CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-705 / S-008

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

ITEM 13.
PATENT AND MARKET EXCLUSIVITY INFORMATION

13.1. Patent Information

NDA Number:	20-705
Applicant:	Agouron Pharmaceuticals, Inc. 10350 North Torrey Pines Road La Jolla, California 92037-1020
Active Ingredient:	piperazine, 1-[3-[(1-methyl-ethyl)amino]-2-pyridinyl]-4-[[5-[(methylsulfonyl)amino]-1H-indol-2-yl]carbonyl]-, monomethanesulfonate
Medical Use:	Treatment of HIV-1 infection in combination with appropriate antiretroviral agents
Strengths:	100 mg, 200 mg
Dosage Form:	Tablets
Trade Name:	RESCRIPTOR®
Generic Name:	delavirdine mesylate
Patent Statement:	US Patent Number: 5,563,142 Expiration Date: October 8, 2013 Patent Type: Drug Substance Patent Owner: Pharmacia & Upjohn

The undersigned declares that US Patent Number 5,563,142 covers the drug substance delavirdine mesylate, which is the subject of this application for which traditional approval is sought.

Linda S. Evans
Assistant General Counsel, Patents

13.2. Request for Market Exclusivity

RESCRIPTOR (delavirdine mesylate) was approved under the accelerated approval regulations and has been marketed in the United States since 1997.

The present supplemental application for traditional approval contains reports of new clinical investigations that are essential to approval of the sNDA. Therefore, an additional 3-year market exclusivity is requested as provided for by 21 CFR 314.108(b)(5).

Agouron Pharmaceuticals, Inc., certifies that the active moiety, delavirdine mesylate, meets the criteria for exclusivity specified in 21 CFR 314.50(j)(4).

EXCLUSIVITY SUMMARY for NDA # 20-705 SUPPL# 008

Trade Name Rescriptor® Generic Name delavirdine mesylate

Applicant Name Agouron Pharmaceuticals, Inc HFD- 530

Approval Date May 17, 2001

PART I: IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete Parts II and III of this Exclusivity Summary only if you answer "YES" to one or more of the following questions about the submission.

   a) Is it an original NDA? YES/___/ NO /_X_/

   b) Is it an effectiveness supplement? YES /_X_/ NO /___/

      If yes, what type(SE1, SE2, etc.)? SE7

   c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "NO.")

      YES /_X_/ NO /___/

      If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

      _____

      _____

      If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

      _____

      _____

d) Did the applicant request exclusivity?

YES /___/ NO /_X_/

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

_____

_____

e) Has pediatric exclusivity been granted for this Active Moiety?

YES /___/ NO /_X_/

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule previously been approved by FDA for the same use? (Rx to OTC) Switches should be answered No - Please indicate as such).

YES /_X_/ NO /___/

If yes, NDA # **20-705** Drug Name **RESCRIPTOR Tablets**

Explanation: This supplement is for Traditional Approval of a product approved under the accelerated approval (Subpart H) regulations. This is a review of 52 and 54-week data from two studies 0021part II(52-week) and 0013C(54-week) that were submitted with the original NDA. The active ingredients, dosage form, strength, route of administration, and dosing schedule remain the same.

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

3. Is this drug product or indication a DESI upgrade?

YES /___/ NO /___/

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9 (even if a study was required for the

PART II: FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES
(Answer either #1 or #2, as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES /___/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA # _____ _____

NDA # _____ _____

NDA # _____ _____

2. Combination product.

If the product contains more than one active moiety (as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES /___/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA # _____ _____

NDA # _____ _____

NDA # _____ _____

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9. IF "YES," GO TO PART III.

PART III: <u>THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS</u>

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2, was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES /___/ NO /___/

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis

for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

For the purposes of this section, studies comparing two products with the same ingredient(s) are considered to be bioavailability studies.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES /___/ NO /___/

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval **AND GO DIRECTLY TO SIGNATURE BLOCK ON Page 9:**

_____

_____

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES /___/ NO /___/

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES /___/ NO /___/

If yes, explain: _____

_____

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES /___/ NO /___/

If yes, explain: _____

_____

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Investigation #1, Study # _____

Investigation #2, Study # _____

Investigation #3, Study # _____

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

(a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES /___/ NO /___/

Investigation #2 YES /___/ NO /___/

Investigation #3 YES /___/ NO /___/

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

NDA # _____ Study # _____
NDA # _____ Study # _____
NDA # _____ Study # _____

(b) For each investigation identified as "essential to the approval," does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES /___/ NO /___/

Investigation #2 YES /___/ NO /___/

Investigation #3 YES /___/ NO /___/

If you have answered "yes" for one or more investigations, identify the NDA in which a similar investigation was relied on:

NDA # _____ Study # _____

NDA # _____ Study # _____

NDA # _____ Study # _____

(c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

Investigation #__, Study # _____

Investigation #__, Study # _____

Investigation #__, Study # _____

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

(a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1	
IND # _____ YES /___/	NO /___/ Explain: _____
	_____
	_____
Investigation #2	
IND # _____ YES /___/	NO /___/ Explain: _____
	_____
	_____

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1	
YES /___/ Explain _____	NO /___/ Explain _____
_____	_____
_____	_____
Investigation #2	
YES /___/ Explain _____	NO /___/ Explain _____
_____	_____
_____	_____

