

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Tibotec Therapeutics Clinical Affairs, A Division of Centocor Ortho Biotech Services, LLC.
TMC114HIV4023, Amendment 2 Version 18-FEB-2009

A multicenter, open-label, randomized study to assess the metabolics, efficacy, and safety of once-daily darunavir versus atazanavir in HIV-infected treatment-naïve adult patients

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Your contacts at the Hospital of the University of Pennsylvania, Philadelphia for this study are:

Principal Investigator:	Pablo Tebas, MD	(215) 349-8092
Coordinator:	Joseph Quinn, RN	(215) 349-8092
Study Nurse:	Larisa Zifchak, RN	(215) 349-8092

*Infectious Disease Clinical Trials Unit, 502 Johnson Pavilion, Philadelphia, PA 19104
24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call*

INVITATION TO PARTICIPATE:

You are being invited to participate in this research study. The following information is provided in order to help you make an informed decision whether or not to participate in this study. The consent form may contain words that you do not understand. Please ask the study doctor or the research staff to explain any words or information that you do not clearly understand.

INTRODUCTION:

PREZISTA™ is a protease inhibitor with the generic name of darunavir. Its function is to help prevent the spread of human immunodeficiency virus (HIV) in the body. PREZISTA is marketed in the U.S. to treat human immunodeficiency virus (HIV) infection in adults. If you were to get a prescription of Prezista from your HIV care provider the dose would be 600 mg Prezista/100 mg Ritonavir (standard of care). In the study we will be using a ONCE daily dose of 800mg Prezista/100 mg Ritonavir (investigational dose that is not approved by the FDA).

PURPOSE:

The purpose of this research study is to compare changes in triglyceride and other lipids from Baseline (Day 1) to Week 12 for PREZISTA/ritonavir 800/100 mg once daily versus REYATAZ (atazanavir)/ritonavir 300/100 mg once daily in combination with a fixed background regimen consisting of Truvada® (emtricitabine [FTC]/tenofovir [TDF] 200/300 mg). This study will also evaluate the safety (adverse events), effectiveness and tolerability of PREZISTA/ritonavir and atazanavir/ritonavir over 48 weeks.

DESCRIPTION OF THE STUDY:

Up to 60 patients, both male and female, will be participating in this study, at approximately 16 centers in the United States. About 5 to 8 people are expected to participate at the University of Pennsylvania. To take part in this study, you must never have taken drugs for more than 10 days to treat your HIV infection. The study will consist of a screening period of 28 days followed by a 48-week treatment period. There will be a total of 10 required study visits. Including 2 follow up visits after completion or discontinuation of the study. Treatment will consist of PREZISTA/ritonavir 800/100 mg or atazanavir/ritonavir 300/100 mg once daily in combination with a fixed background regimen consisting of Truvada® (emtricitabine [FTC]/tenofovir [TDF] 200/300 mg). Everyone in the study will

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receive Truvada® and subjects will be randomized (flip of a coin) to receive PREZISTA/ritonavir 800/100 mg or atazanavir/ritonavir 300/100 mg once daily by the study sponsor or their representative

Screening Visit (Week -4): This visit will be completed to determine your eligibility for enrollment into the study. The informed consent will be reviewed and signed during this visit. This is to occur before any study specific procedures occur. During this visit, you will be asked to report some personal information, such as alcohol use, recreational drug use, any illnesses (including HIV related illness) you have had as well as surgeries and your current medical condition. You will be asked about any medications you take, including medicines for HIV. If you are female you will be asked about the time of your last period. The research staff will complete a physical exam of all body parts, take your body measurements, including height, weight and vital signs (temperature, respirations, blood pressure, and pulse) and take some blood to send to the lab for testing. The blood will be used to test for the following:

- Fasting Safety Labs (not having anything to eat or drink for 8 hours before the blood is drawn)
- HIV viral load (amount of virus in your blood)
- Immune function (CD4 cells, also known as T-cells)
- Resistance of your HIV to HIV medications
- Lipid assessments (total cholesterol, LDL, HDL, ApoA1, and ApoB)
- Serum glucose and insulin
- Blood (serum) pregnancy test for all women.
- Hepatitis panel

You must notify the research staff if you are pregnant, think you may be pregnant, or if you are trying to become pregnant.

