’s procedures for Study documentation and adverse event reporting.

2. Principal Investigator. The Institution will conduct the Study under the direction of the Institution’s Principal Investigator, Dennis M. Israelski, M.D., (“**Principal Investigator**”), who shall be responsible for performing the Study and for direct supervision of any individual performing portions of the Study at the Institution. The Institution agrees that the Principal Investigator and each consultant, independent contractor, employee or agent engaged by the Institution to assist in the performance of the Study has signed a written agreement that binds such party to obligations no less restrictive than those contained in this Agreement, including but not limited to the obligations of non-disclosure and non-use of Confidential Information (as defined below), and assignment and ownership of inventions. In the event the Principal Investigator becomes unwilling or unable to perform the duties required to conduct the Study under this Agreement, the Institution and the Sponsor shall attempt to identify a qualified and mutually acceptable replacement for the Principal Investigator. In the event a mutually acceptable replacement cannot be identified and agreed upon by the parties, then the Study may be terminated by either party hereto in accordance with the terms of Section 7.1 (“**Study Termination**”) of this Agreement.

3. Term. The term of this Agreement will be from 19-June-2003 through 19-June-2006 ("**End Date**"), unless earlier terminated pursuant to the terms of Section 7.1 ("**Study Termination**"). In the event that the Study is not completed prior to the End Date, the parties hereto may agree in writing to extend the term of this Agreement until such time as the Study is completed or for such other period as is mutually agreed upon by the parties in writing.

4. Obligations of the Institution. The Institution shall conduct the Study in good scientific manner, and in compliance in all material respects with all requirements of applicable laws and regulations, internal institutional procedures and guidelines, and all applicable good laboratory and clinical practices, and shall use its best efforts to achieve the objectives of the Study efficiently and expeditiously. The Institution shall ensure that, prior to commencing the Study, the Institution's Investigational Review Board ("**IRB**") shall and the Institution shall have provided to Sponsor a letter from the IRB to such effect.

5. Materials. Sponsor shall deliver to the Institution the Study Drug and certain materials as identified in the Protocol and such materials, collectively, "**Study Materials**") for use in the Study. The Study Materials represent significant investments of Sponsor and shall remain the exclusive property of Sponsor. The Institution shall not use the Study Materials provided for any purpose other than conducting the Study on Sponsor's behalf pursuant to this Agreement. The Institution shall retain exclusive control over the Study Materials provided by Sponsor and shall not transfer the Study Materials, or any portion thereof, to any individual or entity who is not working under this Agreement or is not a patient enrolled in the Study without the prior written consent of Sponsor. The use of the Study Materials shall be subject to the Protocol and the provisions of Section 9 ("**Confidentiality**") below.

6. Protocol Modifications. The Institution and/or the Principal Investigator may not make any changes to the study Protocol without prior written approval of Sponsor in Sponsor's sole discretion. The Institution will submit all changes to the IRB. Protocol modifications that impact on patient safety or the validity of the study must be approved by the IRB and submitted to Sponsor.

7. Termination.

7.1 Study Termination. Sponsor may terminate this Agreement at any time (i) if the Institution or the Principal Investigator fails to comply with the terms of this Agreement or the Protocol, (ii) upon thirty (30) days' prior written notice to the Institution, or (iii) pursuant to Section 2 ("**Principal Investigator**") or 11 ("**Representations and Warranties**") of this Agreement. The Institution may terminate this Agreement upon or after the breach of any material provision of this Agreement by Sponsor if Sponsor has not cured such breach within thirty (30) days after Sponsor's receipt of written notice thereof from the Institution. Notwithstanding any termination of this Agreement, Sections 7.2 ("**Final Report**"), 8 ("**Study Results and Retention of Records**"), 9 ("**Confidentiality**"), 13 ("**Indemnification**"), 16 ("**Limitation of Liability**") and 17 ("**General Terms**"), and hereof shall survive such termination and shall remain in full force and effect.

7.2 Final Report. A final report setting forth the significant research findings shall be prepared by the Principal Investigator and submitted to the Sponsor within ninety (90)

days following the termination of the Study or the effective date of early termination of this Agreement.

## 8. Study Results and Retention of Records.

8.1 Study Results. Sponsor shall be the sole owner of all data, information and other results (excluding subject and patient records), including without limitation data forms and protocols, that are (i) provided by Sponsor, (ii) resulting from the Institution's performance of its obligations under this Agreement, or (iii) otherwise relating to the Study or the Study Materials (collectively, the "**Study Results**"). Following completion of the Study, the Institution shall provide Sponsor with copies of all Study Results, excluding subject and patient records.

