

Bristol-Myers Squibb Pharmaceutical Research Institute, AI443002

**PHARMACOGENETIC BLOOD DNA
CONSENT FORM TO PARTICIPATE IN A SUBSTUDY of
Placebo-Controlled, Single Ascending Dose Study to Evaluate the Safety, Tolerability,
Pharmacokinetics, and Antiviral Activity of BMS-791325 in Subjects Chronically Infected with
Hepatitis C Virus Genotype 1**

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24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call

This consent form may contain words that you do not understand. Please ask the study doctor or a member of the study staff to explain any words that you do not know or any information that is unclear or confusing.

The information below will help you decide whether you want to provide an additional blood sample and health information for pharmacogenetic and other related research. The Study Doctor will collect the sample and information and provide these to BMS. BMS (and not the Study Doctor) will conduct the pharmacogenetic research described in this form.

Your participation in this pharmacogenetic research is voluntary. If you decide that you do not want to participate in the pharmacogenetic research you may still participate in the main clinical trial AI443002. In connection with the pharmacogenetic research, you will also be asked to sign a separate form, known as a HIPAA form, authorizing the use and disclosure of your protected personal health information for this additional study. There is no set number of patients expected to participate in this research.

INTRODUCTION

Cells in the human body contain genes composed of deoxyribonucleic acid (DNA). The genes contain key instructions for cell function and help determine the characteristics of each individual. Pharmacogenetic research uses DNA samples from healthy and ill individuals to do the following:

- study the causes of human diseases
- help understand how different individuals respond to drugs
- obtain information to help develop new methods to diagnose and treat diseases

DESCRIPTION OF THE STUDY

The Study Doctor will replace your name with a code number and provide both the blood sample and your health information to BMS. BMS will place your coded information in a database and will store ("bank") your blood sample for up to 15 years, for use in pharmacogenetic research during this 15 year timeframe. When (or before) the 15 year period ends, your blood sample will be destroyed. Your

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health information collected from the main clinical trial will be kept on file in accordance with BMS retention policies.

BMS will use DNA information obtained from your blood sample, along with your health information collected from the main clinical trial, to study the causes and progression of Hepatitis C and drug related response. The health information will be limited to information collected by your study doctor and data generated from any blood samples collected in the main clinical trial. You will not be contacted in the future by BMS to provide any further information.

This research may help us understand how individuals with specific medical conditions respond to drug treatments. BMS researchers may also try to identify additional genes associated with these medical conditions, which may eventually lead to new treatments.

By signing this consent form, you give BMS permission to use your health information, your blood sample, and the DNA obtained from your sample for all the research described in this form.

STUDY PROCEDURES

If you agree to participate, one blood sample (approximately two teaspoons) will be drawn from your arm by study personnel. This sample is in addition to any blood samples that will be drawn for the purpose of your medical care or the main clinical trial.

The Study Doctor and/or staff personnel are the only ones who will know your specific personally identifiable information that would allow someone to identify you and contact you. The Study Doctor will replace your personal information with a coded identification number when your samples and health information are given to BMS. BMS does not intend to use any information to identify or contact you.

RISKS OF PARTICIPATION

Risks associated with drawing blood from your arm include pain, bruising, lightheadedness and, on rare occasion, infection or numbness. Precautions will be taken to avoid these difficulties. Whenever possible, blood for the pharmacogenetic research discussed above will be drawn at the same time as samples for other required laboratory tests. If not, an additional needle stick may be required.

There are also non-physical risks associated with taking part in this study, such as the risks associated with a loss of privacy or confidentiality. For example, if your identity as a participant in pharmacogenetic research or your identifiable genetic or health information were disclosed to unauthorized persons, there is the possible risk of discrimination by employers or insurance providers. Risks of such improper disclosure are very small because we have adopted strict privacy and confidentiality procedures for this research. (See the "Privacy and Confidentiality" section of this Informed Consent).