Baseline Visit (Day 1):

The research staff will review all the information from the previous visit to ensure you are still able to participate in the study. The research staff will ask you about all the medicines you are taking and whether you have been sick since your last visit. A brief physical exam will be completed including weight and vital signs (temperature, respirations, blood pressure, and pulse). For all female subjects, a urine pregnancy test will be completed. You must notify the research staff if you are pregnant, think you may be pregnant or if you are trying to become pregnant. You will also be asked to complete the Assessment of Body Change and Distress (ABCD) questionnaire. The questionnaire will ask you about any body changes, physical and emotional distress, social concerns and health behavior you have experienced since starting your HIV medications. A CT scan will be performed on your abdomen (stomach) and mid-thigh. Blood will be taken to send to the lab. The blood will be used to test for the following:

- Fasting Safety Labs (not having anything to eat or drink for 8 hours before the blood is drawn)
- HIV Viral Load (amount of virus in your blood)
- Immune function (CD4 cells, also known as T-cells)
- Lipid assessments (Total cholesterol, LDL, HDL, ApoA1 and ApoB)
- Serum glucose and insulin
- Inflammatory and bone markers assessments

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Once all of the study procedures are done and you qualify for enrollment into the study, you will receive a 30-day supply of PREZISTA/ritonavir or atazanavir/ritonavir in combination with a fixed background regimen consisting of Truvada®.

Treatment Period (Week 4, 8, 12, 24, 36 and 48):

During the treatment period, the research staff will see you regularly. You will be asked to report any illnesses, surgeries, or reactions to the medication you may have experienced since your last visit. The research staff will ask you about all the medicines you are taking. You will need to bring any pill bottles or pill organizers that you may use so the research staff can see how many pills were taken since the last visit.

During all of these visits, the research staff will be taking blood for lab tests. You will be asked to come in fasting (not having anything to eat or drink for 8 hours) for lab tests that are performed at Weeks 4, 8, 12, 24, 36 and 48. The blood taken at every visit will be used to perform lipid assessments, serum glucose and insulin assessments, HIV viral load, immune function tests, and safety labs. Some of the blood taken at weeks 4, 12, 24 and 48 will also be used to assess inflammatory markers. In addition, some of the blood taken at Week 48 will be used to assess bone markers. For women able to get pregnant, a urine sample will be checked for pregnancy at every visit.

Vital signs (temperature, respirations, blood pressure, and pulse) and weight will be measured at every visit. A brief physical examination will be performed at Weeks 12, 24 and 48. CT scans of the abdomen (stomach) and mid-thigh will performed at Week 48.

The ABCD questionnaire will be administered prior to any other procedures or assessments that are performed at weeks 12 and 48. The research staff will provide you with medication at Weeks 4, 8, 12, 24, and 36.

Follow up (Weeks 49 and 52): During these visits you will be asked to come in fasting (not having anything to eat or drink for 8 hours) for lab tests. The research staff will draw blood for safety labs, immune function tests and HIV viral load. You will be asked to report any illnesses, surgeries, or reactions to the medication you may have had since your last visit. The research staff will ask about any and all medications you have taken during your time on the study.

Withdrawal Visit

If you discontinue prior to Week 48 you will be asked to return for a final visit. At the visit, you will be asked about any medications that you have taken since your last visit. You will also be asked to report any illnesses, surgeries or reactions to the medication that you may have had since your last visit. You will also need to bring back any pill bottles and remaining pills that were given to you. A brief physical exam, vital signs (temperature, respirations, blood pressure and pulse) and weight will be collected. For all females who can get pregnant, a urine pregnancy test will be completed. You will be asked to come in for lab tests. Blood will be taken at this visit. The blood will be used to test for the following:

- Fasting Safety Labs (not having anything to eat or drink for 8 hours before the blood is

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- HIV Viral Load (amount of virus in your blood)
- Immune function (CD4 cells, also known as T-cells)
- Resistance of your HIV to HIV medications
- Lipid assessments (Total cholesterol, LDL, HDL, ApoA1 and ApoB)
- Serum glucose and insulin

POSSIBLE RISKS/SIDE EFFECTS:

Risks of PREZISTA™ (darunavir)

HIV therapy, however beneficial, may also cause side effects or adverse events. Tests with PREZISTA have been performed in laboratories, animals and healthy volunteers, as well as previous clinical studies in HIV-1 infected patients.

Any adverse events described here as occurring rare or rarely means that they have occurred in less than 2% of people who have taken PREZISTA.

The most frequent side effects of PREZISTA (seen in more than 10 percent of subjects) when taken in combination with ritonavir and other HIV medications were diarrhea, nausea, headache and skin rash, mostly mild or moderate in severity. These side effects of HIV therapy can often be easily managed by your study doctor.

