

## AMERICAN COLLEGE OF SURGEONS ONCOLOGY GROUP

April 12, 2007

Dear Research Participant (or name),

You are currently participating in the research study called: ACOSOG Z9001: A Phase III Randomized Double-blind Study of Adjuvant STI571 (also known as imatinib or Gleevec<sup>TM</sup>) Versus Placebo in Patients Following the Resection of Primary Gastrointestinal Stromal Tumor (GIST). We recently performed an early analysis of the experiences of the patients who are being treated as a part of the study and want to tell you these results. Because you are a participant in this research study, it is very important that you read this letter. This information is provided to help you understand what the results mean for you.

## Why is this Research Study Being Done?

The standard treatment for primary GIST is complete removal of the tumor by surgery without any additional therapy. This research study is designed to see if giving you a drug called imatinib (also known as Gleevec) for 1 year after surgery significantly reduces the risk that your cancer will return.

## What Has Happened?

A group of cancer research specialists not directly involved in the study regularly look at the results from all patients who joined this research trial. They look to see how effective the treatment is and check to make sure side effects that patients are having are not too severe.

These experts have just informed us of a finding that is important to the patients being treated on this study. When the experts looked at how patients on the study were doing, they found that the patients being treated with imatinib were doing better -- that is to say, they were significantly less likely to have a recurrence of their cancer than the patients who received placebo. Because of this finding, it is recommended that study participants who are being treated with placebo stop the placebo therapy as soon as they are notified by their doctor that they are on placebo and be offered the opportunity to switch to imatinib therapy.

## Ask Your Doctor.

Your doctor will tell you which treatment you received.

If you are one of the patients currently taking imatinib, you should continue taking your assigned treatment for one full-year.

If you are one of the patients currently taking placebo (as of April 1, 2007), we will no longer administer the placebo drug that you were getting. Instead, you will be offered the option of taking a full year of imatinib therapy. You should discuss this option with your doctor to see if it is the best one for you. If you decide to take imatinib, the National Cancer Institute will continue to provide the drug for you for a period of one year.

If you completed your assigned treatment prior to April 1, 2007, it is important to ask your doctor what these findings mean for you and you should discuss any potential changes in your care with your doctor.

As in any clinical trial, you may always decide to stop participating at any time just by informing your doctor of your wishes.

What we have learned from this study is very important. The results from this study are going to help many people with GIST. Thank you for participating in the ACOSOG Z9001 study. By doing so, you have directly helped improve the lives of people who have GIST.