(c) Notwithstanding an answer of "yes" to (a) or (b), are

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /___/ NO /___/

If yes, explain: _____

_____

_____

Sean J. Belouin, RPh
Regulatory Project Manager

5/14/2001
Date

Debra Birnkrant, M.D.
Acting Division Director

5/16/01
Date

cc:
Archival NDA 20-705 S-008
HFD-530/Division File
HFD-530/RPM/Belouin
HFD-530/CRPM/DeCicco
HFD-530/ActingDivDir/Birnkrant
HFD-093/Mary Ann Holovac
HFD-104/PEDS/T.Crescenzi

Form OGD-011347
Revised 8/7/95; edited 8/8/95; revised 8/25/98, edited 3/6/00

PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA Number:	N 020705		
Trade Name:	RESCRIPTOR (DELAVIRDINE MESYLATE) TABS		
Generic Name:	DELAVIRDINE MESYLATE		
Supplement Number.	008	**Supplement Type:**	SE7
Dosage Form:			
Regulatory Action:	OP	**Action Date:**	7/17/00
COMIS Indication:	TREATMENT OF HIV-1 INFECTION		

This page was last edited on 5/15/01

Signature

5/15/01

Date

ITEM 16.
DEBARMENT CERTIFICATION

Agouron Pharmaceuticals, and it's parent company Pfizer Inc., hereby certifies that it is not debarred, and did not and will not use in any capacity the services of any person debarred under Section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application.

Furthermore, Pharmacia & Upjohn, the sponsor of the clinical studies included in this sNDA, has submitted to Agouron Pharmaceuticals a similar certification in conjunction with this application. A copy of this certification is attached.

DEBARMENT CERTIFICATION FOR RESCRIPTOR Tablets, NDA 20-705

Pursuant to section 306(k)(1) of the Federal Food, Drug and Cosmetic Act, the applicant certifies that, the applicant did not and will not use in any capacity the services of any person listed pursuant to section 306(e) as debarred under subsections 306(a) or (b) of the Act in connection with this application.

Ed L. Patt

Ed L. Patt
Associate Director
Global Regulatory Affairs, CMC

10/28/99

Date

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 5-15-2001

FROM: Linda L. Lewis M.D., Medical Reviewer
Division of Antiviral Drug Products/HFD-530

TO: Original NDA 20-705, S-008
HFD-530/Division files

SUBJECT: Medical Officer's Review of Financial Disclosure Issues regarding RESCRIPTOR® Traditional Approval, NDA 20-705, S-008

Agouron Pharmaceuticals has made available financial disclosure statement summaries provided to them by Pharmacia & Upjohn. Access to financial disclosure information was a difficult issue in the transfer of DLV to Agouron. This information was not required and, therefore, had not been collected at the time the studies were conducted. After requests from Agouron, Pharmacia & Upjohn sent letters of inquiry to the physicians involved in the pivotal trials requesting financial disclosure information. Response rates were relatively poor and a significant number of inquiry letters were returned undeliverable. The summary information available indicates only 1 physician who had received significant compensation from Pharmacia & Upjohn. This is unlikely to impact the results of these multi-center trials.

ITEM 19.
FINANCIAL DISCLOSURE CERTIFICATION

The pivotal clinical studies included in this sNDA for traditional approval are Pharmacia and Upjohn sponsored studies 0021 Part II and 0013C. For purposes of financial disclosure, Agouron and FDA agreed prior to this submission that these 2 studies would be the only "covered" clinical studies included in the sNDA.

Prior to sNDA submission, Agouron made repeated attempts to obtain financial disclosure information for studies 0021 Part II and 0013C from Pharmacia & Upjohn, the sponsor of the covered clinical studies. Registered letters requesting this information were sent on February 15, 2000 and again on April 27, 2000.

Pharmacia & Upjohn initially declined to provide this information on the basis that both studies were completed prior to February 2, 1999, the effective date of 21 CFR 54. After detailed discussions with Agouron regarding the specifics of the regulation, Pharmacia & Upjohn finally agreed to provide requested financial disclosure information. Letters were sent by certified mail to each investigator and sub-investigator who participated in studies 0021 Part II and 0013C requesting that they complete a Pharmacia & Upjohn financial survey of disclosable interests.

On June 7, 2000, Pharmacia & Upjohn informed Agouron that there were no disclosures of financial interest, as defined in 21 CFR 54.2, for investigators who responded to the financial disclosure survey. Pharmacia & Upjohn also provided a tabulation of investigator responses to the financial disclosure survey to allow Agouron to complete FDA Form 3454 for Studies 0021 Part II and 0013C. These tabulated summaries follow FDA Form 3454 for each of the covered clinical studies.

On June 28, 2000, Agouron received additional correspondence from Pharmacia & Upjohn indicating a disclosure of financial interest from

A completed FDA Form 3455 is included in this section for [redacted] double-blinded study, Agouron Pharmaceuticals does not believe that this disclosure of financial interests biases the study results.

FDA FORM 3454
STUDY 0021 PART II

WITHHOLD 35 PAGE(S)

B5

privacy

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: 3/31/02

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☐ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	
see attached list for protocol #M/3331/0021 Part II	

☑ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☑ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	Timothy M. Cunniff	TITLE	Director, FDA Liaison Worldwide Regulatory Affairs
FIRM/ORGANIZATION	Agouron Pharmaceuticals, Inc.		
SIGNATURE	Timothy MCunniff	DATE	June 19, 2000

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

FORM FDA 3454 (3/99)

Created by Electronic Document Services/USDHHS: (301) 443-2454 EF

Rescriptor
M/3331/0021 Part II

A double-blind, randomized, combination therapy trial of delavirdine mesylate (DLV) and zidovudine (ZDV) and lamivudine (3TC) versus DLV and ZDV versus ZDV and 3TC3 as initial therapy in HIV-1 infected individuals with CD4 counts of 200-500 cells/mm.

Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
Dr. Mary Albrecht			x	
Deaconess Hospital				
One Deaconess Rd.				
Kennedy Building, 6th Floor				
Boston, MA 02215				
Dr. Jerome Groopman			x	
Scott Hammer			x	
Christine Wanke			x	
Matthew Samore			x	
AW Karchmer	x			
John Doweiko	x			
Eva Piessons			x	
Eoin Coakley	x			
Yehuda Carmedli			x	
Dr. Raymond Bachhuber	x			
Wisconsin AIDS Research Cons.				
820 N. Plankinton				
Milwaukee, WI 53203				
Paula Jones			x	
Brian P. Buggy	x			
Susan Russler	x			
Niraj Sawhney			x	
Cyril Hetsko			x	
James Levin	x			
Charles Brummitt	x			
Ian Gilson	x			
Maria Teresa Seville	x			
Kelly Balliet			x	
Katherine Kulak			x	
Dr. Jeffrey A. Beal	x			
2325 S. Harvard, Ste. 600				
Tulsa, OK 74114-3300				
Dr. Ann C. Collier	x			
Univ. of Washington AIDS				
Clinical Trials Unit				
325 9th Ave., Box 359929				
Seattle, WA 98104				
Robert Coombs, MD	x			
Dana Cummings, ARNP				x
Charles Cooper, RN				x
Sher Storey, PA-C	x			
Becky Royer, PA-C	x			

Rescriptor
M/3331/0021 Part II

A double-blind, randomized, combination therapy trial of delavirdine mesylate (DLV) and zidovudine (ZDV) and lamivudine (3TC) versus DLV and ZDV versus ZDV and 3TC3 as initial therapy in HIV-1 infected individuals with CD4 counts of 200-500 cells/mm.

	Financial Disclosure Response			
Investigator Name/Address	**No**	**Yes**	**No Response**	**No Longer at Site**
Carol Hooper, MD	X			
Cecilia Schulte, MD				X
Karen Novak	X			
Margot Perrin, RN	X			
Jeanne Conley, RN	X			
Thomas Hooten, MD			X	
Kimberly Marquis, MD				X
Rose Vasquez, ARNP				X
Andrea York, RN				X
James Lund, MD				X
Lili Sacks, MD				X
John Nienow, MD				X
Dr. Brian Conway	X			
St. Paul's Hospital				
1081 Burrard St.				
Vancouver, BC V6Z 1Y8, Canada				
Dr. Julio Montaner			X	
Dr. Marianne Harris			X	
Dr. Timothy P. Cooley	X			
Boston University Medical Center				
Evans Bldg., 5th Floor, room 556				
88 E. Newton St.				
Boston, MA 02118				
Dr. Patrick Daly	X			
Nelson-Tebedo Community clinic				
4012 Cedar Springs				
Dallas, TX 75219				
Dr. Robert Eng			X	
Infectious Disease (111)				
VA Medical Center				
385 Tremont Ave.				
East Orange, NJ 07018				
Dr. Douglas Fish			X	
Albany Medical College				
Albany Medical Center Hosp.				
66 Hackett Blvd. - A-158				
Albany, NY 12208				
Steven Szebenyi, MD			X	
Peter Piliero, MD			X	
Cynthia Miller, MD			X	

Rescriptor
M/3331/0021 Part II

A double-blind, randomized, combination therapy trial of delavirdine mesylate (DLV) and zidovudine (ZDV) and lamivudine (3TC) versus DLV and ZDV versus ZDV and 3TC3 as initial therapy in HIV-1 infected individuals with CD4 counts of 200-500 cells/mm.

Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
Perry Smith, MD			x	
Johnathan Curtin, MD			x	
Harold Burger, MD			x	
Mary Jo Fink, MD			x	
Barbara Weiser, MD			x	
Amy Eckstein, RPA			x	
Robin Weiss, RPA			x	
Scott Remick (former PI)			x	
Dr. Alvan Fisher RETURNED/ UNDELIVERABLE				
Omega Medical Research				
400 Reservoir Ave., Ste. LL1J				
Providence, RI 02907				
Dennis Mikolich, MD				
Rinchen-Tzo Emgushov, MD				
Lisa Cranadall, RN				
Lynne Haughey, RN				
Johnna Pezzullo, RN				
Dr. Peter Frame			x	
University of Cincinnati Medical Center				
Holmes Division-Mail Location 0405				
Cincinnati, OH 45267-0405				
R. Baughman, MD			x	
W. Bullock, MD			x	
B. Wong, MD			x	
S. McKenzie, MD			x	
K. Skahan, MD			x	
M Dohn, MD			x	
K. Johnson, MD			x	
L. Haglund, MD			x	
C. Linnemann, MD			x	
G. Roselle, MD			x	
G. Smulian, MD			x	
N. Walker, MD			x	
J. Feinberg, MD			x	
Jill Leonard, RA			x	
Dr. Marshall J. Glesby RETURNED/UNDELIVERABLE				
Community Research Initiative on AIDS				
275 Seventh Ave., 20th Floor				
New York, NY 10001				
Dr. Mitchell Goldman	x			
Wishard Hospital				

Rescriptor
M/3331/0021 Part II

A double-blind, randomized, combination therapy trial of delavirdine mesylate (DLV) and zidovudine (ZDV) and lamivudine (3TC) versus DLV and ZDV versus ZDV and 3TC3 as initial therapy in HIV-1 infected individuals with CD4 counts of 200-500 cells/mm.

Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
RM (OPW) 430				
1001 W. 10th St.				
Indianapolis, IN 46202				
Jean Craft, RN (Decker)	x			
Kenneth Fife, MD	x			
Paula Hartman, RN				x
Heather Nixon, RN				x
Kristin Todd-Christman, RN	x			
Beth Zwickl, RN	x			
Dr. C. Jeffrey Goodgame Returned/Non-deliverable				
Central Florida Research Initiative				
340 N. Maitland Ave.				
Maitland, FL 32751				
Eileen Wright, MD				
Andrea Hamlin, MD				
Scott Morrow, MD				
Roberto Ortiz, MD				
Karen West, ARNP				
Robert Kuhnhenn, DO				
Jan Raff, ARNP				
Kathie Smith, ARNP				
Dr. Christopher Grace	x			
Fletcher Allen Health Care				
MCHV Campus				
111 Colchester Ave.				
Burlington, VT 05454				
W. Kemper Altson, MD	x			
Mary Ramundo, MD	x			
Dieter Gump, MD			x	
Dr. Stephen L. Green	x			
Hampton Roads Medical Specialists				
2112 Executive Drive				
Hampton, VA 23666				
Michelle Kingsbury, MD			x	
Dr. Richard N. Greenberg			x	
University of Kentucky Medical Center				
800 Rose Street				
Chambers Bldg. Room 210E				
Lexington, KY 40536-0084				
Robert Noble, MD			x	
Karen Bowen, RN			x	

Rescriptor
M/3331/0021 Part II

A double-blind, randomized, combination therapy trial of delavirdine mesylate (DLV) and zidovudine (ZDV) and lamivudine (3TC) versus DLV and ZDV versus ZDV and 3TC3 as initial therapy in HIV-1 infected individuals with CD4 counts of 200-500 cells/mm.

Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
Jenny Cox, RN			x	
Beverly Shields-Todd, RN			x	
Vernon Hackworth, BA			x	
Anna Huang, MD			x	
Saeed Shariaty, LPN			x	
Gail Kassler-Stone, RN			x	
J. Donald Coonrad, MD			x	
Melissa Moore, RN			x	
Rebecca Gelhot-Shadler			x	
Jose Salgado, MD			x	
Dr. David W. Haas	x			
Vanderbilt University Medical Center				
1211 21st Avenue, S.				
Nashville, TN 37212				
Mike Morgan, FNP	x			
Victoria Harris, EdD	x			
Rhonda Sanzotta, RN				x
Lisa Clough, MD	x			
Tracy Osborne, MD				x
Patricia Enright, RN				x
Stephen Raffanti, MD				x
Rick Boden, MD				x
Dr. David H. Henry RETURNED / UNDELIVERABLE				
Graduate Hospital				
Tuttleman Center				
1840 South St.- 2nd Floor				
Philadelphia, PA 19146				
Bernard Mason, MD				
Arthur Staddon, MD				
Patricia Ford, MD				
Dr. W. Keith Henry		X		
St. Paul Ramsey Medical Center				
640 Jackson St., Ste. 125				
St. Paul, MN 55101				
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Ronald Schut, MD	X			
Marcia Meredith, RN	X			
Holly Melroe, RN	X			
Ellen Kane, RN				
Julia Beatty, RN				X
Jane Simpson, LP	X			
Denise Bomar, RN				X

Rescriptor
M/3331/0021 Part II

A double-blind, randomized, combination therapy trial of delavirdine mesylate (DLV) and zidovudine (ZDV) and lamivudine (3TC) versus DLV and ZDV versus ZDV and 3TC3 as initial therapy in HIV-1 infected individuals with CD4 counts of 200-500 cells/mm.

	Financial Disclosure Response			
Investigator Name/Address	**No**	**Yes**	**No Response**	**No Longer at Site**
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Dr. D'unno			x	
Dr. Powel H. Kazanjian			x	
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Eric Engels, MD			x	
Joel Katz, MD			x	
Paul Sax, MD			x	
Scott Thaler, MD			x	
Gary Engleberg, MD			x	
Dr. Philip H. Keiser			x	
Veterans Affairs Medical Center				
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Dallas, TX 75216				
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Steven Rademacher, MD			x	
James Smith, MD			x	
Magdi Wassef, MD			x	
Daniel Skiest, MD			x	
Athol Ware, MBBS			x	
Dr. Princy N. Kumar	x			
Georgetown University Medical Ctr.				
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Joseph Timpone, MD	x			
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Dr. Daniel R. Kuritzkes	x			
University of Colorado Health Sciences Ctr.				
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Denver, CO 80262				
Robert Schooley, MD	x			
Mary Bessemssen, MD	x			
Elizabeth Connick, MD	x			
Nancy Madinger, MD	x			
Kenneth Baum, MD	x			
Miguel Mogyoros, MD				x
John Gerber, MD	x			
Janet Kuhns, MD				x