Liver problems, which may be life-threatening, have been reported with the use of PREZISTA. It was not always clear if PREZISTA caused these liver problems. Patients with liver disease such as hepatitis B and hepatitis C may have worsening of their liver disease with PREZISTA. You will receive regular blood tests to look for liver problems during this study.

PREZISTA is a type of sulfa drug (sulfonamide). You should tell your study doctor if you have a sulfa allergy since it is recommended to use PREZISTA with caution in patients who have sulfa allergies. Your study doctor will talk to you about potential risks of taking this medication when you have a sulfa allergy.

Skin rash has also been reported with PREZISTA, and is also seen with other HIV drugs. It is usually mild or moderate in severity, and typically resolves within one week. It does not usually cause patients to stop the medication. However, certain cases of moderate and all cases of severe skin rashes will require you to stop your HIV drug regimen and might need additional study visits.

Stevens-Johnson Syndrome (a form of severe skin rash) has been reported in patients taking PREZISTA. Stevens-Johnson Syndrome is a rare but serious condition that may cause rash and painful blisters on your skin and mucous membranes (eyes, nose, mouth) and can result in death. If your skin should show any unusual qualities during the study (mainly skin rash, but including unusual boils or blisters) you should inform the study doctor immediately. You should go to the study site for a prompt medical evaluation. It is highly recommended that you see the study doctor as soon as any rash or skin condition appears.

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Chronic HIV therapy has been linked to changes in body shape and how patients feel about the way their bodies look. At present, no information on the potential effect of PREZISTA on these body changes is known. Please refer to the study doctor if you feel you are experiencing any changes.

Different HIV drugs may affect the way fat and sugar are processed in your body. The most frequently seen lab abnormalities with PREZISTA given with ritonavir are increases in blood fats (triglycerides and cholesterol) and sugars (glucose). If you should experience changes in blood fats and sugars, your study doctor will evaluate your condition. Your study doctor will tell you if you need to modify the foods you eat and level of exercise that you get. It is also possible that you may need a medical intervention, such as a medication.

Rare cases of pancreatitis (a condition causing severe abdominal pain and vomiting) have been reported in patients taking PREZISTA combined with ritonavir and other HIV medications. Therefore, pancreatic function will be monitored throughout the study. It is not recommended to use the combination of Tenofovir (TDF) and Didanosine (DDI) due to an increased risk of pancreatitis (inflammation of the pancreas). If abnormalities are detected, your study doctor will evaluate your condition and provide you with the necessary recommendations.

Rare cases of immune reconstitution syndrome (a condition in which improvement in the body's defense leads to an inflammatory reaction) have been reported with PREZISTA given with ritonavir and other HIV drugs. This treatable condition may occur during the early phase of treatment in patients with a favorable response to HIV therapy. If you notice any symptoms of inflammation, please inform your doctor immediately.

Please ask your study doctor for information on expected side effects associated with other prescribed HIV therapy. If you should get a rash or experience other side effects, please contact your study doctor.

Risks of NORVIR® (ritonavir)

NORVIR® is also known as ritonavir and is administered as a capsule, containing 100 mg ritonavir. In patients taking ritonavir, pancreatitis (a condition causing severe abdominal pain and vomiting) and increases in blood levels of fats (cholesterol and triglycerides), which may be associated with increased risk of heart disease and strokes, have been observed. The most common side effect associated with ritonavir therapy is diarrhea, generally mild to moderate. Other side effects of ritonavir are stomach pain, weakness, headache, abnormal stools, nausea (upset stomach), vomiting, loss of appetite, changes in taste, tingling feeling or numbness in hands or feet or around the lips, difficulty sleeping and rash.

Risks of REYATAZ® (atazanavir sulfate)

REYATAZ comes from a class of drugs known as Protease Inhibitors, commonly known as "PI s". The most common risks and side effects associated with REYATAZ are nausea (upset stomach), rash, headache, abdominal pain, vomiting, insomnia, peripheral neurologic symptoms, dizziness, myalgia (muscle aches), diarrhea, depression and fever. Other common side effects of REYATAZ are jaundice and scleral icteris. Jaundice is a yellowing of the skin caused by an increase in bilirubin levels. Scleral icteris is a yellowing of the eyes and is also caused by increased bilirubin. Both have been observed in clinical trials and is usually mild to moderate. It does not usually require patients to stop the

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medication. However you should inform the study doctor as soon as you notice any skin changes or rash.

