CLINICAL RESEARCH AGREEMENT
BETWEEN
PPD DEVELOPMENT, LP
AND
SAN MATEO MEDICAL CENTER

THIS CLINICAL RESEARCH AGREEMENT (this "Agreement"), effective _____, 2005, is made by and between PPD Development, LP, a Texas limited partnership ("PPD"), and San Mateo Medical Center, located at 222 W. 39th Avenue, San Mateo, CA 94403 ("Institution") with Joanne Imperial, MD, located at 222 W. 39th Avenue, San Mateo, CA 94403 ("Principal Investigator").

WHEREAS, PPD, acting as an independent contractor on behalf of Valeant Research & Development ("Sponsor"), desires to conduct a clinical research study entitled "Analysis of Hepatitis C Viral Kinetics and Viramidine Pharmacokinetics Utilizing Two Treatment Regimens in Therapy-naïve Patients with Chronic Hepatitis C" (the "Study"), which shall be conducted according to Sponsor's protocol no. RNA003142-202 incorporated herein by reference (the "Protocol");

WHEREAS, the Protocol shall be approved by Sponsor, PPD, Institution and an appropriate Institutional Review Board ("IRB");

WHEREAS, PPD desires to engage the services of Institution to participate in the Study; and

WHEREAS, Institution desires to participate in conducting the Study with Joanne Imperial, MD, an employee of the Institution, acting as Principal Investigator on behalf of Institution.

NOW, THEREFORE, in consideration of the mutual promises herein contained and other good and valuable consideration, the parties agree as follows:

1. **Performance of Study**

a. Institution represents that it and the Principal Investigator have the experience, capabilities, adequate subject population and resources, including but not limited to sufficient personnel and equipment, to accurately, efficiently and expeditiously perform the Study 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.

b. Institution represents that Principal Investigator shall not participate in any study which by its nature will prevent it from fulfilling its obligations hereunder.

c. Institution and Principal Investigator agree to conduct the Study in accordance with the Protocol and good clinical practice standards, this Agreement, and all applicable laws, rules and regulations including but not limited to the Federal Food, Drug and Cosmetic Act, as amended, and regulations of the U.S. Food and Drug Administration ("FDA"); and specifically in accordance with the FDA Form 1572, as described in 21 C.F.R. 31253, which Principal Investigator has completed, signed and delivered to Sponsor contemporaneous with signing this Agreement. To the extent terms and conditions in this Agreement and the Protocol conflict, the terms and conditions of the Protocol shall control. The Institution further agrees that in the performance of the Study the Principal Investigator and research staff shall devote their best efforts to accurately and efficiently perform the work required under this Agreement, which efforts shall include but are not limited to the following:

(1) The Principal Investigator shall exercise independent medical judgment as to the compatibility of each subject with the Study Protocol requirements;

(2) Obtaining from each subject in the Study the most current signed consent form which has been approved by IRB, PPD and Sponsor in accordance with 21 C.F.R. Part 50;

(3) Review of all case report forms ("CRFs") for accuracy and completeness;

(4) Submission of all data in a timely manner;

(5) Notification of Sponsor, PPD and IRB by facsimile and electronic transmission promptly upon knowledge, and in no event later that the time periods specified by the regulations and the IRB, of any unanticipated or serious adverse reactions to the Study drug or control drug;

(6) Notification of Sponsor, PPD and IRB promptly of any deviations from the Protocol;

(7) Maintenance of adequate records with respect to subject identification, clinical observations, laboratory tests and drug receipt and disposition;

(8) Cooperation with PPD and Sponsor in their efforts to monitor the Study.

d. Upon completion of the Study or early termination thereof pursuant to this Agreement, all unused Study drug, compounds, devices and related Study materials furnished to Institution and Principal Investigator by or on behalf of Sponsor or PPD shall be returned as directed by PPD at PPD's expense. The Institution and Principal Investigator shall keep all Study drugs in a locked, secured area at all times and maintain complete, up-to-date records showing receipt of shipments of the Study drugs, dispensing of the Study drugs and returns of the Study

drugs as required by the Protocol, applicable federal, state and local laws, regulations and guidelines.

