

**CLINICAL TRIAL AGREEMENT  
BETWEEN  
PPD DEVELOPMENT, LP,  
SAN MATEO COUNTY, SAN MATEO MEDICAL CENTER  
AND  
JOANNE IMPERIAL, MD**

**THIS CLINICAL TRIAL AGREEMENT** ("Agreement") is made this May 22, 2008 ("Effective Date") by and between PPD Development, LP ("PPD") with its principal place of business at 929 North Front Street, Wilmington, NC 28401, San Mateo County, San Mateo Medical Center with its principal place of business at 222 West 39th Avenue, San Mateo, CA 94403 ("Institution"), and Joanne Imperial, MD, with his/her offices located at 222 West 39th Avenue, San Mateo, CA 94403 ("Principal Investigator").

**WHEREAS**, PPD, a clinical research organization acting as an independent contractor on behalf of Pharmasset, Inc. ("Sponsor"), desires to engage the services of the Institution and Principal Investigator for the conduct of a clinical research study entitled "A Multi-center, Randomized, Double-Blind, Active-Control, 96 Week, Phase III Trial of the Efficacy and Safety of Clevudine Compared with Adefovir at Weeks 48 and 96 in Nucleoside Treatment-Naïve Patients with HBeAg Negative Chronic Hepatitis due to Hepatitis B Virus" ("Study") in accordance with Sponsor's protocol no. CI-PSI-5268-06-306 ("Protocol"); and

**WHEREAS**, Institution and the Principal Investigator desire to participate in the conduct of the Study.

**NOW, THEREFORE**, in consideration of the mutual promises and covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

**1. Performance of the Study**

a. Institution and Principal Investigator shall provide those certain services related to the conduct of the Study and set forth in the Protocol, which Protocol is made a part of this Agreement and incorporated by reference herein ("Services"). The Services shall be provided in accordance with the terms of this Agreement, the Protocol, and all applicable laws, rules and regulations; provided, however that such Protocol has been approved by PPD, Sponsor, and the appropriate Institutional Review Board ("IRB"). If there is any discrepancy or conflict between the terms contained in the Protocol and this Agreement, the terms of the Protocol shall govern and control.

b. In connection with the provision of the Services, Institution shall be responsible for providing, at its sole cost and expense, adequate personnel, equipment and other resources necessary to perform the Services.

c. Institution and Principal Investigator represent that it/he/she does not and will not, at any time during the Term of this Agreement, participate in any other study which, by its nature or its terms, will prevent it/him/her from fulfilling any of the obligations hereunder.

d. Institution and Principal Investigator represent that the Services shall be performed using best efforts, which shall include, but not be limited to, the following:

(1) Exercising independent medical judgment as to the compatibility of each subject with the Protocol requirements;

- (2) Obtaining a signed informed consent from each Study subject pursuant to Section 1(e) below;
- (3) Reviewing all case report forms for accuracy and completeness;
- (4) Submitting all data and other information related to the Study in a timely manner;
- (5) Notifying Sponsor, PPD, and IRB, in writing, of any unanticipated or serious adverse reactions to the Study drug or control drug and following the procedures set forth in the Protocol;
- (6) Notifying Sponsor, PPD, and IRB, in writing, of any deviations from the Protocol;
- (7) Maintaining adequate records with respect to Study, including without limitation, records relating to subject identification, clinical observations, laboratory tests, and drug receipt and disposition and allow PPD and/or Sponsor to inspect and audit such records and other Study-related information upon reasonable advance notice; and,
- (8) Cooperating with PPD and Sponsor in their efforts to monitor the Study;

e. Institution and Principal Investigator shall obtain, in accordance with 21 C.F.R. Part 50, an informed consent from Study subjects to participate in the Study. The form of such informed consent must be the most current form approved by IRB, Sponsor, and PPD, and must contain language necessary to permit regulatory agencies, the IRB, Sponsor, and PPD to have full access to and use of Protected Health Information, as defined in the Health Insurance Portability Accountability Act of 1996 ("HIPAA") and its implementing regulations and official guidelines promulgated thereunder.