Risks of TRUVADA® (emtricitabine and tenofovir DF)

TRUVADA is a combination of two drugs in one pill, containing 200 mg EMTRIVA® and 300 mg VIREAD®. Truvada comes from a class of drugs known as Nucleoside/Nucleotide Reverse Transcriptase Inhibitors, commonly known as "NRTIs" or "nukes". The most common risks and side effects from NRTIs include fatigue, headache, mild stomach discomfort, nausea (upset stomach), insomnia (difficulty sleeping), rash, vomiting and diarrhea.

More serious and potentially life-threatening risks and side effects include pancreatitis, severe liver problems, anemia (low red blood cells), lactic acidosis (a buildup of lactate in the body), peripheral neuropathy (pain, tingling and/or numbness typically in your hands and/or feet), lipodystrophy (changes in fat distribution in your body), decreased kidney function and metabolic disorders (changes to lipid and sugar levels in your blood).

Risks from the CT scans

This research study involves exposure to radiation from the CT scans and therefore you will receive a radiation dose. This radiation dose is not necessary for your medical care and will occur only as a result of your participation in the study. At doses much higher than you will receive, radiation is known to increase the risk of developing cancer after many years. At the doses you will receive, it is very likely that you will see no effects at all.

The CT that is being done for this protocol is not diagnostic and will not be reviewed by a radiologist at the Hospital of the University of Pennsylvania. Your scan will be sent to a central reading facility by code number where it will be read and reviewed. The data will only be used for the study. You will NOT receive a report of this test.

Blood Draw Risks

Blood drawing may cause some discomforts, bleeding or bruising where the needle enters the body (1%). A small blood clot may form where the needle enters the body or there may be swelling in the area. Rarely, fainting or local infection may occur. Care will be taken to prevent these complications.

Reproductive Risks

Since effects on contraception and fetal development are not fully known for PREZISTA (if applicable), REYATAZ (if applicable) and TRUVADA, you are advised to use an adequate birth control method when having heterosexual intercourse (see list below).

Women who can get pregnant or are breast-feeding

It is recommended that HIV infected women do not breastfeed their infants to avoid passing HIV infection from mother to child. You may not take part in this study if you are breast-feeding, are pregnant, think that you may be pregnant, or are trying to get pregnant. If you are pregnant or breast-feeding, there may be risks to you and the baby that are not known at this time. Women who are able to get pregnant will be tested for pregnancy during the study. You must avoid getting pregnant in order to take part in this research study.

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You should use a method of birth control that is acceptable to you, the study doctor, and the sponsor or practice heterosexual abstinence (no sexual intercourse). Women of childbearing potential must be willing to practice one of the following birth-control methods for the duration of the study and until at least 30 days after:

- (1) use a double barrier method to prevent pregnancy (i.e., use a condom without spermicide with either diaphragm or cervical cap), or,
- (2) use hormonal based contraceptives in combination with a barrier contraceptive (i.e., male condom without spermicide, diaphragm or cervical cap or female condom), or,
- (3) use an intra uterine device (IUD) in combination with a barrier contraceptive (i.e., male condom without spermicide, diaphragm or cervical cap or female condom), or,
- (4) be non-heterosexually active, practice sexual abstinence or have a vasectomized partner (confirmed sterile).

It is important for you to tell the study doctor at once if you get pregnant or think that you might be pregnant while you are in the research study. If this happens, the study doctor will discuss with you what you should do. Since there might be risks for unborn children that are currently unknown, you will be asked to stop taking part in the study if you get pregnant. You may also be asked questions about your pregnancy and the baby.

Male patients

It is advised that you use a condom to reduce the risk of transmission of HIV when having sexual intercourse. Since effects of the study drugs on conception and fetal development are not fully known, it is important that you follow adequate birth control methods from screening onwards until one month after the last study drug administration if you are having heterosexual intercourse and have not been surgically sterilized (at least one month before screening).

These methods include using a condom combined with hormonal contraceptives, intrauterine device, diaphragm, cervical cap or practicing heterosexual abstinence. When using a condom, the sponsor recommends using a condom without spermicide. These restrictions are not applicable if your female sexual partner has had a tubal ligation (had her "tubes tied"), a total hysterectomy (surgical removal of the womb) or if she is postmenopausal for at least two years. You must inform your study doctor if your partner becomes pregnant during the study or within one month after the last study drug administration.