8.2 Record Retention. The Institution shall comply with all records retention requirements under applicable law.

8.3 Transfer of Records. The Principal Investigator may withdraw from the responsibility to maintain records and transfer custody of the records to any other person, reasonably acceptable to Sponsor, who will accept responsibility for them in writing in accordance with Section 8.2 ("Record Retention"); provided, however, that such person shall agree in writing to comply with such records retention requirements, and the Principal Investigator shall give written notice of such transfer to Sponsor and the FDA not later than ten (10) working days after the transfer occurs.

## 9. Confidentiality.

9.1 Confidential Information. During the term of this Agreement, it is possible that the Institution and the Principal Investigator will acquire confidential or proprietary information, appropriately marked or identified as such, of Sponsor (together with the Study Results, the "**Confidential Information**"). The Confidential Information is and will remain the sole and exclusive property of Sponsor, and to the extent the Institution or Principal Investigator acquires any right, title or interest thereto, the Institution and Principal Investigator hereby assign all such right, title and interest to Sponsor. During the term of this Agreement and for a period of five (5) years thereafter, each shall maintain the confidentiality of this Agreement and keep confidential and not disclose to any third party the Confidential Information and use the Confidential Information only for purposes of conducting the Study. To the extent it is reasonably necessary to fulfill its obligations under this Agreement, the Institution and the Principal Investigator may disclose (i) Confidential Information to Institution employees on a need-to-know basis on the condition that such persons agree in writing, or are subject to a written Institution policy, to not disclose or use the Confidential Information for the same time periods and to the same extent as the Institution and the Principal Investigator are required hereunder, and (ii) Confidential Information to governmental or other regulatory authorities to the extent that such disclosure is required by applicable law, regulation or court order, provided that the Institution shall give advance written notice to Sponsor thereof and sufficient opportunity to object to such disclosure or to request confidential treatment thereof.

9.2 Exclusions. Notwithstanding the foregoing, Confidential Information shall not include any information disclosed to the Institution by Sponsor which: (i) is public

knowledge as of the Effective Date or subsequently becomes such through no breach of the Agreement by the Institution; (ii) is rightfully in Institution's possession prior to Sponsor's disclosure as shown by written records; (iii) is disclosed to Institution by an independent third party without an obligation of confidentiality; or (iv) is independently developed by or for Institution by persons without access to or use of Confidential Information.

## 10. Publication Rights.

10.1 Publication Right. Sponsor recognizes the value of disseminating research results and the Institution and the Principal Investigator shall be free to publish Study Results, subject to the obligations of this Section 10 ("Publication Rights").

10.2 First Publication. The first publication of Study Results by the Institution or the Principal Investigator shall be made in conjunction with the publication of the results from the principal investigators at all clinical study centers participating in the Study under the same Protocol. Authorship and contents of the publication shall be mutually acceptable to all of the principal investigators at the clinical study centers participating in such Study and Sponsor. Prior to such publication, Sponsor shall have the right to review and require modification of such publication to ensure the accuracy of the contents thereof and to delete Confidential Information therefrom. If the principal investigators choose not to publish within a mutually acceptable time, Sponsor reserves the right to publish the Study Results.

10.3 Subsequent Publication. Following such first publication, in any event in which the Institution and the Principal Investigator desire to independently publish information about the Study Results, the Institution shall furnish Sponsor with a written copy of any proposed publication or disclosure at least ninety (90) days in advance of submission for publication or presentation to permit Sponsor to review such material. Sponsor shall have the right (i) to propose modifications to the publication for patent reasons and to delete Confidential Information therefrom, and (ii) to request a reasonable delay in publication in order to protect patentable information. If Sponsor requests such a delay, Institution shall delay submission or presentation of the publication for a period of ninety (90) days to enable Sponsor to prepare and file applicable patent applications.

## 11. Representations and Warranties.

11.1 General. The Institution and the Principal Investigator each represent and warrant to Sponsor that (i) each has the legal authority and right to enter into this Agreement; (ii) neither has any obligation to any other party that is in conflict or has the potential to conflict with its obligations under this Agreement; (iii) neither will enter into any agreement with any third party to fund or support the Study without the express written consent of Sponsor; (iv) this Agreement has been duly executed and delivered by each and constitutes a valid, binding obligation enforceable against each of them in accordance with its terms; and (v) no clinical study or trial in which the Principal Investigator or the Institution was involved was terminated for any reason prior to completion, it has not received any Observations, Notice of Adverse Findings, or any regulatory letter from the FDA, or it was never disqualified from receiving investigational drugs or medical devices by the FDA.

11.2 Negative Actions. In the event that any of the events described in clause (v) of Section 11.1 (“General”) above occur during the course of this Study, the Institution and the Principal Investigator shall provide Sponsor with a full written explanation of the circumstances of such an incident within ten (10) days of the occurrence of such an incident. If the Institution or the Principal Investigator becomes debarred under the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 306(a) or (b), this Agreement will immediately terminate. If the Institution or the Principal Investigator receives a notice of action or a threatened debarment with respect to its debarment, Institution will notify Sponsor and Sponsor shall have the right to terminate this Agreement immediately.