f. Prior to the commencement of Services, Institution and Principal Investigator shall review the Protocol and notify PPD if it/she/he cannot comply with any of the terms contained therein. If in the course of performing the Services, generally accepted standards of clinical research and medical practice relating to the benefit, well-being and safety of the subjects require a deviation from the Protocol, such standards will be followed. In such case, the party aware of the need for a deviation shall immediately notify PPD and Sponsor of the facts supporting such deviation as soon as the facts are known to said party. Said notification shall be followed by written confirmation of same.

## **2. Term and Termination**

a. The term of this Agreement shall begin on the Effective Date and shall continue until the objectives of the Study are accomplished ("Term"), unless sooner terminated pursuant to this Section 2.

b. PPD may, in its sole discretion, terminate this Agreement, with or without cause, upon thirty (30) days' prior written notice to Institution and Principal Investigator.

c. This Agreement may be terminated by PPD effective immediately for any of the following reasons:

(1) authorization and approval to conduct the Study is withdrawn by the Food and Drug Administration ("FDA");

(2) the Study data and test results support termination of the Study for any reason, including the safety and welfare of Study subjects;

(3) PPD determines, in its sole discretion, that Principal Investigator has failed to recruit or enroll a sufficient number of subjects for participation in the Study to make it likely that the statistical requirements applicable to the Study will be met; or

(4) The services agreement between PPD and Sponsor for the conduct of the Study is terminated.

d. This Agreement may be terminated by Institution or Principal Investigator upon thirty (30) days' prior written notice of termination for material breach by PPD, if said breach is not cured within said 30-day period.

e. Immediately upon receipt of a notice of termination, Institution and Principal Investigator shall cease entering subjects into the Study, cease conducting procedures to the extent medically permissible on subjects already entered into the Protocol, and refrain from incurring additional costs and expenses to the extent possible.

f. In the event of termination, the sum payable under this Agreement shall be limited to prorated fees based on actual Services performed pursuant to the Protocol as determined in accordance with Section 3 below and the budget attached hereto and incorporated herein by reference as Exhibit A (the "Budget"). Any amounts not due to the Institution or Principal Investigator pursuant to this Agreement, but already paid, shall be returned to PPD without demand within thirty (30) days of the site close-out visit by PPD.

g. Notwithstanding anything herein to the contrary, if during the Term of this Agreement, information becomes available to PPD or Sponsor which places the safety or efficacy of the Study drug or related product in doubt or if the Study drug is approved by FDA, the parties shall negotiate, in good faith, a modification of this Agreement to (i) reduce the number of subjects to be studied, (ii) terminate the Study, and/or (iii) modify any other relevant provision of this Agreement.

h. Upon completion of the Study or earlier termination thereof, Institution and/or Principal Investigator shall prepare and forward a final report containing all relevant information for the Study as described in the Protocol, including all data and Study results to PPD, and shall return all PPD and Sponsor Information, as defined herein, to its respective owner.

i. Upon completion of the Study or early termination thereof, all unused Study drug, compounds, devices and related Study materials furnished to Institution and/or Principal Investigator by or on behalf of Sponsor or PPD shall be returned to PPD.

### **3. Payments**

a. Sponsor, through PPD, shall compensate Institution and Principal Investigator for the Services in accordance with the Budget; provided, however, that the Services have been properly performed in accordance with the Protocol and this Agreement. Institution and Principal Investigator will not be compensated for any Study subjects who were enrolled without a properly

executed informed consent form in accordance with Sections 1(d)(2) and 1(e) and who do not meet the inclusion/exclusion criteria. Notwithstanding anything to the contrary contained herein, all payments shall be made to the payee and at the address indicated on the W-9 form or other applicable form provided to PPD, which form shall be submitted to PPD upon execution hereof. The payee shall be responsible for compensating all other entities and individuals who were involved in the conduct of the Study, e.g. Principal Investigator.