e. Any alteration of or amendment to the Protocol must be approved in writing by Principal Investigator, Institution, IRB and Sponsor prior to such alteration or amendment becoming effective. Notwithstanding the foregoing, if in the course of performing this Agreement, generally accepted standards of clinical research and medical practice relating to the benefit, well-being and safety of any subject requires 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 said deviation as soon as the facts are known to said party. Said notification shall be followed by written confirmation of same.

f. The Institution agrees to assist PPD and Sponsor during normal business hours and at mutually agreeable times in resolving any discrepancies or errors on Study CRFs and in verifying Institution's original Study source records to ensure complete and accurate capture on delivered CRFs.

g. In the event Principal Investigator becomes either unwilling or unable to perform the duties required by this Agreement, Institution will cooperate, in good faith and expeditiously, to find a replacement investigator acceptable to the IRB, PPD, and Sponsor but in no event later than ten (10) days after the departure of the previous Principal Investigator.

2. Term and Termination

a. The term of this Agreement shall begin upon its execution by the parties hereto and shall continue until the objectives of the Study are accomplished unless sooner terminated as provided herein.

b. PPD reserves the right to discontinue work to be performed by Institution and Principal Investigator and to cancel this Agreement upon thirty (30) days written notice to Institution.

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 FDA;

(2) PPD determines in its sole discretion that test results support termination of the Study for 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) Sponsor terminates its clinical research agreement with PPD for conduct of the Study, unless Sponsor otherwise assumes the obligations of PPD hereunder and undertakes to continue with the conduct of the Study.

d. This Agreement may be terminated by Institution upon thirty (30) days written notice of termination for the material breach by PPD if said breach is not cured within said thirty (30) day period.

e. Immediately upon receipt of a notice of termination, Principal Investigator shall cease entering subjects into the Study, shall cease conducting procedures to the extent medically permissible on subjects already entered into the investigational Protocol, and shall 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 work performed pursuant to the Protocol as determined in accordance with the budget attached as Exhibit A and incorporated herein by reference (the "Budget"). Any funds not due Institution under this methodology for payment but already paid to Institution shall be returned to PPD 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. Provisions herein regarding confidentiality of proprietary information, publication, publicity, intellectual property rights and indemnification shall survive termination of this Agreement.

3. <u>Payments</u>

a. The approved reimbursement rate for the Study to be conducted by Institution is provided for in the Budget.

b. Payments are dependent upon the data as described in the Protocol being submitted to PPD in a timely and satisfactory manner on the CRF provided. Payment for partially completed cases, i.e., early withdrawals, shall be made pro-rata for procedures performed according to the Budget. No payment shall be made for any cases with protocol violations.

c. Institution hereby acknowledges and agrees that payments due under this Agreement are pass-through payments from Sponsor and that PPD shall have no payment obligations hereunder to Institution until such time as said payments are received by PPD from Sponsor. PPD shall exercise reasonable efforts to ensure timely receipt of pass-through payments from Sponsor.

4. Regulatory Inspections and Audits

In the event Institution or Principal Investigator receives notice that the Study site shall be or is the subject of an investigation or audit by any governmental or regulatory authority, the party receiving such notice shall notify PPD and Sponsor immediately by telephone and facsimile. 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 and will provide in writing to the Sponsor, upon Sponsor's request and expense, copies of all materials, correspondence, statements, forms and records which are received, obtained, or generated pursuant to any such investigation or audit.

5. Publication Rights

Institution and Principal Investigator shall not publish, present or use any data or results arising out of the performance of this Study for their own instruction, research or publication without the prior express written consent of Sponsor.

