

From: Russell White <whiter@api.org>
Sent: Thursday, May 24, 2007 3:02 PM (GMT)
To: BenzConsort-OC@listserve.api.org; BenzConsort-TC@listserve.api.org
Subject: Shanghai Health Study - Draft Cinpathogen contract
Attach: Cinpathogen 2007-102814 DRAFT 52407.doc

Attached is the draft contract with Cinpathogen for your review. Talk to you at 1:30 PM EDT.

<<Cinpathogen 2007-102814 DRAFT 52407.doc>>

Russell White

Regulatory and Scientific Affairs
American Petroleum Institute
1220 L Street NW
Washington, DC 20005-4070

Tel: 202-682-8344
Fax: 202-682-8270



Red Cavaney
President and Chief Executive Officer

1220 L Street, NW
Washington, DC 20005-4070
USA
Telephone 202-682-8100
Fax 202-682-8110
Email rcavaney@api.org
www.api.org

Richard D. Irons, Ph.D, DABT
Cinpathogen, Inc.
4800 Baseline Road, #-104 PMB253
Boulder, CO 80303

Contract No. 2007-102814

Dear Dr. Irons:

This letter of agreement between the American Petroleum Institute (API) and Cinpathogen, Inc. (Cinpathogen) authorizes Cinpathogen to complete work on a multi-year research protocol for:

- Analysis of Disease Progression for Aplastic Anemia, Myelo-Dysplastic Syndrome, Acute Myelogenous Leukemia and Benzene Poisoning in Shanghai, China
- Molecular Epidemiology of Benzene-Exposed Workers in Shanghai, China
- Diagnosis AML and Lymphoid Neoplasms in Shanghai, China

This agreement shall fund activities through the end of the study, which will end no later than December 31, 2008. Cinpathogen will perform the work as described in its Business Plan dated May 2007 (Appendix A), will complete the milestones described in Cinpathogen-API Contract Milestones dated May 21, 2007 (Appendix B), and will perform tasks and prepare deliverables outlined in Charter: Data and Process Quality Assurance Team dated April 27, 2007 or any successor document (Appendix C), all attached and made a part hereof. API acknowledges that Cinpathogen has subcontracted with Fudan University for a portion of the work under this agreement. Cinpathogen will be responsible for the performance of and subsequent payment to Fudan University as related to this agreement. This agreement is subject to the following terms and conditions:

1. Cinpathogen agrees that the project manager and principal investigator for this agreement shall be Richard D. Irons, Ph.D., DABT. Cinpathogen shall give API, within 10 business days of a change, written notice of the replacement or reduction in the level of effort of the project manager and principal investigator. API shall have the right to approve a reduction in effort and, in the case of replacement of the project manager and principal investigator, API shall have the right to approve a successor.
2. Technical and administrative aspects of this agreement will be under the direction of Howard J. Feldman, Regulatory Analysis & Scientific Affairs Director, American Petroleum Institute, 1220 L Street, NW, Washington, D.C. 20005, or whomever he designates. The designated API representative for work conducted hereunder is Russell White (202-682-8344; e-mail: whiter@api.org). Cinpathogen shall send all correspondence and reports relating to this agreement to his attention at the foregoing address.

