

MARQUETTE GENERAL HEALTH SYSTEM
Regional Medical Center
CONSENT TO PARTICIPATE IN AN INVESTIGATIONAL STUDY

TITLE: ARIES (AVF3991n) - An observational study of AVASTIN (Bevacizumab) in combination with chemotherapy for treatment of metastatic or locally advanced and unresectable colorectal cancer and locally advanced or metastatic non-small cell lung cancer (Excluding Predominant Squamous Cell Histology).

INVESTIGATORS: **Sheetal Acharya,MD**
 Mohammed Al-Nsour,MD
 Daniel Arnold,MD
 Jorge Frank, MD
 Gustavo Morel,MD
 Suresh Nukala,MD
 Irina Sachelarie,MD
 Aaron Scholnik, MD

This consent form may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not understand.

PURPOSE AND BACKGROUND

You are being asked to participate in this study because you have cancer that has not yet been treated or has been treated for less than 3 months before enrolling in this study and because you and your physician have determined that you are or will be treated with AVASTIN® (bevacizumab) in combination with chemotherapy. Participation in this study will in no way change the care you will receive from your physician.

The goal of this study is to collect information on how patients who have colorectal cancer or non–small cell lung cancer do while receiving Avastin in combination with other chemotherapy drugs. This study will also evaluate the frequency of complications associated with Avastin and chemotherapy.

Avastin is a drug that has been approved by the Food and Drug Administration (FDA) for first- and second-line treatment of patients with metastatic colorectal cancer and for first-line treatment of non–small cell lung cancer in combination with certain kinds of chemotherapy. It is not a chemotherapy drug. Instead, it is a drug that interferes with the development of new blood vessels in a growing tumor and has helped some patients with metastatic colorectal cancer and metastatic non–small cell lung cancer live longer. Your doctor will talk with you about receiving this drug as part of your cancer treatment.

Participation in this study is entirely voluntary. Approximately 250 study centers in the United States will enroll a total of approximately 4000 patients into the study.

The purpose of this Informed Consent Form is to inform you about this research study so that you may make an informed decision whether you would like to participate, and to inform you of how your personal health information may be used or given to others during the study and after the study is finished.

PROCEDURES

If you choose to participate in this study, there will be no changes to the treatment you will receive from your doctor. This study does not require you to undergo any specific treatment or evaluations. This study will require your doctor to provide information to Genentech, the Sponsor of the study. Your doctor will provide information about the history of your cancer and the past treatments you have received for it. Your doctor will provide to Genentech information about your ongoing cancer treatment, your response(s) to treatment, and any complications you may experience. Your doctor will continue to provide this information four times per year throughout your participation in this study.

POSSIBLE RISKS AND DISCOMFORT

Because this study involves no procedures or treatments other than those prescribed by your doctor and no changes to your doctor's normal medical practice, there are no risks specifically related to your study participation.

POTENTIAL BENEFITS

You may not receive any direct health benefit from participating in this study. However, the knowledge gained from this study may aid in the advancement and understanding of metastatic colorectal cancer or non-small cell lung cancer and their treatments, and, consequently, may help other people with these cancers in the future.

ALTERNATIVE TREATMENTS AND PROCEDURES

This study will not change your normal medical treatment as prescribed by your physician.

TERMINATION OF PATIENT PARTICIPATION

Your participation in this study may be ended at any time by your doctor or because Genentech finds it necessary to limit or terminate this study. Termination of the study will in no way change the care you will receive from your physician.

PATIENT WITHDRAWAL PROCEDURES

You may withdraw from this study at any time. Withdrawal from participation in this study will not in any way compromise your medical care. You will continue to receive the medical care to which you were previously entitled prior to your participation in the study.

ADDITIONAL COSTS

There will be no additional costs to you during the course of study.

RESEARCH-RELATED INJURIES

Because this study involves only the sharing of medical information and requires no specific procedures, tests, or treatments, no research-related injuries are expected.

CONFIDENTIALITY

To the extent permitted by law and by signing the consent form, you allow access for representatives of the FDA, other national regulatory authorities, Institutional Review Boards, and Genentech monitors/representatives and collaborators to inspect your research and clinical records without removal of identifying information, such as your name, initials, date of birth, sex, race, and location of the research study. If information from this study is presented publicly or published in a medical journal, you will not be identified by name, picture, or any other personally identifying information.