6. Confidentiality

During the term of this Agreement and for a period of five (5) years following the termination of this Study, Institution, Principal Investigator and Institution's employees and agents shall not, directly or indirectly, use for their respective benefit or disclose or use for the benefit of any third party or for any purposes other than for the performance of the Study any data, records or other information (hereinafter, collectively "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. Such Information shall remain the confidential and proprietary property of Sponsor and shall be disclosed only to Institution, Principal Investigator and Institution's employees or agents who have a "need to know". The obligation of nondisclosure shall not apply to the following Information:

a. Information that is or becomes publicly available through no fault of Institution or Principal Investigator;

b. Information that is disclosed to Institution and Principal Investigator by a third party legally entitled to disclose such information;

c. Information that is already known to Institution and Principal Investigator as shown by its prior written records, provided Institution and Principal Investigator so advises Sponsor within twenty (20) days after disclosure of the Information to Institution and Principal Investigator by PPD or Sponsor;

d. Information disclosed to a government authority or by order of a court of competent jurisdiction, provided that a) such disclosure is subject to all applicable governmental or judicial protection available for like material; b) reasonable advance notice is given to

Sponsor; and c) Principal Investigator and Institution shall take reasonable steps to limit the scope of such disclosure.

All information of each party containing personal data shall be handled in accordance with all applicable privacy laws, rules and regulations.

7. Publicity

PPD and Sponsor may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of Institution consistent with U.S. copyright laws, provided such use does not constitute an endorsement of any commercial product or service by Institution. Institution shall not disclose the existence of this Agreement or the Institution's association with PPD or Sponsor without the express written approval of the party whose name is the subject of the potential disclosure.

8. Intellectual Property Rights

a. Any inventions or discoveries (whether patentable or not), innovations, suggestions, ideas and reports made or developed by Institution and Principal Investigator during the course of this Study shall be promptly disclosed to Sponsor and shall become the sole and exclusive property of Sponsor. Upon Sponsor's request, and at Sponsor's expense, Institution and Principal Investigator shall take such actions as Sponsor, in its sole discretion, deems necessary or appropriate to obtain patent or other proprietary protection in Sponsor's name with respect to any of the foregoing.

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.

9. Independent Contractor Relationship

a. Institution is performing professional services for PPD as an independent contractor and not as an employee or agent of PPD or Sponsor. Institution shall have no authority to enter into binding obligations on behalf of PPD or Sponsor. Institution, its 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 to Institution for services rendered under this Agreement shall be made in full at the amount provided for in the Budget 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 solely Institution's responsibility and Institution shall timely pay all such taxes for which it is liable.

10. Indemnification

a. Indemnification between the Institution and Sponsor shall be governed by a separate letter agreement.

b. Each Party (the "Indemnifying Party") hereby agrees to indemnify and hold harmless the other party and Sponsor from any loss, injury, harm, costs or expenses, including reasonable attorney's fees, incurred by the other party or Sponsor as a result of Indemnifying party's negligence or willful misconduct related to this Study or resulting from the Indemnifying Party's breach of any of its obligations under this Agreement.

11. Debarment and Disqualification

a. Institution represents and warrants that neither it, its employees, nor any other person retained by it to perform the Study pursuant to this Agreement, (i) is under investigation by the FDA for debarment action or is presently debarred pursuant to the Generic Drug Enforcement Act of 1992, as amended (21 U.S.C. §301 et seq), or (ii) has a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 CFR Section 312.70 or its successor provisions. In addition, Institution represents and warrants that it has not engaged in any conduct or activity which could lead to any of the above mentioned disqualification or debarment actions. If during the term of this Agreement Institution or any person employed or retained by it 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.

b. For the purposes of this Section, reference to the FDA and the Generic Drug Enforcement Act shall also be deemed a reference to any other governmental or regulatory authorities having jurisdiction over the subject matter of the particular Study or any other laws and regulations applicable to the Study.

12. Miscellaneous

a. Institution warrants and represents that it possesses and shall carry at its own expense comprehensive general liability insurance with limits of not less than $1,000,000 per occurrence and $3,000,000 in the aggregate, and professional malpractice insurance (or similar errors and omissions insurance) with limits of not less than $1,000,000 per occurrence and $3,000,000 in the aggregate. Institution shall maintain such coverage for the duration of the Agreement and for two (2) years thereafter. Proof of said insurance shall be supplied to PPD upon execution of this Agreement.

b. Institution 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 performing the Services for PPD, Institution is not in violation of any terms and conditions of any agreement for services or employment with any other individual or entity.

d. This Agreement shall be construed in accordance with the laws of the State of North Carolina without regard to its conflict of laws provisions.

e. This Agreement, and any and all exhibits, attachments, etc., constitutes the entire agreement between the relevant parties and supersedes all prior agreements, whether written or oral.

f. This Agreement, and any and all exhibits, attachments, etc., may be modified only by written document signed by the relevant parties hereto.

g. This Agreement may not be assigned or transferred by Institution without the prior written consent of PPD.