An equal opportunity employer

SHELL-MCCLURG-053805

3. This agreement shall cover work authorized by API as of January 1, 2007, and shall terminate September 30, 2008, although Cinpathogen will prepare manuscripts for submission to appropriate scientific journals after the termination date.
4. Cinpathogen agrees to perform the work under this agreement for a total amount not to exceed \$5,215,440 as detailed below. This amount includes the cash advance of \$800,000 that API paid to Cinpathogen on April 16, 2007.
 - a. **Direct labor and fringe benefits plus 30% overhead** (per Appendix A, Section 5.2) – an amount not to exceed \$1,986,920.
 - b. **Direct costs** (per Appendix A, Section 5.2) – an amount not to exceed \$2,421,000. API will not pay overhead or markup on direct costs.
 - c. **General and administrative expenses** (per Appendix A, Section 5.2) – an amount not to exceed \$806,520, which Cinpathogen will invoice at cost plus 10%.
5. Cinpathogen shall invoice API for services provided and expenses incurred as follows:
 - a. Up to \$4,407,920 representing direct labor/fringe benefits/overhead and direct costs per the schedule of tasks and deliverables table in paragraph 8 below. The following terms apply:
 - i. Cinpathogen will submit quarterly financial reports of expenditures incurred and commitments made by Cinpathogen. Quarterly reports are due by the 21st day of July 2007, October 2007, January 2008, April 2008, and July 2008. Continuance of funding is contingent upon API approval of these quarterly reports. Quarterly reports will include details of all expenditures and receipts or other supporting documentation for direct costs of \$50 or more.
 - ii. If the quarterly financial reports are not received or reveal more than \$800,000 of the total disbursement amount to date for this category remains unspent, API reserves the right to defer disbursement of the next scheduled payment for until receiving a revised financial report from Cinpathogen indicating that the balance is below \$800,000.
 - iii. Pursuant to API policy, Cinpathogen shall credit interest earned on any undisbursed funds (cash on hand). Cinpathogen may pay such interest income directly to API or as a credit against API's next scheduled payment.
 - iv. If any funds disbursed to Cinpathogen remain unspent upon completion or termination of this agreement, Cinpathogen will return such funds to API.
 - b. Up to \$806,520 representing general and administrative expenses, which Cinpathogen shall invoice on a monthly basis. The following terms apply:
 - i. Cinpathogen will submit receipts (originals or copies) for all general and administrative expenses of \$50.00 or more.
 - ii. Reimbursement of travel expenses shall be limited to coach class for domestic travel or business class for international travel and reasonable accommodations associated with the conduct of this project.
 - c. API shall pay undisputed invoice amounts within 30 days of receipt. Invoices must reference the above contract number and shall be submitted to Russell White.

6. Cinpathogen will use moneys provided under this agreement only for the purpose of conducting this study. To this end, API will not reimburse Cinpathogen for personnel relocation expenses or for Cinpathogen's corporate expenses (e.g., items that Cinpathogen would obtain for operation of its business regardless of this agreement, including but not limited to local phone, stationery, business licenses, office equipment, furniture, etc.).
7. Cinpathogen will maintain general liability and other relevant insurance in sufficient amounts to cover its liabilities under this agreement, and will name API as an additional insured on such policies. Cinpathogen will provide evidence of insurance to API within 2 weeks of the last signature date below.
8. Cinpathogen shall perform tasks and prepare deliverables as specified in the table below and in Appendix B, adhering to the schedule set forth in Appendix B. Cinpathogen will invoice API for direct labor/fringe benefits and direct costs as outlined in the table below. Such payment is tied to Cinpathogen's completion of relevant milestones and deliverables. The criteria used to judge the completeness of the study milestones are included in Appendix B and Appendix C.

Timeframe/Due Date	Milestone/Deliverable	# of copies/medium	Payment Amt*
4/16/07	Receipt of cash advance	Not applicable	\$800,000
Within 2 weeks of last signature date	- Documentation for cash advance per #5c - Certificate of insurance	e-mailed to Russell White – whiter@api.org	
as soon as possible	- Per Appendix B, 1a – update of numbers of AML and NHL cases that can be used in case-control study - Invoice API per #4a above	e-mailed to Russell White – whiter@api.org	\$1,506,000
By 6/30/07	Per Appendix B, 1b, 1c, 1d – reestablish case accrual at participating Shanghai hospitals, continue exposure assessment activities to complete job-exposure matrix, cooperate w/ QA/QC team as required by charter		
On a quarterly basis	- Reports to QA/QC Team - Financial reports to API showing amounts received, expensed and committed	Electronic as appropriate and e-mailed to Russell White – whiter@api.org	
Mid 7/07, mid 1/08, mid 7/08	Semi-annual reports to SRP/ERP and API per Appendix B 2h	e-mailed to Russell White – whiter@api.org	
By 9/15/07	- Appendix B, 2ai – provide to UCo or its designee substantial preliminary test data set w/ all diagnosed and verified AMLs and NHLs - Appendix B, 2aii – provide update on number of cases	Electronic confirmation e-mailed to Russell White – whiter@api.org	\$1,000,000