AUTHORIZATION TO USE AND DISCLOSE MY HEALTH INFORMATION

I authorize (give permission to) Marquette General Health System to use and disclose (share) my health information solely for the purposes of this research study and research directly related to the use of Avastin in disease therapy and diagnosis. I understand that my health information that I am authorizing to be used and disclosed (“Authorized Health Information”) includes all health information about me that has been and will be created or received by Marquette General Health System and that is in my medical records maintained by Marquette General Health System.

I understand that I am free at any time to restrict Marquette General Health System use and disclosure of my Authorized Health Information, without penalty or other consequence. However, I also understand that I may be denied participation in, or continued participation in, this research study if at any time I choose to restrict Marquette General Health System use and disclosure of Authorized Health Information that is necessary for the completion of this research study.

AUTHORIZED PERSONS AND RECIPIENTS

I authorize the following person(s) and groups of persons to request, receive, and use my Authorized Health Information: representatives of the FDA, other regulatory authorities, the Institutional Review Board, and Genentech representatives and Genentech Avastin collaborators and licensees. I authorize Marquette General Health System to disclose my Authorized Health Information to these persons and groups of persons.

RE-DISCLOSURES TO THIRD PARTIES

I understand that once Marquette General Health System discloses my Authorized Health Information to the recipient(s) identified in the previous section Authorized Persons and Recipients, Marquette General Health System cannot guarantee that those recipient(s) will not re-disclose my Authorized Health Information to other persons who may not be bound by this Informed Consent Form.

EXPIRATION DATE

My authorization (permission) to use and disclose (share) my Authorized Health Information will continue indefinitely, but that use and sharing will only be for the purposes described in this Informed Consent Form.

EFFECT OF MY REVOCATION OF AUTHORIZATION TO USE AND DISCLOSE AUTHORIZED HEALTH INFORMATION

I understand that my authorization for Marquette General Health System to use and disclose my Authorized Health Information will remain in effect until I withdraw my permission by sending my written notice of revocation (withdrawal of permission) to the Privacy Office listed in the Questions section below. My written revocation (withdrawal of permission) will be effective immediately upon Marquette General Health System receipt of my written notice, except that the revocation will not have any effect on any actions taken by Marquette General Health System in relying on this authorization before it receives my written notice of withdrawal of permission.

QUESTIONS

If you have any questions about the study and/or its procedures, you may contact your physician at 906-225-3922. During the evenings, weekends, or holidays you may phone Marquette General Hospital at (906) 228-9440, and request to speak with the oncology physician on call. You may call the Patient Advocate at 906-225-3433 for information on experimental patients' rights. If at any time during this research study, you feel that you have not been adequately informed of your rights with respect to the privacy of your health information, or you feel that the privacy of your health information has not been

adequately protected, you may contact or visit Marquette General Health Systems Patient Advocate during normal working hours at 906-225-3433. The privacy office is located at Marquette General Hospital, 580 W. College Avenue, Marquette, MI 49855.

VOLUNTARY PARTICIPATION AND DOCUMENTATION OF CONSENT

My participation in this study is voluntary and I may refuse to participate or withdraw from the study at any time without prejudice or loss of benefits to which I am otherwise entitled. I have received a copy of this consent form and I am aware that the investigator at my hospital will also retain a copy in his or her files. I hereby give my consent to participate in this clinical trial. I also hereby authorize Marquette General Health System to use and disclose my Authorized Health Information in the manner described in this Informed Consent Form.

Institutional Funding:

Funds are provided from the study sponsor to Marquette General Hospital on a per patient basis to help with the institution's costs of participating in this study.

Your signature below means that you have freely agreed to participate in this observational study.

Patient Name (PRINTED)

Patient's Signature

Date

PRINTED Name of person conducting
the informed consent discussion

Signature of person conducting
Informed consent discussion

Date

I certify that the nature and purpose, the potential benefits, and possible risks associated with participation in this research study have been explained to the patient indicated, and that any questions about this information have been answered.

Investigator's Signature

Date

Your signature below means that you do not wish to participate in this observational study.

Patient Name (PRINTED)

Patient's Signature

Date

PRINTED Name of person conducting
the informed consent discussion

Signature of person conducting
Informed consent discussion

Date

Investigator's Signature

Date

IRB approved consent form 03/14/2007

IRB approved Amend. #1 – 10/10/07