Rescriptor
M/3331/0021 Part II

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	Financial Disclosure Response			
Investigator Name/Address	**No**	**Yes**	**No Response**	**No Longer at Site**
Steven Johnson, MD			x	
Wheaton Williams, MD	x			
Graham Ray, RN			x	
Virginia Waite, RN				x
Beverly Putnam, RN	x			
Sara Canmann, RN	x			
Tyler Curiel, MD				x
Dr. Richard Lalonde	x			
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Montreal Chest Hospital Centre				
36500 St. Urbain				
Montreal, Quebec H2X 2P4 Canada				
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Michel Chateauvert, MD			x	
John MacLeod, MD	x			
Norbert Gilmore, MD	x			
Pierre Rene, MD			x	
Jean-Pierre Routy, MD	x			
Sharyn Mannix, MD			x	
Dr. William Lang	x			
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1375Sutter St. #407				
San Francisco, CA 94109				
Bridget Wagner MD				x
Thomas Webber, RN				x
Thomas Bond, PA-C				x
Sally Turk, RN				x
Thomas Young, RN				x
Laura Strauss, PA				x
Dann Clowry, RN				x
Shawn Sheeron, RN				x
Dr. Ruth Lawrence	x			
University of California, Davis Medical Center				
Infectious Diseases Clinic				
4300 X Street				
2410 Professional Bldg.				
Sacramento, CA 95817				
Neil Flynn, MD			x	
Stuart Cohen, MD	x			
Naiel Nassar, MD			x	
Dr. Noe B. Mateo	x			

Rescriptor
M/3331/0021 Part II

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	Financial Disclosure Response			
Investigator Name/Address	**No**	**Yes**	**No Response**	**No Longer at Site**
Henry Ford Hospital				
2799 W. Grand Blvd.				
Detroit, MI 48202				
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Dr. George F. McKinley			x	
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Linda Attoe, MD				x
Rita Chow, MD				x
Grace Minamoto, MD				x
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Linda Williams, MD				x
Dr. Armando Daniel Meza	x			
Texas Tech HSC				
4800 Alberta St.				
El Paso, TX 79905				
Dr. Michael F. Para	x			
The Ohio State Univ. Medical Center				
Infectious Diseases Clinic				
456 West 10th Avenue				
Columbus, OH 43210-1228				
Robert Fass, MD	x			
Susan Hadley, MD				x
Isabela Riberio				x
Susan Koletar, MD	x			
James Smith, MD				x
Harrison Weed, MD	x			
William Maher, MD	x			
Athar Tehsin, MD				x
Dr. Mahmoud H. Mustafa			x	
NOVUM, INC.				
2311 M Street, NW, Ste. 501				
Washington, DC 20037				
Bruce Rahsbaum, MD			x	
Richard Elion, MD			x	
Mitchell Feinman, MD			x	

Rescriptor
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A double-blind, randomized, combination therapy trial of delavirdine mesylate (DLV) and zidovudine (ZDV) and lamivudine (3TC) versus DLV and ZDV versus ZDV and 3TC3 as initial therapy in HIV-1 infected individuals with CD4 counts of 200-500 cells/mm.

	Financial Disclosure Response			
Investigator Name/Address	No	Yes	No Response	No Longer at Site
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Aaron Killian, PharmD			x	
David Pitrak, MD			x	
Alice Pau, PharmD			x	
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T. Andeyanju, MD			x	
S. Baler, MD			x	
M. Seville, MD			x	
JR Lentino, MD			x	
Dr. Robert R. Redfield	x			
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J. Mark Brint, MD				x
Melissa Appleton, MD	x			
Cathy Corbett, MD			x	
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Lamar Bailey, MD				x
Dr. Daryl See	Returned/Undeliverable			
UCI Medical Center				

Rescriptor
M/3331/0021 Part II

A double-blind, randomized, combination therapy trial of delavirdine mesylate (DLV) and zidovudine (ZDV) and lamivudine (3TC) versus DLV and ZDV versus ZDV and 3TC3 as initial therapy in HIV-1 infected individuals with CD4 counts of 200-500 cells/mm.

Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
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Barbara Lewis, PA-C			x	
Suzanne Schuck, RN	x			
Susan LeLacheur, PA-C			x	
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Chris Rathbun, PharmD	x			
Dr. Robert P. Smith	X			
AIDS Consultation Service				
Maine Medical Center				
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Michael Coyne, MD			x	
Patricia-Stogsdill, MD			x	
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David Butcher, MD				
Lawrence Dall, MD				
Steven Daugherty, MD				
Wolfe Gerecht, MD				
Beth Henry, MD				

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	Financial Disclosure Response			
Investigator Name/Address	**No**	**Yes**	**No Response**	**No Longer at Site**
Yolanda Huet-Vaughn, MD			x	
Paul Jost, MD			x	
Thomas Maddox, MD			x	
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Robert Neihart, MD			x	
Carin Reust, MD			x	
Mary O'Connor, MD			x	
David Smith, MD			x	
Diane Voss, MD			x	
Alan Salkand, MD			x	
Angelo Llana, MD			x	
Michael Driks, MD			x	
Ireneo Diaz, MD			x	
Dennis Palmer, MD			x	
Alan Taege, MD			x	
Sharon Lee, MD			x	
Sharon Snavely, MD			x	
Dr. Jack Stapleton	x			
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200 Hawkins Drive				
Iowa City, IA 52242				
Julie Katseres, RN	x			
Susan Balter, MD				x
Dr. Roy T. Steigbigel	x			
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HSC T-15, Room 080				
SUNY at Stony Brook				
Stony Brook, NY 11794				
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Peter Mariuz, MD				x
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Jennifer Schranz, MD				x
Rowena Lobo, MD				x
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Brenda Taylor, MD	x			
Dr. Susan Swindells	x			
University of Nebraska Medical Center				

