INSTITUTE: National Cancer Institute

STUDY NUMBER: 13-C-0208 PRINCIPAL INVESTIGATOR: Brigitte Widemann, M.D.

STUDY TITLE: Phase II Trial of Vandetanib (ZD6474, Caprelsa®) in Children and Adults with Wild-Type Succinate Dehydrogenase-Deficient Gastrointestinal Stromal Tumors

Continuing Review Approved by the IRB on 12/03/18

Amendment Approved by the IRB on 12/06/17 (F) Date posted to web: 12/13/18

Parent QoL

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary**.**

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

Why is this study being done?

You have a have a son or daughter who is 8 years of age or older who has Gastrointestinal stromal tumors (GIST), one of the most common forms of tumors in the mesenchymal tissue (loose connective tissue) in the GI system (mouth, esophagus, stomach and intestines). He/She is taking part in a research study with a new cancer drug called vandetanib. The overall purpose of this study is to see if vandetanib can shrink tumors in people with GIST. In addition to

studying the physical effects of vandetanib, we are also trying to understand the effects of GIST and vandetanib on your child's symptoms. We are giving a number of questionnaires to your son or daughter to assess some known symptoms of GIST and some of the known side effects of vandetanib. The information obtained from parent questionnaires is an important and standard part of a comprehensive neuropsychological assessment of a child.

Therefore we ask for your participation in the study to complete 7 questionnaires assessing your child's everyday social-emotional functioning and symptoms. It will take about 10 minutes to complete these questionnaires. We will ask you to fill out these questionnaires once before your child starts vandetanib, once at the first restaging visit (about month 3) and then again after stopping vandetanib.

Your participation is voluntary, and you can decide to participate now, but withdraw your consent at any time.

The information obtained from these questionnaires will be put into a secure computer database and used to answer questions being asked in this study. We also would like to ask for your additional permission to possibly use this information that we already are collecting and storing for this study to answer other questions that may arise in the future or after the current study ends. Anything we learn and share with others will not include any names or other information that could identify you.

If you decide not to have this information stored for possible future GIST research you can still participate in the current study.

Please indicate below if you agree or disagree to storage and possible use of information obtained from the parent questionnaires on this study for future GIST research:

Agree: ☐ Disagree: ☐ Initials:____

Risks or Discomforts of Participation

There are no risks to completing the questionnaires other than the time it will take to do so. The questionnaires are saved in a locked file, and your results are saved in a secure, password-protected database to which only investigators on this study have access.

Potential Benefits of Participation

Are there benefits to taking part in this study?

These questionnaires are for research purposes and there is no direct benefit to you. However, your participation in this study and the knowledge gained from these questionnaires may benefit those who are diagnosed with GIST taking vandetanib in the future. In addition, these results can be used to better understand side effects your child may be having because of the vandetanib and to develop recommendations to help your child with any problems in these areas.

Alternative Approaches or Treatments

What other choices do I have if I do not take part in this study?

You may choose not to complete the questionnaires described above. If you decide not to participate in this part of the study, your son or daughter will still be able to participate in the vandetanib protocol.

Research Subject's Rights

Joining this research study is voluntary. You may ask the study doctor, psychologist, or other members of the GIST research team any questions about the questionnaires involved in this study. If you decide at any time that you do not want to participate in this portion of the study any more, then tell us and we will stop it.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people including representatives of the NCI or AstraZeneca, the pharmaceutical company that makes vandetanib.

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Brigitte Widemann, M.D., Building 10, Room 1-5750, Telephone: 240-760-6203. You may also call the Clinical Center Patient Representative at 301-496-2626. If you have any questions about the use of your data for future research studies, you may also contact the Office of the Clinical Director, Telephone: 240-760-6070.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Signature of Adult Patient/ Legal Representative _____ Date _____

Print Name _____

B. Parent's Permission for Minor Patient.

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.
(Attach NIH 2514-2, Minor's Assent, if applicable.)

Signature of Parent(s)/Guardian _____ Date _____

Print Name _____

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian _____ Date _____ Print Name _____

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM DECEMBER 03, 2018 THROUGH DECEMBER 17, 2019.

Signature of Investigator _____ Date _____

Print Name _____

Signature of Witness _____ Date _____

Print Name _____