May 29, 2014

RE: RTOG 0848: A Phase II-R and A Phase III Trial Evaluating Both * Erlotinib (Ph II-R) and Chemoradiation (PhIII) as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma

Dear Study Participant,

The purpose of this letter is to share important information regarding the above mentioned study, as you are a participant in this study who is currently receiving the study drug, erlotinib.

In 2013, new information became available related to the study drug, erlotinib. A study performed in Europe showed that the addition of erlotinib to gemcitabine was not helpful for patients with locally advanced pancreatic cancer. Given this new information, new patients entering this study will not be given erlotinib. Also, the study showed an increased rate of severe diarrhea in patients receiving both erlotinib and gemcitabine. An increased rate of severe diarrhea is expected for erlotinib when given in combination with gemcitabine which also causes diarrhea, and this result is similar to prior experience with the drug. As a participant in this study you should discuss with your study doctor if you would like to continue receiving erlotinib, stop taking erlotinib, or stop participating in this study.

If you choose to continue taking erlotinib, you will take erlotinib and gemcitabine and continue with study procedures outlined in the informed consent form.

If you choose to stop taking erlotinib you may also choose to stay on the study. If you would like to stay on the study you will receive gemcitabine only and continue with study procedures outlined in the informed consent form.

Another option is to choose to stop participating in the study. If you stop participating in the study you will receive your usual care from your doctor.

Please take your time to make a decision and discuss these options with your family, friends, and study doctor.

It is important that you are aware of this new information and that you tell your healthcare professionals if you have an adverse reaction while taking part in this study. If you have questions about this information, please contact your study doctor. If you have questions about your rights as a research participant you should contact the research review board person listed on your consent form.

Thank you for your participation.
Sincerely,

Ross A. Abrams, MD

I have been given a copy this letter. I have read it or it has been read to me. I understand the information and my questions have been answered.

Participant _______________________________ Date _______________