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. The obligations of the parties contained in Sections 4 (Regulatory Inspections and Audits), 5 (Publication Rights), 6 (Confidentiality), 7 (Publicity), 8 (Intellectual Property Rights), 10 (Indemnification), 12(a) (relating to insurance), and 12.1 (relating to Sponsor as third party beneficiary) shall survive the termination or expiration of this Agreement.

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. 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
9330 Scranton Road, Suite 200
San Diego, CA 92121
Telephone: 858-638-2526
Facsimile: 858-638-1913
Attn.: Wendy Kaneko, Project Manager

If to Institution:

San Mateo Medical Center
222 W. 39th Avenue
San Mateo, CA 94403
Telephone: 650-573-2385
Facsimile: 650-571-7802
Attn.: Joanne Imperial, MD

If to Sponsor:

Valeant Research & Development
3300 Hyland Avenue
Costa Mesa, CA92626
Telephone: 1-800-548-5100
Facsimile: 714-641-7287
Attn.: Andrea Armfield, CRA

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

l. Sponsor shall be an intended third party beneficiary hereunder and the parties hereto agree that the terms and conditions of this Agreement may be enforced by Sponsor directly against the Institution, the Principal Investigator, and PPD despite any claims or defenses one party may have against the other.

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.

[The remainder of this page is intentionally left blank. Signature page follows.]

Accepted and Agreed:

PPD DEVELOPMENT, LP

By: PPD GP, LLC
Its General Partner

By:_____ Date:_____
Wendy Kaneko
Project Manager

SAN MATEO MEDICAL CENTER

By:_____ Date:_____

Name: Richard S. Gordon

Title: President, Board of Supervisors
San Mateo County

I HAVE READ AND UNDERSTAND THE ABOVE AGREEMENT AND AGREE TO ABIDE BY THE TERMS THEREOF.

PRINCIPAL INVESTIGATOR

By: _____ Date: 9/9/05
Joanne Imperial, MD

Exhibit A

Please insert copy of payment schedule and budget (3 pages total) as sent via email by Adessa Shaddix.

EXHIBIT A

TITLE OF PROJECT:	Analysis of Hepatitis C Viral Kinetics and Viramidine Pharmacokinetics Utilizing Two Treatment Regimens in Therapy-naïve Patients with Chronic Hepatitis C
PROTOCOL NUMBER:	RNA003142-202
INSTITUTION:	San Mateo Medical Center
SPONSOR:	Valeant Research & Development
INVESTIGATOR:	Joanne Imperial, MD
Study Costs:	$9,830.00 for each completed Study subject. To be considered completed, Study subjects will meet all eligibility criteria and will have completed the Follow-up Week 24 Visit. **Total Per Study subject:** $9,830.00
Start-up Payment: (Recoupable)	$9,830.00 (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]
Subsequent Payments broken down:	Payment Trigger: once the initial payment of $9,830.00 is completely depleted through 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. These payments will be made on a quarterly (every three month) 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 site]

Screening:	$750.00	- 10% ($75.00)= $675.00
Monotherapy Week 2:	$1,000.00	- 10% ($100.00)= $900.00
Monotherapy Week 4:	$455.00	- 10% ($45.50.00)= $409.50
Combined Therapy Week 2:	$1,540.00	- 10% ($154.00)= $1,386.00
Combined Therapy Week 4:	$520.00	- 10% ($52.00)= $468.00
Combined Therapy Week 8:	$380.00	- 10% ($38.00)= $342.00
Combined Therapy Week 12:	$610.00	- 10% ($61.00)= $549.00
Combined Therapy Week 18:	$375.00	- 10% ($37.50)= $337.50
Combined Therapy Week 24:	$610.00	- 10% ($61.00)= $549.00
Combined Therapy Week 30:	$375.00	- 10% ($37.50)= $337.50
Combined Therapy Week 36:	$375.00	- 10% ($37.50)= $337.50
Combined Therapy Week 42:	$375.00	- 10% ($37.50)= $337.50
Combined Therapy Week 48:	$610.00	- 10% ($61.00)= $549.00
Follow up Week 4:	$355.00	- 10% ($35.50)= $319.50