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Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
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Carlos Gadea, MD				
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Dr. C. Fordham von Reyn	x			
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Thomas Taylor, MD			x	
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Stephen Kagan, MD				
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Phillip Brachman, MD				
Hieu Nguyen, MD				
Joel Rosenstock, MD				
Alvaro Lopez, MD				
John Hostetler, MD				
Andrew Pugliese, MD				
Carlos Lopez, MD				
Louise Tashjian, MD				
Jonathan Krone, MD				

Rescriptor
M/3331/0021 Part II

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Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
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Kalliope Halkias, MPH			x	
Allis Emmett, RN			x	
Linda Gipson, RN			x	
Judith Lyvers-Torres, ARNP			x	
Vicki Kenyen, RN			x	
Dr. Cecilia M. Shikuma	x			
Leahi Hospital				
3675 Kilauea Avenue				
Honolulu, HI 96816				
Russell Wong, MD	x			
Amy Kindrick, MD				x

FDA FORM 3454
STUDY 0013C

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: 3/31/02

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox

☐ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	
see attached list for protocol # M/3331/0013B part C	

☑ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☑ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME Timothy M. Cunniff	TITLE Director, FDA Liaison Worldwide Regulatory Affairs
FIRM/ORGANIZATION Abbott Pharmaceuticals, Inc.	
SIGNATURE Tim M Cunniff	DATE June 19, 2000

Paperwork Reduction Act Statement

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Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

FORM FDA 3454 (3/99)

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Protocol M/3331/0013B
A study of the Tolerance and Efficacy of a Combination of Delavirdine Mesylate and Nucleoside Therapy in the Treatment of HIV Infected Patients

BELGIUM

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Domaine Universitaire				
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Belgium				
☐ **Michel Moutshen, MD**	x			
☐**J. Demonty, MD**	x			
☐ **J.C. Legrand**	x			
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Dept. de Medecine Interne				
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B-6000 Charleroi				
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Avenue Hippocrate 10				
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Protocol M/3331/0013B
A study of the Tolerance and Efficacy of a Combination of Delavirdine Mesylate and Nucleoside Therapy in the Treatment of HIV Infected Patients

	Investigator Name/Address	Financial Disclosure Response			
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	France				
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	13 avenue Jacques Loeb				
	64109 Bayonne				
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	Marie-Claude Gemaine, MD	x			
	Sophie Farbos	x			
	J.P. Bru			x	
	J Gaillat			x	
	Centre Hospitalier General				
	Service des Maladies infectieuses				
	74011 Annecy				
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	J.P. Cassuto			x	
	Hospital Cimiez				
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	Hacene Fezori, MD			x	
	Prof. P. Dellamonica	x			
	Hospital de l'Archet				
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	France				
	Jacques Durant, MD	x			
	Pascal Pugliese	x			
	Veronique Rahelinirina, MD	x			
	V. Joly	x			
	Hopital Bichat-Claude Bernard				
	46 Rue Henry-Huchard				
	75877 Paris Cédex 18				
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Protocol M/3331/0013B
A study of the Tolerance and Efficacy of a Combination of Delavirdine Mesylate and Nucleoside Therapy in the Treatment of HIV Infected Patients

Investigator Name/Address	Financial Disclosure Response			
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☐ **Nadia Meslem MD**			x	
☐ **Agnes Villemant MD**	x			
☐ **J.Y. Lacut**				x
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CHU Pellegrin				
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France				
☐ **Michel Depon, MD**				x
☐ **Marie-Claire Paty, MD**				x
☐ **A. Lafeuillade**				x
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☐ **Monsieur le Docteur Gilles Hittinger**				x
☐ **Dr. Pierre Pellegrino**				x
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☐ **Dr. Hacene Zerazhi**				x
☐ **Dr. Anne Marie Touchais**				x
☐ **Dr. Olivier Boulat**				x
☐ **Dr. G. Brun**				x
☐ **Prof. F. Lucht**				x
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A study of the Tolerance and Efficacy of a Combination of Delavirdine Mesylate and Nucleoside Therapy in the Treatment of HIV Infected Patients

Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
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☐ **Fatima Talfour, MD**				X
☐ **D. Zucman**	X			
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40, rue Worth				
92151 Suresnes				
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☐ **Dr. Veronique Bortollotti**				X

Protocol M/3331/0013B
A study of the Tolerance and Efficacy of a Combination of Delavirdine Mesylate and Nucleoside Therapy in the Treatment of HIV Infected Patients

	Investigator Name/Address	Financial Disclosure Response			
		No	Yes	No Response	No Longer at Site
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	Augusta-Viktoria-Krankenhaus				
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	Germany				
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☐	**R. Baumgarten**	x			
	Krankenhaus Prenzlauer Berg				
	II. Med. Abt.				
	Frobelstr, 19				
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	Germany				
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	10179 Berlin				
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Protocol M/3331/0013B
A study of the Tolerance and Efficacy of a Combination of Delavirdine Mesylate and Nucleoside Therapy in the Treatment of HIV Infected Patients

Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
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☐ **Stefan Hansen, MD**				x
☐ **Ursula Lenzner, MD**				x
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Turmster. 76 A				
10551 Berlin				
Germany				
☐ **Jolhen Burkle, MD**				x
☐ **Elle Lauenroth-Mai, MD**	x			
☐ **Hans Heiken, MD**			X	
☐ **Gerd-Christian Sutor, MD**			X	
☐ **Matthias Stoll, MD**			X	

Protocol M/3331/0013B
A study of the Tolerance and Efficacy of a Combination of Delavirdine Mesylate and Nucleoside Therapy in the Treatment of HIV Infected Patients

	Investigator Name/Address	Financial Disclosure Response			
		No	Yes	No Response	No Longer at Site
HUNGARY					
☐	**D. Banhegyi, MD**			X	
	Gyali ut-5-7				
	Budapest				
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	Hungary				
	☐ **Eszter Miskovitis**			X	
	☐ **Zsuzsanna Geriei**			X	
	☐ **Janos Szlavic**			X	

Protocol M/3331/0013B
A study of the Tolerance and Efficacy of a Combination of Delavirdine Mesylate and Nucleoside Therapy in the Treatment of HIV Infected Patients

	Investigator Name/Address	Financial Disclosure Response			
		No	Yes	No Response	No Longer at Site
ITALY					
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	Clinic of Infectious & Tropical Diseases				
	University of Brescia				
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	Italy				
	☐ **Francesco Castelli**	x			
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	☐ **Lina Tomasoni**	x			
	☐ **Carlo Torti**			x	
	☐ **Alessandra Donisi**			x	
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	Via Massarenti 11				
	40138 Bologna				
	Italy				
	☐ **Ennio Ricchi, MD**			X	
	☐ **Paolo Costigliola, MD**	x			
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	☐ **Sabrina Spinosa Guzman, MD**			X	
	☐ **Vincenzo Colangeli, MD**	x			
	☐ **Claudio Venturi, MD**	x			
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	☐ **Dr. Lucca Guerra, MD**			x	
	☐ **Dr. Ciro Fulgaro, MD**			x	
	☐ **Dr. Micola Dentale, MD**			x	

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	Investigator Name/Address	Financial Disclosure Response			
		No	Yes	No Response	No Longer at Site
☐	**Prof. Mauro Moroni**	x			
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	☐ **Dr. ssa Antonella D'Arminio Monforte**	x			
	☐ **Dr. ssa Teresa Bini**	x			
	☐ **Dr. ssa Clara Abeli**	x			
	☐ **Dr. ssa Giancarla Moscatelli**	x			
☐	**G. Pastore, MD**	x			
	Infectious Disease Institute				
	Policlinic-Bari University				
	Italy				
	☐ **Gioacchino Angarano, MD**	x			
	☐ **Maria Federico, MD**			x	
	☐ **Nicoletta Ladisa, MD**	x			
	☐ **Laura Monno, MD**	x			
☐	**M.L. Soranzo, MD**	x			
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	Italy				
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	☐ **Bernardino Salassa, MD**			x	
	☐ **Claudia Spezia, MD**	x			

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POLAND

Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
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☐ **Jozef Higersberger, MD**	x			
☐ **Andrzej Piasek, PhD**	x			

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SOUTH AFRICA

Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
☐ **A. Karstaedt**	X			
Perinatel HIV Research Unit				
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P O Bertsham				
2013				
South Africa				
☐ **Dr. G. Gray**	X			
☐ **Dr. S. Johnson**				X
☐ **Dr. N. Schlapobersky**				X
☐ **Dr. Z. Goondiwala**				X
Dr. L. Mohapi	X			
☐ **Robin Wood, MD**	X			
Somerset Hospital				
Private Bag				
Green Point, 8051				
South Africa				
☐ **Linda Bekker, MD**	X			
☐ **Francois Cilliers, MD**	X			
☐ **Gary Maartens, MD**	X			
☐ **Elizabeth O'Keefe, MD**				X

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	Investigator Name/Address	Financial Disclosure Response			
		No	Yes	No Response	No Longer at Site
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	☐ **Christopher Wood, MD**				
	☐ **C.S. Bradbeer, MD**	x			
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	☐ **Dr. C. Elliot**			x	
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	Claude Nicol Centre				
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Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
United Kingdom				
☐ **Dr. E. O'Moore**	x			
☐ **Julie McIntosh-Roffey, RN**				x
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Royal Hallamshire Hospital				
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St. Georg's Hospital				
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London SW17 0QT				
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☐ **Elisabeth Davidson, MD**	x			
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☐ **S.P.R. Jebakumar**			x	
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☐ **M.A. Johnson, MD**	x			
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☐ **Mark Aitkins, MD**			x	