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BENEFITS OF PARTICIPATION

It is not anticipated that there will be any direct benefit to you as a result of your participation in the pharmacogenetic research. Your participation may contribute to an increase in the knowledge and understanding of medical conditions and how different individuals respond to drugs, or help in the development of new methods to diagnose and treat diseases. Neither you nor your doctors will be contacted by BMS in connection with the research or any information about the results of genetic tests performed on the sample that you donate for this research.

COMPENSATION

If you decide to participate in the substudy, you will be given \$10 as compensation for this extra sample.

ALTERNATIVES

The alternative to participating in this trial is to not participate. Your participation in the main clinical trial will not change should you decide not to participate in this study.

WITHDRAWAL OF CONSENT AND DESTRUCTION OF SAMPLES

You may withdraw this consent and discontinue your participation in the pharmacogenetic research described above at any time without affecting your participation in the main clinical trial.

To withdraw your consent, you must contact the Study Doctor (see page 1 of this document) because only he/she has access to all of your identifying information. The Study Doctor will retain records that link information that identifies you (for example, your name and contact information) with your coded blood sample and health information, for the period of time required by applicable law. If you withdraw your consent for the pharmacogenetic research during this time, you may request that your blood sample and DNA obtained from your blood sample be destroyed by BMS and no longer used in BMS research. However, after these records linking your identity to your sample are destroyed, it will no longer be possible for BMS to discard your sample if you withdraw your consent. BMS shall be entitled to retain and use any research results that we obtain prior to your withdrawal of consent.

PRIVACY AND CONFIDENTIALITY

BMS is sensitive to the privacy risks associated with genetic research, and we have adopted internal company procedures to further safeguard your privacy and confidentiality. For example, when we analyze your sample or send your blood sample to laboratories for DNA analysis, the sample is identified by a randomly-generated bar code number. The link between your coded identification number and the bar code number on your sample is kept in a secure BMS database and is not shared with the laboratories that analyze your sample.

BMS pharmacogenetic research is not intended to provide you with clinical information. Although you have the right, subject to policies of the University of Pennsylvania to access information in your

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medical records, including information related to the main clinical trial (once that study is complete), the information that BMS will maintain in its databases and create during future pharmacogenetic studies is for research purposes only. BMS will not initiate the return of any genetic information to you or your health care provider. At some point in the future information about the results of the studies may be published; however, you will not be identified in any such publication.

It is possible, however, that members of regulatory authorities, such as the United States Food and Drug Administration, or the European Medicines Agency (EMA) and other persons required by law may have access to the research results.

BMS may use other laboratories, investigators, commercial or academic third parties as our "agents" to assist in this research. If BMS does so, your sample and some of your health information will be shared with these agents. BMS will require any agent that we use in the research to protect your privacy.

DEVELOPMENT FOR COMMERCIAL GAIN

BMS will pay the Study Doctor to obtain your blood sample for pharmacogenetic research and to transfer your health and medical information to BMS. The DNA obtained from your blood sample may be used for the development of new therapies, diagnostic methods, medicines, treatments for disease, information, materials and other developments which may be patented or otherwise have commercial value to BMS, the Study Doctor, or other third parties. By consenting to participate in this research, you authorize the use of your sample for the research described above, and you acknowledge that there are no plans to provide financial benefits or compensation to you should this occur.

QUESTIONS

You are encouraged to ask any questions related to this research. If you wish further information regarding your rights as a research subject, you may contact the Director of Regulatory Affairs at the University of Pennsylvania by telephoning (215) 898-2614. If you ever have questions pertaining to your participation in this research study or about research-related injuries, you may contact the investigators or study nurse listed on the first page of this form. All of your questions should be answered to your satisfaction before you consent to participate in this study.

CONSENT

I have read the preceding information describing this sample collection and all my questions regarding collection of my blood sample and medical/health information for pharmacogenetic and related research have been answered to my satisfaction. I understand that after agreeing to participate in this research, I may later decide to revoke this consent at any time.

I agree to provide a blood sample and to permit my medical and health information to be used and disclosed for pharmacogenetic and related research as described above. I understand that I will receive a signed copy of this consent form.

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Subject Signature

Printed Name

Date

Witness Signature

Printed Name

Date

Physician/Designee's Signature

Printed Name

Date