Timeframe/Due Date	Milestone/Deliverable	# of copies/medium	Payment Amt*
	that can be used in case control study		
By 2/28/08	• Invoice API per #4a above • Report to SRP/ERP to include ➢ Per Appendix B, 2c – study cohort of cases collected through 12/31/07 ➢ Per Appendix B, 2aiii – provide an update of number of cases that can be used in case control study • Invoice API per 4b above	Electronic confirmation e-mailed to Russell White – whiter@api.org	\$800,000
By 6/30/08	• Per Appendix B, 2b – Provide to UCo or its designee final data set as described • Per Appendix B, 2d – job-exposure matrix for cases and controls used in case control study • Invoice API per 4b above	Electronic confirmation e-mailed to Russell White – whiter@api.org	\$302,000
By 11/1/08	Per Appendix B, 2e, 2f – submit for publication to appropriate scientific journals manuscripts as described		
* The amounts referenced above include \$400,000 for the laboratory transition personnel budget and \$400,000 for the costs for continued publication of study findings.			

9. Cinpathogen, Fudan University, and the University of Colorado and its subcontractor, ExxonMobil Biomedical Sciences, have the exclusive right to publish the findings derived from the studies.
10. Cinpathogen acknowledges that the protocols and conduct of the research during the life of the agreement are subject to annual review and approval by an independent Scientific Review Panel (SRP), as well as by an Ethics Review Panel (ERP), both of which API has established. These panels shall be notified immediately when a change in protocol is proposed. Both the SRP and the ERP must approve any significant changes in protocol that would affect the scope of work.
11. Cinpathogen will provide draft manuscripts to the SRP for comment following the guidelines in Cinpathogen's March 18, 2007 Research Protocol and Criteria Document, Section 3.1-A (Appendix D), attached and made a part hereof, until completion or termination of this agreement. The authors will carefully consider each and every comment from the SRP. However, the preparation of presentations and manuscripts is the sole responsibility of the authors.
12. API shall have the right at all reasonable times during the course of the study, and for period of up to 3 years following completion of the study, to inspect Cinpathogen's facilities, including equipment and technical and financial records relating to the work conducted hereunder, for the purpose of insuring conformance with this agreement and with generally accepted good scientific practices, and to verify the accuracy of invoices.

Such inspection shall include the right to photocopy records pertaining to work conducted hereunder, including individual timesheets of project personnel and excluding information on study participants.

13. It is agreed that either party (API or Cinpathogen) shall have the right to terminate this agreement by giving a 30-day written notice of such termination to the other party. Upon receipt of such notice of termination, Cinpathogen shall cease incurring costs on this project, except with the prior approval of API for such costs which are necessary to close out the project. In the event of such termination, API's sole obligation will be to reimburse Cinpathogen for actual costs (professional fees and direct expenses) incurred as of the date of termination and subsequent costs (professional fees and direct expenses) incurred with prior approval of API. In no event shall such payment include costs and/or anticipated fees for unperformed work or exceed the maximum amount of the agreement as set forth in paragraph 4. Cinpathogen agrees to complete any tasks in progress, should API so request.
14. It is understood that Cinpathogen is acting as an independent contractor in its performance of any and all work hereunder. Cinpathogen shall hold API, its members, officers and employees harmless from any wrongful or negligent acts or omissions on the part of Cinpathogen, its subcontractors or its designates.
15. The laws of the District of Columbia, U.S.A. shall govern this agreement.
16. Any change, modification, extension, termination, or waiver of this agreement or any of its provisions must be in writing and signed by an authorized official of both parties.
17. Cinpathogen will not use the trademark or name of the American Petroleum Institute or any abbreviation thereof, in any publicity, advertising, or for other promotional purposes without the prior written approval of API. However, Cinpathogen may acknowledge API as the sponsor of the research, and shall so advise API in writing.
18. In the event of inconsistencies between this agreement and its attachments, the express terms of this agreement shall govern.
19. Paragraphs 5-19 shall survive the termination of this agreement.

If the above terms and conditions are acceptable, please sign below and return one original signed copy of this agreement to API.

CINPATHOGEN, INC.

AMERICAN PETROLEUM INSTITUTE

Richard D. Irons, Ph.D., DABT

Red Cavaney
President

Date: _____

Brenda S. Hargett
Vice President & Chief Financial Officer

Date: _____