11.3 No Debarred Entities. The Institution and the Principal Investigator each represents and warrants to Sponsor that it has not used, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred, and neither shall use, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred.

11.4 Notification of Threatened Debarment. In the event that the Institution or the Principal Investigator become aware of the debarment or threatened debarment of any individual, corporation, partnership, or association providing services to the Institution which directly or indirectly relate to Institution’s activities under this Agreement, Institution shall notify Sponsor immediately and Sponsor shall have the right to terminate this Agreement immediately.

11.5 Sponsor Warranties. Sponsor represents and warrants that Sponsor has (i) the legal authority and right to enter into this Agreement, (ii) no obligation to any other party that is in conflict with Sponsor’s obligations under this Agreement, and (iii) this Agreement has been duly executed and delivered by Sponsor and constitutes a valid, binding obligation enforceable against Sponsor in accordance with its terms.

11.6 Exclusions. EXCEPT FOR THE LIMITED WARRANTIES SET FORTH IN THIS SECTION 11 (“REPRESENTATIONS AND WARRANTIES”), NEITHER SPONSOR, THE INSTITUTION, NOR THE PRINCIPAL INVESTIGATOR MAKES OR RECEIVES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, AND EACH EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NONINFRINGEMENT.

11.7 Data Distribution. The Institution and the Principal Investigator understand that his/her data may be distributed by Sponsor to all investigators involved in this project or may be used to obtain market approval from regulatory agencies for the product.

## 12. Payment and Other Support.

12.1 Contract Total. The Sponsor shall pay the Institution up to an estimated total sum of \$101,500.00 (the “**Contract Total**”) for the Institution’s and the Principal Investigator’s performance of all obligations hereunder pursuant to the Study Protocol. All amounts paid by Sponsor hereunder shall be used by the Institution for the sole purpose of conducting the Study. Payment of the estimated Contract Total shall be made by the Sponsor to

the Institution in accordance with the Study budget attached as Exhibit B ("Study Budget") to this Agreement, and according to the following payment schedule:

10 percent (10%) of the estimated Contract Total ten (10) days after the completion of the study initiation visit;

30 percent (30%) of the estimated Contract Total upon receipt of the Institution's notice to Sponsor of enrollment and current participation in the study of one-third (1/3) of the estimated patient total;

25 percent (25%) of the estimated Contract Total upon receipt of the Institution's notice to Sponsor of enrollment and current participation in the study of two-thirds (2/3) of the estimated patient total;

20 percent (20%) of the estimated Contract Total upon receipt of the Institution's notice to Sponsor of completion of enrollment and current participation in the study of 100 percent (100%) of the estimated patient total. If completed enrollment is less than targeted total, the fourth payment will be incorporated into the final payment;

15 percent (15%) of the estimated Contract Total as the final contract payment, upon completion of all case report forms and the submission of the final Study report (pursuant to Section 7.2 ["Final Report"]) to the Sponsor less the amount of all prior payments.

Completion . . . . The estimated Contract Total payable to the Institution for the Study assumes completion of all evaluable patients in accordance with the scope of work set forth in the Study Protocol and that all evaluable patients will equal the estimated patient total. If the number of evaluable patients is less than the estimated patient total, the final contract payment shall be reduced by the pro rata portion of the estimated Contract Total associated with the difference in number of patients. Payment includes all applicable administrative and institution fees. For partially completed enrolled patients, the Sponsor shall add to the final payment a prorated amount of the estimated Contract Total in proportion to the number of patients enrolled in the Study and the duration of the partially completed patients' participation in the Study. All costs outlined in Exhibit B ("Study Budget") shall remain firm for the duration of the Study, unless otherwise agreed to in writing by the Institution and the Sponsor.

12.2 Accounting. Upon request by Sponsor, the Institution shall provide to Sponsor a report of expenditures shown by major cost categories.

12.3 Payment Information. All payments to be made by the Sponsor to the Institution hereunder shall be made payable to San Mateo Medical Center, Clinical Trials and Research Unit (Tax I.D. Number: 94-6000532) in United States dollars and directed as follows:

Sent to: Anita Booker  
San Mateo Medical Center, Clinical Trials and  
Research Unit M/S HOS316CTR  
222 West 39<sup>th</sup> Avenue  
San Mateo, CA 94403

13. Indemnification.

13.1 Sponsor Indemnification. The Sponsor shall defend, indemnify, and hold harmless the Institution from and against any third party liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Institution in connection with any third party claims, suits, actions, demands, or judgments to the extent: (i) arising out of any theory of product liability (including, but not limited to, actions in the form of tort, warranty, or strict liability) concerning the Study, or (ii) arising out of any side effect or adverse reaction, illness, or injury resulting from Institution's performance of the Study or occurring to any person involved in . . . . Institution shall promptly notify the Sponsor of any such claims, suits, actions, demands, or judgments and the Institution and the Principal Investigator shall reasonably cooperate with the Sponsor in the handling thereof.