b. Payments are dependent upon the reports and other information pursuant to Section 2(h) being submitted to PPD in a timely and satisfactory manner. Payment for partially completed cases, i.e., early withdrawals, shall be made on a pro-rata basis for Services performed according to the Budget. Institution and Principal Investigator will not be paid for any Services performed that are deemed violations of or deviations from the Protocol or this Agreement.

c. Payments due under this Agreement are pass-through payments from Sponsor. PPD shall make payment to Institution upon its receipt of funds from Sponsor. PPD represents that Institution has been made a third party beneficiary to the services agreement between Sponsor and PPD for the conduct of the Study to the extent necessary for Institution to enforce payment obligations directly from Sponsor.

#### 4. **Representations and Warranties**

The Institution and Principal Investigator each represent and warrant that it/he/she:

a. has the experience, capabilities, adequate subject population, and other resources, including but not limited to, sufficient personnel and equipment, to accurately, efficiently and diligently perform the Study.

b. will perform the Services hereunder in a professional and competent manner, and will utilize due diligence and devote the necessary personnel and equipment at all times to perform the Study hereunder in such manner.

c. will conduct the Study in strict accordance with the Protocol and this Agreement.

d. and its/his/her employees or any other person retained by it to perform the Services pursuant to this Agreement: (i) is not presently debarred pursuant to the Generic Drug Enforcement Act of 1992, as amended (21 U.S.C. §301 et. seq.) or any other laws and regulations applicable to the Study; (ii) is not under investigation by the US Food and Drug Administration or any other governmental or regulatory authorities having jurisdiction over the subject matter of the particular Study (collectively, "FDA") for debarment action; (iii) does not have a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 CFR Section 312.70 or its successor provisions; and (iv) has not engaged in any conduct or activity which could lead to any of the above mentioned disqualification or debarment actions.

e. shall act, and shall require any persons or entities performing the Services on its/his/her behalf to act, in accordance and compliance with any and all applicable laws, rules, and regulations, including but not limited to the Federal Food, Drug and Cosmetic Act, as amended, and HIPAA.

**5. Regulatory Inspections and Audits**

In the event Institution or Principal Investigator receives notice that the Study site shall be the subject of an investigation or audit by any governmental or regulatory authority, the party receiving such notice shall notify PPD immediately. In the event the party does not receive prior notice of said investigation or audit, the party shall notify PPD as soon as practicable after receiving knowledge of said investigation or audit.

**6. Publication Rights**

All data or results arising out of the performance of this Study shall be considered Information as defined below and shall not be used for the commercial benefit of the Institution or Principal Investigator. The Institution and Principal Investigator agree that the Sponsor shall have the right to the first publication of the results of the Study which is intended to be a joint, multi-center publication of the Study results made by Sponsor in conjunction with the principal investigators and institutions from all appropriate sites contributing data, analysis and comments. Notwithstanding the foregoing, following the first publication, the Institution and/or Principal Investigator may publish data or results from the Study; provided, however, that the Institution and/or Principal Investigator submits the proposed publication to Sponsor for review at least sixty (60) days prior to the date of the proposed publication. Sponsor may remove from the proposed publication any information that Sponsor, in its sole discretion, considers to be confidential and/or proprietary other than Study data and results. However, if a multi-center publication is not submitted within twelve (12) months after conclusion, abandonment or termination of the Study at all sites, or if Sponsor confirms there will be no multi-center Study publication, the Institution and/or Principal Investigator may publish the Study results subject to Sponsor's rights as set forth herein. The Institution and the Principal Investigator agree not to publish any Study related material other than in accordance with this Section 6.