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Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
☐ **Elizabeth Bowen, MD**				X
☐ **Marc Lipman, MD**			X	
☐ **Sara Madge, MD**	X			
☐ **Mervyn Tyrer, MD**			X	
☐ **Debbie Farmer, RN**				X
☐ **Nicola Saint, RN**				X
☐ **David Stobbs, RN**				X
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Glasgow G20 9HB				
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☐ **Dr. J. Scullion**				X
☐ **Dr. ST Green**				X
☐ **Dr. B. McCarron**				X
☐ **Dr. B. Pottinger**			X	
☐ **Dr. E. Walker**				X
☐ **Dr. GP McCann**				X
☐ **Dr. Y. Mulugeta**				X
☐ **Dr. A. Butt**				X
☐ **Dr. S. Eves**			X	
☐ **Dr. WC Love**				X
☐ **C. Leen, MD**	X			
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☐ **Peter Flegg, MD**				X
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Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
☐ **Elke Mutchelknauss, MD**				x
☐ **David Wilks, MD**	x			
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☐ **Gail Crowe, MD**			x	
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Investigator Name/Address	Financial Disclosure Response			
	No	Yes	No Response	No Longer at Site
☐ **Beng Tin Goh, MD**	x			
☐ **Mary Moffat, MD**			x	
☐ **John Sweeney, MD**				x
☐ **Venkatasubbramanian Ramasubramian, MD**			x	
☐ **Nicola Saulsbury, MD**				x
☐ **Brendan Houriham, MD**			x	
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☐ **Stephen Taylor, MD**				x
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☐ **Martin Dedicoat, MD**				x
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FDA FORM 3455
KEITH HENRY, M.D.
STUDY 0021 PART II

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: 3/31/02

DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

The following information concerning KEITH HENRY, M.D. (*Name of clinical investigator*), who participated as a clinical investigator in the submitted study 00 21 PART 11 (*Name of clinical study*), is submitted in accordance with 21 CFR part 54. The named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:

Please mark the applicable checkboxes.

☐ any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;

☒ any significant payments of other sorts made on or after February 2, 1999 from the sponsor of the covered study such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;

☐ any proprietary interest in the product tested in the covered study held by the clinical investigator;

☐ any significant equity interest as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

NAME	TITLE
TIMOTHY M. CUNNIFF	DIRECTOR, FDA LIAISON WORLDWIDE REGULATORY AFFAIRS
FIRM/ORGANIZATION	
AGOURON PHARMACEUTICALS, INC.	
SIGNATURE	DATE
T M Cunniff	June 29, 2000

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Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

FORM FDA 3455 (3/99)

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Investigator: W.K Henry

CLINICAL INVESTIGATOR FINANCIAL DISCLOSURE STATEMENT FOR P&U CLINICAL TRIAL

The personal data collected hereby will be processed by Pharmacia & Upjohn and its business partners to meet requirements set by the United States Food and Drug Administration (FDA).

Please complete all of the information below. Please print or type. Retain a copy of this form for your records.

1. Protocol Title: A double-blind, randomized, combination therapy trial of delavirdine mesylate (DLV) and zidovudine (ZDV) and lamivudine (3TC) versus DLV and ZDV versus ZDV and 3TC as initial therapy in HIV-1 infected individuals with CD4 counts of 200-500 cells/mm^3

2. Protocol Number: M/3331/0021 Part II

3. Name and Institution Address of Investigator or Subinvestigator Keith Henry
Regions Hospital 640 Jackson St. St. Paul, MN 55101

4. Name(s) of Organization(s) or Institution(s) through which you may receive compensation from Pharmacia & Upjohn unrelated to this or other P&U trials (if different from above address provided):

5. Telephone: 651-221-1280 | 6. Fax: 651-221-8616

7. **Indicate by marking YES or NO if any of the financial interests or arrangements of concern to FDA applied to you, your spouse, or dependent children. If response is yes to any question, please provide detailed information regarding nature of interest and monetary amount.**

7a. YES [ ] NO [X]	Financial arrangements whereby the value of the compensation was influenced by the outcome of the Protocol.. This could include, for example, compensation that was explicitly greater for a favorable outcome, or compensation to the investigator in the form of an equity interest in the sponsor or in the form of compensation tied to sales of the product, such as a royalty interest. If yes, please describe:
7b. YES [X] NO [ ]	Significant payments of other sorts made between 1 February 1999 and 1 September 1999, excluding the costs of conducting the study or other clinical studies. This could include, for example, payments made to the investigator or the organization/institution to support activities that have a monetary value greater than $25.000 (i.e. a grant to fund ongoing research, compensation in the form of equipment, or retainers for ongoing consultation or honoraria). If yes, please describe: Speaker's bureau for Pharmacia and Upjohn and Glaxo-Wellcome.
7c. YES [ ] NO [X]	A proprietary or financial interest in the test product such as a patent, trademark, copyright, or licensing agreement. If yes, please describe:

I certify that the information provided above is true and complete.

8. Signature: Keith Henry	9. Date: 5/15/20

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-705/S-007

Agouron Pharmaceuticals, Inc.
Attention: Mathew E. Moran
Manager, Regulatory Strategy and Registration
10350 North Torrey Pines Road
La Jolla, CA 92037

Dear Mr. Moran:

We acknowledge receipt of your April 12, 2001 correspondence notifying us that you are withdrawing your June 29, 2000 supplemental new drug application for Rescriptor®(delavirdine mesylate).

Therefore, in accordance with 21 CFR 314.65, this supplemental application is withdrawn as of the date of our receipt of your notification, April 13, 2001. This withdrawal does not prejudice any future filing of the application. You may request that the information contained in this withdrawn supplemental application be considered in conjunction with any future submission.

If you have any questions, call Sean J. Belouin, R.Ph., Regulatory Project Manager, at 301-827-2335.

Sincerely,

{See appended electronic signature page}

Anthony W. DeCicco, R.Ph.
Chief, Project Management Staff
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research