13.2 Exclusions. The Sponsor's indemnification hereunder shall not apply to any liability, damage, loss, or expense to the extent that it is attributable to the (i) Institution's negligent activities, reckless misconduct, intentional misconduct, or omissions, (ii) failure of the Institution to comply with all applicable local, state, or federal laws or regulations, (iii) failure of the Institution to adhere to the terms of the Study or the Study Protocol, (iv) failure of the Institution to adhere to the Sponsor's written instructions related to the use of the Study Drug, or (v) other breach of this Agreement.

13.3 Case Management. The Sponsor, at its own expense, shall have the exclusive right to manage claims, control litigation, and select counsel, including the right to compromise or settle any claims, actions, suits, demands, or judgments, provided that it shall not compromise or settle any such action with an admission of liability or wrongdoing by the Institution without the Institution's written consent.

13.4 Illness or Injury. The Sponsor also shall reimburse the Institution for the costs of care and treatment of any illness or injury to a Study patient arising from or related to the administration of the Study Drug to the Study patient in accordance with the Study Protocol, to the extent that such costs are not covered by the Study patient's medical or hospital insurance or governmental programs providing such coverage.

13.5 Institution Indemnification. The Institution shall defend, indemnify, and hold the Sponsor harmless from and against any and all third party liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Sponsor in connection with any third party claims, suits, actions, demands, or judgments to the extent: (i) arising out of Institution's negligent activities, reckless misconduct, intentional misconduct, or omissions, (ii) arising out of failure of the Institution to comply with all applicable local, state, or federal laws or regulations, (iii) arising out of failure of the Institution to adhere to the terms of the Study or the Study Protocol, (iv) arising out of failure of the Institution to adhere to the Sponsor's written instructions related to the use of the Study Drug, or (v) arising out of any other breach of this Agreement.

14. Insurance. The Institution and the Principal Investigator, at their own expense, shall maintain in full force and effect during the term of this Agreement: (i) liability insurance (in

the form of general liability policies, umbrella policies, clinical trial policies or otherwise), written on an occurrence basis, and including coverage for bodily injury, property damage, personal injury, broad form contractual liability and product liability, with limits of \_\_\_\_\_ of not less than ten (10) million dollars per occurrence and in the aggregate; (ii) workers compensation and employer's liability insurance, with at least the minimum statutorily mandated limits in each jurisdiction where Institution or Principal Investigator have operations subject to workers compensation statutes; and (iii) professional liability insurance, applicable to actual or alleged wrongful acts of Institution or Principal Investigator or their agents, contractors and employees in connection with the Study or actions undertaken or omissions made pursuant to this Agreement, with minimum limits of liability of not less than ten (10) million dollars per claim. Institution and Principal Investigator shall maintain such Professional liability insurance at least for five years following Study termination. Institution and Principal Investigator shall name Sponsor as an additional insured on the liability insurance maintained pursuant to this Agreement. Institution and Principal Investigator shall provide Sponsor with copies of policies, endorsements or such other proof of each coverage required by this Section 14 as Sponsor may reasonably request from time to time. In any event, prior to commencement of the Study, Institution and Principal Investigator shall provide Sponsor with certificates of insurance and endorsements showing that Sponsor is an additional insured as required by this Section.

15. Notices. With the exception of Study funds paid by the Sponsor pursuant to Section 12 ("Payment Information") hereof, all notices required or permitted to be given under this Agreement shall be in writing, shall be deemed effective upon receipt by addressee, and shall be sent as follows:

If to the Sponsor:

Eduardo B. Martins, M.D., Ph.D.  
Medical Director  
SciClone Pharmaceuticals, Inc.  
901 Mariner's Island Blvd,  
Suite 205  
San Mateo, CA 94404

Phone: 650-358-1450  
Fax: 650-358-3469

If to the Institution:

Mark Traves, PAC  
Clinical Trials Coordinator  
San Mateo Medical Center  
222 West 39<sup>th</sup> Avenue  
San Mateo, CA 94403

Phone: 650-573-2793  
Fax: 650-522-8973

Notices relating exclusively to medical or scientific issues shall be sent to the Principal Investigator (with a copy to the Institution if such notices cover a change in the Study Protocol):



If to the Principal Investigator:

Dennis M. Israelski, M.D  
Chief of Infectious Diseases and AIDS Medicine  
San Mateo Medical Center  
222 West 39<sup>th</sup> Avenue  
San Mateo, CA 94403

Phone: (650) 573-2172

Fax: (650) 571-7802

16. Limitation of Liability. IN NO EVENT SHALL THE SPONSOR BE LIABLE TO THE INSTITUTION OR THE PRINCIPAL INVESTIGATOR FOR ANY SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR RELATING TO THE STUDY, THIS AGREEMENT, OR THE SUBJECT MATTER HEREOF, HOWEVER CAUSED AND WHETHER SUCH CLAIM IS BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE, EVEN IF AN AUTHORIZED REPRESENTATIVE OF THE SPONSOR IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

17. General Terms.

17.1 Independent Contractors. The relationship of the Sponsor to the Institution and the Principal Investigator shall be that of independent contractors and no party shall have authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on any other party, except as may be explicitly provided for herein or authorized in advance in writing by such other party.

17.2 Use of a Party's Name. No party shall use any other party's name, nor issue any public statement about this Agreement, including its existence, without the prior written permission of such other party, except as required by law (and, in such case, only with prior written notice given to the other party). Such prior permission shall not be unreasonably withheld. The parties agree that in order for the Institution to satisfy its reporting obligations, it may identify the Sponsor as the Study sponsor and the amount of funding received from the Sponsor for the Study, but will not include in such report any information which identifies the name of the Study Drug or the therapeutic areas of the Study.

17.3 Return of Unused Materials. Within thirty (30) days following termination or completion of the Study, all unused Study Materials, compounds, devices, case reports, whether or not completed, and other related materials that were furnished to the Institution by or on behalf of the Sponsor shall be returned to the Sponsor or destroyed at the Sponsor's request.

17.4 This Agreement and all rights and obligations hereunder shall not be assigned by the Institution without the prior written consent of Sponsor. Sponsor may freely assign this Agreement. Any purported assignment or transfer in violation of this Section 17.4 shall be void.

17.5 Complete Agreement and Modification. This Agreement constitutes the entire agreement among the parties pertaining to the Study Protocol and supersedes all prior agreements and understandings, whether oral or written. No modification, amendment or waiver of this Agreement shall be binding unless executed in writing by the parties. In the case of conflict between the terms of this Agreement and the Study Protocol or other attachments, the terms of this Agreement shall control. The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

17.6 Waiver. No waiver of any term or provision of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be, or construed as, a further or continuing waiver of any such term or provision, or of any other term or provision, of this Agreement.

17.7 Force Majeure. Except for the obligation to pay monies due, neither party will be liable for performance delays or for non-performance due to causes beyond its reasonable control, including without limitation, fire or other casualty or accident, earthquakes, strikes or labor disputes, war or other violence, any law, order proclamation, regulations, ordinance, demand or requirement of any government agency.

17.8 Construction. The validity, interpretation, and performance of this Agreement shall be governed and construed in accordance with the laws of the State of California. The headings in this Agreement are for the convenience of reference only and shall not affect its interpretation. This Agreement and any amendments hereto shall be executed in counterparts and all such counterparts taken together shall be deemed to constitute one and the same instrument.

17.9 Execution. This Agreement may be executed in one or more counterparts, all of which together shall constitute one and the same agreement. This Agreement may be executed by facsimile signature.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

For and on behalf of:

Institution:

SAN MATEO COUNTY

By: \_\_\_\_\_

Name: Rose Jacobs Gibson  
President, Board of Supervisors  
Title: San Mateo County

Sponsor:

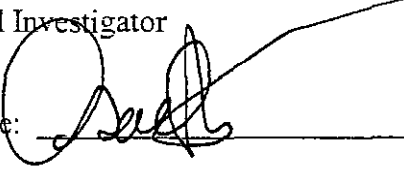
SCICLONE PHARMACEUTICALS, INC.

By: 

RICHARD A. WALDRON  
Name: Alfred R. Rudolph, MD  
Chief Financial Officer  
Title: Chief Operating Officer

Read and Agreed to:

Principal Investigator

Signature: 

Print Name: Dennis M. Israelski, M.D. \_\_\_\_\_

**EXHIBIT A**

**Study Protocol**

**EXHIBIT B**

**Study Budget**

Study Personnel - Section left blank due to the \$10,000 flat per patient fee agreed upon by Dr. Dennis Israelski on June 17, 2003. Personnel fees are included in the "fee per visit" in Visit Milestones section below.