**7. Confidentiality**

a. Institution and its employees and agents, and Principal Investigator shall not disclose to any third party or use for any purpose other than in the fulfillment of their respective obligations hereunder, any data, records or other information disclosed to Institution and Principal Investigator by Sponsor or PPD, or generated as a result of this Study, without the prior written consent of Sponsor (or PPD as the case may be) (hereinafter, collectively "Information"). Such Information shall remain the confidential and proprietary property of Sponsor (or PPD as the case may be) and shall be disclosed only to Principal Investigator and the Institution's employees or agents on a "need to know" basis. Notwithstanding the foregoing, the obligations of confidentiality and nondisclosure shall not apply to the following Information:

1. Information that is or becomes publicly available through no fault of Institution or Principal Investigator;
2. Information that is disclosed to Institution and/or Principal Investigator by a third party legally entitled to disclose such information;
3. Information that is already known to Institution and/or Principal Investigator as demonstrated by its prior written records;
4. Information that is independently developed without the use or benefit of Information.

5. Information that is published by Institution and/or Principal Investigator in accordance with Section 6 of this Agreement.

6. Information that is required to be disclosed pursuant to controlling law, a government authority or by order of a court of competent jurisdiction; provided, however, that reasonable advance notice is given to Sponsor (or PPD as the case may be), and Principal Investigator and Institution take all reasonable steps to limit the scope of such disclosure and cooperate with Sponsor (or PPD as the case may be) in its efforts to limited such disclosure.

## **8. Privacy**

Institution shall comply and shall require any of the persons or entities performing the Services on its behalf, including without limitation, Principal Investigator, to comply, with all applicable laws, rules, regulations, and guidelines governing the privacy of personally identifiable information and patient health information, including without limitation, HIPAA and the European Data Protection Directive [EC/95/46].

## **9. Publicity and Use of Names**

PPD and Sponsor may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of Institution and/or Principal Investigator consistent with U.S. copyright laws, provided such use does not constitute an endorsement of any commercial product or service by Institution or Principal Investigator. Institution and/or Principal Investigator shall not disclose the existence of this Agreement or its association with PPD or Sponsor, or use the name of Sponsor or PPD in any press release, article or other method of communication with the general public, without the express prior written approval of the party whose name is the subject of the potential disclosure.

In addition, PPD and Sponsor may use Institution and Principal Investigator contact details and study status in study specific newsletters and on the worldwide web for the purpose of conducting this Study. Newsletters may be distributed to all participating sites and postings to the worldwide web are for the purpose of providing information to potential patients regarding the study giving them the ability to contact participating sites.

## **10. Intellectual Property Rights**

a. Any inventions or discoveries (whether patentable or not), innovations, suggestions, ideas and reports arising out of or in connection with the performance of the Study by Institution and/or Principal Investigator ("Intellectual Property") shall be promptly disclosed to Sponsor, and shall be the exclusive property of Sponsor. Upon Sponsor's request, and at Sponsor's sole expense, Institution and Principal Investigator shall take all reasonable actions necessary or appropriate to: (i) transfer and assign any and all right, title and interest in and to any Intellectual Property to Sponsor; and (ii) assist Sponsor in obtaining patent or other proprietary protection in Sponsor's name.

b. Neither PPD nor Sponsor shall transfer to Institution or Principal Investigator by operation of this Agreement any patent right, copyright or other proprietary right of Sponsor.

**11. Independent Contractor Relationship**

a. Institution and Principal Investigator are performing Services for PPD as independent contractors and not as employees or agents of PPD or Sponsor. Neither Institution nor Principal Investigator shall have the authority to enter into binding obligations on behalf of PPD or Sponsor. Institution and Principal Investigator and its respective employees and agents, shall not participate in any PPD or Sponsor employee benefit plans nor receive any other compensation beyond that stated herein.

b. Payments for Services rendered under this Agreement shall be made in full in accordance with the Agreement, without deductions for taxes of any kind, in conformity with Institution's non-employee status. Any taxes due and payable as a result of the payments by PPD to Institution shall be Institution's sole responsibility and Institution shall timely pay all such taxes for which it is liable.