Follow up Week 8:	$350.00	- 10% ($35.00)= $315.00
Follow up Week 12:	$355.00	- 10% ($35.50)= $319.50
Follow up Week 18:	$350.00	- 10% ($35.00)= $315.00
Follow up Week 24:	$445.00	- 10% ($44.50)= $400.50
Final Payment:	$983.00	

Screen Failure Payments: Payments will be calculated at 100% of the value of assessments completed, as evidenced by CRFs and reviewed by the monitor, not to exceed $600.00 per SF. There is a maximum of 5 paid screen failures/site. Therefore the maximum budget for screen failures will be $3000.00 ($600.00 x 5).

Valeant VKS
Protocol # RNA003142-202
Exhibit A
Site Budget

STUDY PROCEDURE	Screen Visit*	MONOTHERAPY Day 1	MW2	MW4	COMBINATION THERAPY Day 1	Day 2	TW 1	TW 2	TW 4	TW 8	TW 12	TW 18	TW 24	TW 30	TW 36	TW 42	TW 48	FOLLOW UP FW 4	FW 8	FW 12	FW18	FW 24	totals
Medical History	100	100																					200
Depression Screening	35																						35
Physical Exam	100				100						100		100				100					100	600
Physical Assessments		10	10				10	10	10	10		10		10	10	10		10	10	10	10		140
ECG	75																						75
Chest X-ray	100																						100
Vital signs, Ht/Wt	20	20	20		20		20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	400
Adverse Event Review		25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	525
ConMed Review	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	550
Lab phlebotomy/processing	45	35	35		35		35	30	35	35	35	30	35	30	30	30	35	35	30	35	30	35	675
Urine drug test	10																						10
PK samples		140		140					140		140		140				140						840
Investigator Fee	75	75	75	75	75	75	75	75	75	75	75	75	75	75	75	75	75	75	75	75	75	75	1650
Coordinator Fee	125	125	125	125	125	125	125	125	125	125	125	125	125	125	125	125	125	125	125	125	125	125	2750
Pharmacy Fee/Dispensing		25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25						400
Patient Reimbursement	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	880
TOTAL / VISIT	750	620	380	455	470	315	380	375	520	380	610	375	610	375	375	375	610	355	350	355	350	445	9630

total cost per completed subject **$9,830.00**

Screen Failures		$ 600.00	x	5	=	$3,000.00

Screen Failure reimbursement amounts will be calculated at 100% of the value of assessments completed, as reviewed by the monitor, not to exceed $600.00 per SF. There is a maximum of 5 paid screen failures/site. Therefore the maximum budget for screen failures will be $3000.00 ($600.00 x 5).

Total Clinical Budget for nine randomized (9) subjects: **$88,470.00**

Total Screen Failure Budget: **$ 3,000.00**

Total Additional Cost Budget: **$ 5,750.00**

Grand Total Study Budget: **$97,220.00**

Additional Costs: List additional non-clinical budget items below, including a description, estimated unit cost and estimated frequency. Totals are based on estimations and are solely for budgeting purposes. Additional cost items will be paid to the Institution by invoice only, at Valeant's discretion. Overhead will not be paid for additional costs unless specified below.

Description	Unit cost		Frequency		Max Budget
Liver Biopsy	$ 1,000.00	x	3	=	$3,000.00
Fundoscopic Exam	$ 100.00	x	5	=	$ 500.00
Pharmacy Set-up	$ 1,000.00	x	1	=	$1,000.00
Long-Term Document Storage	$ 1,250.00	x	1	=	$1,250.00
					$5,750.00

PI SIGNATURE

DATE