Per Patient Charges

	% time allotted to study	Hourly Charge	X	Total # of Hours =	Line Total
Principal Investigator	_____	_____	_____	_____	_____
Study Coordinator	_____	_____	_____	_____	_____
<b>Section Subtotal</b>					<b>_____</b>

Visit Milestones

Per Patient Charge

	Fee Per Visit	# of Visits	Line Total
Screening	\$1,300.00	1	\$1,300.00
Baseline/Day 0 (eligible patients)	\$900.00	1	\$900.00
Study Visit Month 1	\$400.00	1	\$400.00
Study Visit Month 2	\$400.00	1	\$400.00
Study Visit Month 3	\$500.00	1	\$500.00
Study Visit Month 4	\$400.00	1	\$400.00
Study Visit Month 5	\$400.00	1	\$400.00
Study Visit Month 6	\$500.00	1	\$500.00
Study Visit Month 7	\$400.00	1	\$400.00
Study Visit Month 8	\$400.00	1	\$400.00
Study Visit Month 9	\$500.00	1	\$500.00
Study Visit Month 10	\$400.00	1	\$400.00
Study Visit Month 11	\$400.00	1	\$400.00
Study Visit Month 12 or Early Withdrawal Visit	\$900.00	1	\$900.00
Study Visit Month 15/3 Month Follow up Visit	\$900.00	1	\$900.00
Study Visit Month 18/6 Month Follow up Visit	\$1,300.00	1	\$1,300.00
<b>Section Subtotal</b>			<b>\$10,000.00</b>

Other Expenses (Itemize)

	Line Total
Administrative pass through costs:	
IRB = \$1,500	\$1,500.00

Total Cost per Patient (Irregardless of screening liver biopsy and screening abdominal ultrasound status; inclusive of screening, Month 12, and Month 18 EKG; inclusive of Month 18 liver biopsy)  
 Total Estimated Contract Total, inclusive of projected IRB costs (paid as pass through)

\$10,000.00
\$101,500.00

Note: Patients who terminate the study early will be pro-rated accordingly.  
 Assume 10 patients enrolled.

Investigator Signature: \_\_\_\_\_ Date: 6/24/03

SciClone Representative Signature: \_\_\_\_\_ Date: 7/18/03

**Addendum to the Agreement with SciClone Pharmaceuticals, Inc.**

**Non-Discrimination.** No person shall be excluded from participation in, denied benefits of, or be subject to discrimination under this Agreement on the basis of their race, color, religion, national origin, age, sex, sexual orientation, pregnancy, childbirth or related conditions, medical condition, mental or physical disability, or veteran's status. Contractor shall ensure full compliance with federal, state, and local laws, directives, and executive orders regarding non-discrimination for all employees and Subcontractors under this Agreement.

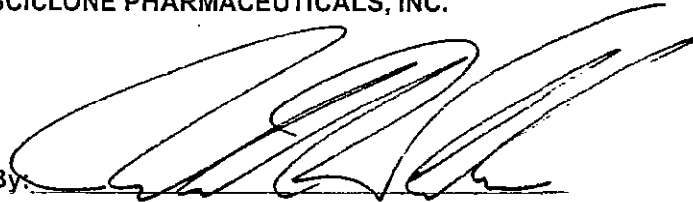
Violation of the non-discrimination provisions of this Agreement shall be considered a breach of this Agreement and subject Contractor to penalties, to be determined by the County Manager, including, but not limited to: i) termination of this Agreement; ii) disqualification of Contractor from bidding on or being awarded a County contract for a period of up to three (3) years; iii) liquidated damages of TWO THOUSAND FIVE HUNDRED DOLLARS (\$2,500) per violation; iv) imposition of other appropriate contractual and civil remedies and sanctions, as determined by the County Manager.

To effectuate the provisions of this paragraph, the County Manager shall have the authority to: i) examine Contractor's employment records with respect to compliance with this paragraph; ii) set off all or any portion of the amount described in this paragraph against amounts due to Contractor under the Contract or any other contract between Contractor and County.

Contractor shall report to the County Manager the filing by any person in any court of any complaint of discrimination or the filing by any person of any and all charges with the Equal Employment Opportunity Commission, the Fair Employment and Housing Commission or any other entity charged with the investigation of allegations within thirty (30) days of such filing, provided that within such thirty (30) days such entity has not notified Contractor that such charges are dismissed or otherwise unfounded. Such notification shall include the name of the complainant, a copy of such complaint, and a description of the circumstance. Contractor shall provide County with a copy of its response to the complaint when filed.

With respect to the provision of employee benefits, Contractor shall comply with the County Ordinance which prohibits contractors from discriminating in the provision of employee benefits between an employee with a domestic partner and an employee with a spouse.