**12. Indemnification**

a. Indemnification of Institution and Principal Investigator by Sponsor shall be governed by a separate letter agreement.

b. PPD shall indemnify, defend and hold harmless Institution and Principal Investigator from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by Institution or Principal Investigator as a result of PPD's negligence or willful misconduct, or breach of this Agreement.

c. Institution and Principal Investigator shall indemnify, defend and hold harmless PPD and Sponsor from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by PPD or Sponsor as a result of the negligence or willful misconduct of, or breach of this Agreement by, Institution and/or Principal Investigator.

**13. Notice of Debarment and Disqualification**

If at any time during the term of this Agreement, Institution, Principal Investigator, or any person employed or retained by it/he/she to perform the Study: (i) comes under investigation by FDA for debarment action or disqualification, (ii) is debarred or disqualified, or (iii) engages in any conduct or activity which could lead to any of the above mentioned disqualification or debarment actions, said party shall immediately notify PPD of same.

**14. Miscellaneous**

a. Institution and Principal Investigator warrant and represent that each possess and maintain, at their own expense and subject to reasonable deductibles or retentions, comprehensive general liability insurance with liability limits of not less than \$1,000,000 per occurrence and \$3,000,000 in the aggregate; professional liability insurance including coverage for medical malpractice for the participation in and conducting of human clinical trials with liability limits of not less than \$1,000,000 per occurrence and \$3,000,000 in the aggregate; and any other type of insurance required to cover Institution's and Principal Investigator's obligations and liabilities hereunder. Institution and Principal Investigator shall maintain such coverage for the duration of the Agreement and for three (3) years thereafter. Institution and

Principal Investigator shall provide PPD with proof of the above insurance coverages, liability limits and deductibles or retentions before the execution of this Agreement.

b. Institution and Principal Investigator shall be free to dispose of such portion of its time and resources which is not obligated to PPD hereunder in such manner as Institution chooses.

c. By agreeing to the terms and conditions of this Agreement and by performing the Services hereunder, Institution and Principal Investigator will not be violating of any terms and conditions of any agreement for services or employment with any other individual or entity.

d. Governing law, this section intentionally omitted.

e. This Agreement together with any and all exhibits, schedules or other documents executed herewith, constitutes the entire agreement between the parties and supersedes all prior agreements, whether written, oral or otherwise.

f. This Agreement may only be modified in a mutually agreed-upon writing signed by the parties.

g. This Agreement may not be assigned or transferred by Institution or Principal Investigator without the prior written consent of PPD and Sponsor. PPD may assign this Agreement to Sponsor or its designee upon written notice to Institution and Principal Investigator, in which case Institution and Principal Investigator shall release and forever discharge PPD from any and all claims and liability arising out of this Agreement after the effective date of such assignment.

h. If any provision of this Agreement conflicts with the law under which this Agreement is to be construed, or if any such provision is held invalid by a court, such provision shall be deemed to be restated to reflect as nearly as possible the original intentions of the parties in accordance with applicable law and the remainder of this Agreement shall remain in full force and effect.

i. This Agreement shall be binding upon the parties, their heirs, successors, and permitted assigns.

j. Waiver or forbearance by either party with respect to a breach of any provision of this Agreement or any applicable law shall not be deemed to constitute a waiver with respect to any subsequent breach of any provision hereof.

k. Sections 2, 3, 6, 7, 8, 9, 10, 12 and 14 shall survive termination of this Agreement.

l. Any notice required or permitted to be given hereunder by either party hereto shall be in writing and shall be deemed given on the date received if delivered personally, by recognized overnight courier, or by facsimile, or five (5) days after the date postmarked if sent by registered or certified U.S. mail, return receipt requested postage prepaid, to the following address:



If to PPD: PPD Development, LP  
929 North Front Street  
Wilmington, NC 28401  
Telephone: (910) 251-0081  
Facsimile: (910) 762-5820  
Attn.: Parisa Jabbarzadegan