OTHER POSSIBLE RISKS:

The study drug treatment and study procedures may involve risks that are currently unknown or unpredictable. Significant new findings developed during the course of this research, which may affect your willingness to continue participation, will be provided to you. Your study doctor and research staff will ask you about any side effects you have experienced at every visit. If you have any problems, you should let the doctor know immediately.

POSSIBLE BENEFITS OF THE STUDY:

There is no guarantee that you will receive personal benefit from participating in this study. During this study, your condition will be monitored. Information gained from your participation in this

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study may benefit the community and scientists and doctors who work with HIV-1 by providing increased knowledge and information about the treatment of your disease.

ALTERNATIVE PROCEDURES FOR TREATMENTS:

You do not have to participate in this study. PREZISTA, REYATAZ and TRUVADA are commercially available and prescriptions can be obtained from your doctor. If you do not wish to take any of the study drugs, other treatments for HIV are available. Risks of other treatments will be explained to you by your physician.

VOLUNTARY PARTICIPATION/WITHDRAWAL FROM THIS STUDY:

Your participation in this study is completely voluntary. You may decide not to participate or you may withdraw from the study at any time without penalty and without affecting your medical care or eligibility for future medical care at this site. No new data will be added to the database after you withdraw your consent.

If additional information becomes available during the trial that might change your decision to be in the trial, you or your legally authorized representative will be informed in a timely manner.

The study doctor or sponsor also has the right to withdraw you from the research at any time without regard to your consent if they feel that it is in your best interest. In this situation, you will be asked to complete any laboratory tests and examinations your doctor thinks necessary. You will also be asked questions about your experience with the drug.

With your permission, your study doctor, will inform your primary care doctor about your participation in this trial.

SAMPLE HANDLING AND RETENTION:

After the study tests are completed, any of your blood that is left over may be stored (with usual protection of identity) and may be used by the Sponsor for research in the future. Remaining blood samples may be used for additional exploratory studies on pharmacokinetics, metabolites, plasma protein binding, protein analysis, biochemistry and characterization of viral drug resistance. No genetic testing will be performed on your blood.

COST OF TREATMENT:

PREZISTA/ritonavir, REYATAZ/ritonavir and TRUVADA will be provided to you and all study patients free of charge while participating in this study.

COMPENSATION:

You will be compensated \$50 (CASH) for each clinic visit you attend to cover transportation costs, parking, child care, etc., and for your time and inconvenience. Thus, if you attend all study visits (9), the maximum compensation you will receive from the study is \$450. If you are requested to come into the clinic for additional visits or to have your blood re-checked, you will also be compensated (\$25) for that visit.

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Tibotec Therapeutics Clinical Affairs, a division of Centocor Ortho Biotech Services, LLC is paying your study doctor and/or your study doctor's institution, University of Pennsylvania to conduct this study. The amount of this payment is sufficient to cover the doctor's and/or institution's expenses to perform the study but provides minimal personal financial benefit to your study doctor and/or his/her institution.

COMPENSATION FOR INJURY:

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

In the event that you are hurt or injured as a direct result of taking the study drug or the study procedures in this research study, please contact the investigator listed on page one of this form.

In the event of any physical injury resulting from research procedures, medical treatment will be provided without cost to you, but financial compensation is not otherwise offered from the University of Pennsylvania or the sponsor, Tibotec Therapeutics Clinical Affairs, a division of Centocor Ortho Biotech Services, LLC. If you have an illness or injury during this research trial that is not directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

Tibotec Therapeutics Clinical Affairs, a division of Centocor Ortho Biotech Services, LLC will pay for any immediate care and/or treatment beyond what is covered by your health insurance. This agreement to provide free medical treatment does not include treatment for any injury/illness, which is not the result of the research.

STATEMENT OF PRIVACY:

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records. Please refer to the separate "HIPAA Privacy Authorization" document that explains more specifically how your personal information will be protected.

CONTACT INFORMATION :

For questions about this study or a research-related injury, contact:

- Pablo Tebas, MD (215-349-8092)
- Clinical Trials Unit (215-349-8092)

For questions about your rights as a research subject, contact:

- Director of Regulatory Affairs at the University of Pennsylvania by phoning (215) 898-2614

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When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this signed consent form will be given to you. You will also be given the University of Pennsylvania Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

Name of Subject (Please Print in BLOCK LETTERS)	Signature of Subject	Date
Name of Person Obtaining Consent (Please Print)	Signature	Date

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

Authorized subject representative [PRINT]	Authorized subject representative Signature	Date
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Provide a brief description of above person authority to serve as the subject's authorized representative.