**SCICLONE PHARMACEUTICALS, INC.**

By: 

Date: 7/18/03

Name: RICHARD A WALDREN

Name: ~~Alfred R. Rudolph, M.D.~~

Title: Chief Financial Officer

Title: ~~Chief Operating Officer~~

## Addendum to the Agreement with SciClone Pharmaceuticals, Inc.

SciClone Pharmaceuticals, Inc. shall comply with all the provision of the Health Insurance Portability and Accountability Act (HIPAA), as follows:

### Health Insurance Portability and Accountability Act (HIPAA)

#### Business Associate Requirements

##### Definitions

Terms used, but not otherwise defined, in this Schedule shall have the same meaning as those terms are defined in 45 Code of Federal Regulations section 160.103 and 164.501. (All regulatory references in this Schedule are to Title 45 of the Code of Federal Regulations unless otherwise specified.)

- (a) *Designated Record Set*. "Designated Record Set" shall have the same meaning as the term "designated record set" in Section 164.501.
- (b) *Individual*. "Individual" shall have the same meaning as the term "individual" in Section 164.501 and shall include a person who qualifies as a person representative in accordance with Section 164.502(g).
- (c) *Privacy Rule*. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 Code of Federal Regulations Part 160 and Part 164, Subparts A and E.
- (d) *Protected Health Information*. "Protected Health Information" shall have the same meaning as the term "protected health information" in Section 164.501 and is limited to the information created or received by Contractor from or on behalf of County.
- (e) *Required By Law*. "Required by law" shall have the same meaning as the term "required by law" in Section 164.501.
- (f) *Secretary*. "Secretary" shall mean the Secretary of the United States Department of Health and Human Services or his or her designee.

##### Contractor

- (a) Contractor agrees to not use or further disclose Protected Health Information other than as permitted or required by the Agreement or applicable law.
- (b) Contractor agrees to use appropriate safeguards to prevent the use or disclosure of the Protected Health Information other than as provided for by this Agreement.
- (c) Contractor agrees to mitigate, to the extent practicable, any harmful effect that is known to Contractor of a use or disclosure of Protected Health Information by Contractor in violation of the requirements of this Agreement.
- (d) Contractor agrees to report to County any use or disclosure of the Protected Health Information not provided for by this Agreement.
- (e) Contractor agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Contractor on behalf of County, agrees to the same restrictions and conditions that apply through this Agreement to Contractor with respect to such information.



- (f) If Contractor has protected health information in a designated record set, Contractor agrees to provide access, at the request of County, and in the time and manner designated by County, to Protected Health Information in a Designated Record Set, to County or, as directed by County, to an Individual in order to meet the requirements under Section 164.524.
- (g) If Contractor has protected health information in a designated record set, Contractor agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the County directs or agrees to make pursuant to Section 164.526 at the request of County or an Individual, and in the time and manner designed by County.
- (h) Contractor agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by Contractor on behalf of, County available to the County, or at the request of the County to the Secretary, in a time and manner designated by the County or the Secretary, for purposes of the Secretary determining County's compliance with the Privacy Rule.
- (i) Contractor agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for County to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with Section 164.528.
- (j) Contractor agrees to provide to County or an Individual in the time and manner designed by County, information collected in accordance with Section (i) of this Schedule, to permit County to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with Section 164.528.

#### Permitted Uses and Disclosures by Contractor

Except as otherwise limited in this Schedule, Contractor may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, County as specified in the Agreement; provided that such use or disclosure would not violate the Privacy Rule if done by County.

#### Objections of County

- (a) County shall provide Contractor with the notice of privacy practices that County produces in accordance with Section 164.520, as well as any changes to such notice.
- (b) County shall provide Contractor with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect Contractor's permitted or required uses and disclosures.
- (c) County shall notify Contractor of any restriction to the use or disclosure of Protected Health Information that County has agreed to in accordance with Section 164.522.

#### Permissible Requests by County

County shall not request Contractor to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by County, unless the Contractor will use or disclose Protected Health Information for, and if the Agreement provides for, data aggregation or management and administrative activities of Contractor.

Duties Upon Termination of Agreement

- (a) Upon termination of the Agreement, for any reason, Contractor shall return or destroy all Protected Health Information received from County, or created or received by Contractor on behalf of County. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Contractor. Contractor shall retain no copies of the Protected Health Information.
- (b) In the event that Contractor determines that returning or destroying Protected Health Information is infeasible, Contractor shall provide to County notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction of Protected Health Information is infeasible, Contractor shall extend the protections of the Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Contractor

- (a) *Regulatory References.* A reference in this Schedule to a section in the Privacy Rule means the section as in effect or as amended, and for which compliance is required.
- (b) *Amendment.* The Parties agree to take such action as is necessary to amend this Schedule from time to time as is necessary for County to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act, Public Law 104-191.
- (c) *Survival.* The respective rights and obligations of Contractor under this Schedule shall survive the termination of the Agreement.
- (d) *Interpretation.* Any ambiguity in this Schedule shall be resolved in favor of a meaning that permits County to comply with the Privacy Rule.