If to Institution: San Mateo Medical Center  
222 W. 39<sup>th</sup> Avenue  
San Mateo, California 94403  
Telephone: 650-573-2498  
Facsimile: 650-571-7802

If to Principal Investigator: Dr. Joanne Imperial  
222 W. 39<sup>th</sup> Avenue  
San Mateo, California 94403  
Telephone: 650-573-2498  
Facsimile: 650-571-7802

If to Sponsor: Pharmasset, Inc.  
303-A College Road East  
Princeton, NJ 08540  
Telephone: 609-613-4100  
Facsimile: 609-613-4150  
Attn.: Legal Affairs

Any party may change its notice address and contact person by giving notice of same in the manner herein provided.

m. This Agreement, and any subsequent amendment(s), may be executed in counterparts and the counterparts, together, shall constitute a single agreement. A facsimile transmission of this signed Agreement bearing a signature on behalf of a party shall be legal and binding on such party.

n. Institution and Principal Investigator agree that Sponsor is a third party beneficiary to this Agreement and may enforce its rights hereunder as a third party beneficiary. In the event Sponsor is not able to do so for any reason, Institution and Principal Investigator agree that PPD may have the benefit of Sponsor's rights hereunder (including without limitation those rights concerning publication, confidentiality and intellectual property) and may transfer such rights and benefits to Sponsor.

**The remainder of this page left intentionally blank.**

**INSTITUTION AND PRINCIPAL INVESTIGATOR UNDERSTAND AND ACKNOWLEDGE THAT FABRICATION, FALSIFICATION OR ALTERATION BY INSTITUTION, PRINCIPAL INVESTIGATOR OR ANY EMPLOYEES OR AGENTS OF INSTITUTION OF ANY PATIENT DATA OR OTHER INFORMATION PROVIDED BY INSTITUTION OR PRINCIPAL INVESTIGATOR PURSUANT TO THIS AGREEMENT CAN RESULT IN CRIMINAL ACTIONS AND SANCTIONS AGAINST INSTITUTION AND PRINCIPAL INVESTIGATOR AND IN CIVIL LIABILITY TO PPD AND SPONSOR.**

**IN WITNESS WHEREOF**, the parties hereto have caused this Agreement to be executed as of the Effective Date.

**PPD DEVELOPMENT, LP**

**By: PPD GP, LLC  
Its General Partner**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

**INSTITUTION**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

**PRINCIPAL INVESTIGATOR**

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

**Protocol # CI-PSI-5268-06-306  
Exhibit A (page 1 of 4)  
Site Payment Schedule**

**TITLE OF PROJECT:** A Multi-center, Randomized, Double-Blind, Active-Control, 96 Week, Phase III Trial of the Efficacy and Safety of Clevudine Compared with Adefovir at Weeks 48 and 96 in Nucleoside Treatment-Naive Patients with HBeAg Negative Chronic Hepatitis due to Hepatitis B Virus

**PROTOCOL NUMBER:** CI-PSI-5268-06-306

**INSTITUTION:** San Mateo Medical Center

**SPONSOR:** Pharmasset, Inc.

**INVESTIGATOR:** Joanne Imperial

**Study Costs:** \$21, 293.75 for each completed Study subject. To be considered completed, Study subjects will meet all eligibility criteria and will have completed the Follow-up Week 96 Visit.

**Total Per Study Subject:** \$21,293.75

**Start-up Payment: (Recoupable)** \$21,293.75 (equal to one completed Study subject)  
[Payment Trigger: Upon completion of site initiation by PPD. For those sites not requiring a site initiation visit, payment will be made based upon test article release]. If the Institution does not deplete the study subject costs, the remaining start up payment shall be refunded to PPD.