SCICLONE PHARMACEUTICALS, INC.

By: 

Date: 7/18/03

Name: Richard A. Waldron  
Alfred R. Rudolph, M.D.

Title: Chief Financial Officer  
Chief Operating Officer

<b>ACORD. CERTIFICATE OF LIABILITY INSURANCE</b>		OF ID SH SCICL-1	DATE (MM/DD/YY) 07/17/03
<b>PRODUCER</b> California Insurance Center CA Lic. # 0423393 1340 Treat Blvd., Suite 480 Walnut Creek CA 94597 Phone: 925-299-1112 Fax: 925-299-0326		THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW.	
<b>INSURED</b>  SciClone Pharmaceuticals Corp. Attn: Ivan Hui 901 Mariners Island Blvd. San Mateo CA 94404		<b>INSURERS AFFORDING COVERAGE</b>	
		INSURER A:	Federal Insurance Company
		INSURER B:	Calif. State Compensation Fund
		INSURER C:	
		INSURER D:	
		INSURER E:	

**COVERAGES**

THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED, NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN. THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. AGGREGATE LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YY)	POLICY EXPIRATION DATE (MM/DD/YY)	LIMITS	
A	<b>GENERAL LIABILITY</b> <input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY <input type="checkbox"/> CLAIMS MADE <input checked="" type="checkbox"/> OCCUP  <input type="checkbox"/> GEN'L AGGREGATE LIMIT APPLIES PER: <input type="checkbox"/> POLICY <input type="checkbox"/> PROD <input type="checkbox"/> LOC	3532-28-77	10/01/02	10/01/03	EACH OCCURRENCE	\$ 1,000,000
					FIRE DAMAGE (ANY ONE FIRE)	\$ 1,000,000
					WED EXP (ANY ONE PERSON)	\$ 10,000
					PERSONAL & ADJ INJURY	\$ 1,000,000
					GENERAL AGGREGATE	\$ 2,000,000
					PRODUCTS - COMPROP AGG	\$ Excluded
	<b>AUTOMOBILE LIABILITY</b> <input type="checkbox"/> ANY AUTO <input type="checkbox"/> ALL OWNED AUTOS <input type="checkbox"/> SCHEDULED AUTOS <input type="checkbox"/> HIRE/AUTO <input type="checkbox"/> NON-OWNED AUTOS				COMBINED SINGLE LIMIT (Per accident)	\$
					BODILY INJURY (Per person)	\$
					BODILY INJURY (Per accident)	\$
					PROPERTY DAMAGE (Per accident)	\$
	<b>GARAGE LIABILITY</b> <input type="checkbox"/> ANY AUTO				AUTO ONLY - EA ACCIDENT	\$
					OTHER THAN AUTO OWNED EA ACC	\$
					AUTO OWNED AGG	\$
	<b>EXCESS LIABILITY</b> <input type="checkbox"/> OCCUP <input type="checkbox"/> CLAIMS MADE  <input type="checkbox"/> DEDUCTIBLE <input type="checkbox"/> RETENTION \$				EACH OCCURRENCE	\$
					AGGREGATE	\$
						\$
						\$
						\$
B	<b>WORKERS COMPENSATION AND EMPLOYERS' LIABILITY</b>	1561446-02	09/27/02	09/27/03	<input checked="" type="checkbox"/> WE STATE TOP LIMITS <input type="checkbox"/> OFF	
					EL. EACH ACCIDENT	\$ 1,000,000
					EL. DISEASE - EA EMPLOYEE	\$ 1,000,000
	OTHER				EL. DISEASE - POLICY LIMIT	\$ 1,000,000

DESCRIPTION OF OPERATIONS/LOCATIONS/VEHICLES/EXCLUSIONS ADDED BY ENDORSEMENTS/SPECIAL PROVISIONS

<b>CERTIFICATE HOLDER</b> <input checked="" type="checkbox"/> <b>ADDITIONAL INSURED</b> : INSURER LETTER: <u>SANMTO</u>  San Mateo County Medical Cntr Att: Dr. Dennis Israelski, Principle Investigator 222 W. 39th Ave. San Mateo, CA 94403	<b>CANCELLATION</b> SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, THE ISSUING INSURER WILL ENDEAVOR TO MAIL <u>30</u> DAYS WRITTEN NOTICE TO THE CERTIFICATE HOLDER NAMED TO THE LEFT, BUT FAILURE TO DO SO SHALL IMPOSE NO OBLIGATION OR LIABILITY OF ANY KIND UPON THE INSURER, ITS AGENTS OR REPRESENTATIVES. AUTHORIZED REPRESENTATIVE:
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