**Subsequent Payments broken down:** Payment Trigger: once the initial payment of \$21,293.75 is completely depleted through subject visit costs incurred, the subsequent payments will be made upon number of monitored and retrieved case report forms and will also be based on the following payment schedule. Procedures not performed in accordance with the Protocol shall not be paid by PPD/Sponsor. These payments will be made on a quarterly (every three months) basis. [10% will be with held from each visit's payment to be paid as a Final Payment after all queries have been resolved by the Institution

<b>Screening:</b>	\$3,087.50	-	\$308.75	(10%)	=	\$2,778.75
<b>Baseline (Day 1) Period 1</b>	\$881.25	-	\$88.13	(10%)	=	\$793.13
<b>Week 1</b>	\$600.00	-	\$60.00	(10%)	=	\$540.00
<b>Week 2</b>	\$600.00	-	\$60.00	(10%)	=	\$540.00
<b>Week 4</b>	\$618.75	-	\$61.88	(10%)	=	\$556.88
<b>Week 8</b>	\$618.75	-	\$61.88	(10%)	=	\$556.88
<b>Week 12</b>	\$618.75	-	\$61.88	(10%)	=	\$556.88
<b>Week 16</b>	\$618.75	-	\$61.88	(10%)	=	\$556.88
<b>Week 20</b>	\$618.75	-	\$61.88	(10%)	=	\$556.88
<b>Week 24</b>	\$818.75	-	\$81.88	(10%)	=	\$736.88

Exhibit A (page 2 of 4)						
Week 30	\$618.75	-	\$61.88	(10%)	=	\$556.88
Week 36	\$618.75	-	\$61.88	(10%)	=	\$556.88
Week 42	\$618.75	-	\$61.88	(10%)	=	\$556.88
Week 48	\$2,381.25	-	\$238.13	(10%)	=	\$2,143.13
Period 2						
Week 54	\$618.75	-	\$61.88	(10%)	=	\$556.88
Week 60	\$618.75	-	\$61.88	(10%)	=	\$556.88
Week 66	\$618.75	-	\$61.88	(10%)	=	\$556.88
Week 72	\$693.75	-	\$69.38	(10%)	=	\$624.38
Week 76	\$618.75	-	\$61.88	(10%)	=	\$556.88
Week 80	\$618.75	-	\$61.88	(10%)	=	\$556.88
Week 84	\$618.75	-	\$61.88	(10%)	=	\$556.88
Week 88	\$618.75	-	\$61.88	(10%)	=	\$556.88
Week 92	\$618.75	-	\$61.88	(10%)	=	\$556.88
Week 96	\$2,331.25	-	\$233.13	(10%)	=	\$2,098.13
Early Withdrawal	\$743.75	-	\$74.38	(10%)	=	\$669.38

**Screen Failure Payments:**

1) Screen Failure - There is a maximum of 6 paid screen failures/site. Payments will be calculated at 100% of the value of assessments completed, as verified by the monitor, not to exceed \$600.00 per screen failure. This excludes the Liver Biopsy and Ultra Sound that will be paid per the contract for screen failure subjects per the monitor assessments.

2) Pre-Screen Failures - the sponsor will reimburse the site for 10 pre-screen failure subjects at a rate of \$150 per pre-screen failure not to exceed 10 per site. 10 pre-screen failures costs shall be paid upon receipt of correct and approved invoice from Institution. Pre-screening payments are for Pre-screen failures only. Subjects who move on to the Screening Visit will be reimbursed under the budgeted allocation for the Screening Visit.

**Additional Costs:**

Additional cost items, outside of the per subject budget, attached hereto as page 3 and 4, Exhibit A will be paid to the Institution by invoice only, at Sponsor's discretion. Overhead will not be paid for additional costs unless specified on the per subject budget, attached hereto as page 3 and 4, Exhibit A.

**Exhibit A**  
(page 3 of 4)

**Protocol CI-PSI-5268-06-306**

A Multi-center, Randomized, Double-Blind, Active-Control, 96 Week, Phase III Trial of the Efficacy and safety of Clevudine Compared with Adefovir at weeks 48 and 96 in Nucleoside Treatment-Naive Patients with **HBeAg Negative** Chronic Hepatitis due to Hepatitis B Virus

Assessment	Screen	Baseline (Day 1)	Period 1 in weeks															
			1	2	4	8	12	16	20	24	30	36	42	48				
Informed Consent/Demographic	\$150.00																	
Review Inclusion/Exclusion Criteria	\$50.00	\$50.00																
Medical and Medication History	\$175.00	\$175.00																
Physical Exam including Vital Signs/Weight	\$225.00												\$225.00					\$225.00
Brief Physical Exam/Vital Signs/Weight		\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00
12-lead ECG	\$60.00	\$60.00											\$60.00					\$60.00
Lab Processing, including dry ice	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00
Urine Pregnancy test			\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00
Liver Biopsy*	\$1,250.00																	\$1,250.00
Ultra Sound	\$350																	
Adverse Event and Concomitant Medication Recording		\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00
Drug Dispensation/Accountability		\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00
Other- Study coordinator fee	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00
Patient Travel Reimbursement	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00
Total without Overhead	\$2,470.00	\$705.00	\$480.00	\$480.00	\$480.00	\$480.00	\$480.00	\$480.00	\$480.00	\$480.00	\$480.00	\$480.00	\$480.00	\$480.00	\$480.00	\$480.00	\$480.00	\$480.00
Overhead 25%	\$617.50	\$176.25	\$120.00	\$120.00	\$123.75	\$123.75	\$123.75	\$123.75	\$123.75	\$123.75	\$123.75	\$123.75	\$123.75	\$123.75	\$123.75	\$123.75	\$123.75	\$123.75
Total Per Patient Budget	\$3,087.50	\$881.25	\$600.00	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75

\* Liver Biopsy not required at screening if performed within 6 months prior to Baseline. Cost is for outpatient services and includes slide preparation by a pathologist.  
 \*\* MRI will be paid as a pass thru cost at \$1500 if an Ultra Sound is not available at the site.

IRB costs shall be paid upon receipt of correct and approved invoice from Institution. Advertising costs shall be paid upon prior written approval by PPD.

**Exhibit A**  
(page 4 of 4)

**Protocol CI-PSI-5268-06-306**

A Multi-center, Randomized, Double-Blind, Active-Control, 96 Week, Phase III Trial of the Efficacy and Safety of Clevudine Compared with Adefovir at Weeks 48 and 96 in Nucleoside Treatment-Naive Subjects with **HBeAg Negative** Chronic Hepatitis B Virus

Assessment	Period 2 in Weeks										Early Withdrawal		
	54	60	66	72	76	80	84	88	92	96			
Informed Consent/Demographic													
Review Inclusion/Exclusion Criteria													
Medical and Medication History													
Physical Exam including Vital Signs/Weight												\$225.00	
Brief Physical Exam/Vital Signs/Weight	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$125.00	\$60.00
12-lead ECG				\$60.00									\$60.00
Lab Processing -including dry ice	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00
Urine Pregnancy test	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00	\$15.00
Liver Biopsy*												\$1,250.00	
Adverse Event and Concomitant Medication Recording	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00	\$25.00
Drug Dispensation/Accountability	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$120.00	\$80.00
Other- Study coordinator fee	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00
Patient Travel Reimbursement	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00
Total without Overhead	\$495.00	\$495.00	\$495.00	\$555.00	\$495.00	\$495.00	\$495.00	\$495.00	\$495.00	\$495.00	\$495.00	\$495.00	\$595.00
Overhead 25%	\$123.75	\$123.75	\$123.75	\$138.75	\$123.75	\$123.75	\$123.75	\$123.75	\$123.75	\$123.75	\$123.75	\$123.75	\$148.75
Total Per Patient Budget	\$618.75	\$618.75	\$618.75	\$693.75	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75	\$618.75	\$743.75

\$17,035.00  
\$21,293.75

**TOTAL PER PATIENT :**

\$21,293.75