[Month] [Day], [Year]

Dear Research Participant (or Name):

You are receiving this letter because you are currently participating in a research study titled Alliance A221701, “**Phase III placebo-controlled trial to evaluate dexamethasone use for everolimus-induced oral stomatitis: prevention versus early treatment approaches: MIST (My Individualized Stomatitis Treatment)**”. We have information about the study that we would like to share with you.

**WHY WAS THIS RESEARCH STUDY BEING DONE?**

The purpose of this study was to test whether a mouthwash made with a drug called dexamethasone can prevent or reduce the pain caused by mouth sores resulting from everolimus treatment. In this study, you were randomly assigned to receive either dexamethasone mouthwash or placebo.

**WHAT HAS HAPPENED?**

The trial was opened to patient enrollment in February 2019. Unfortunately since that time only 38 patients have participated in this trial. Therefore, it has been determined that it is unlikely that the trial will reach its planned goal of 279 patients. As a result, this study will stop enrolling new patients on November 1, 2020. This decision was not based on any new information from Alliance A221701 about the effect (good or bad) of the dexamethasone treatment.

**ASK YOUR DOCTOR.**

It is important for you to talk about this with your doctor.

After discussion of options with your study doctor, if you wish to continue to receive study drug as a medical/clinical intervention on this study, the study drug will continue to be supplied free-of-charge until 8 weeks after you started treatment. You would also continue the study-specified schedule for visits and monitoring.

Any further treatment will be a decision made between you and your doctor. Regardless of the treatment option that you choose, we would like to continue to collect information about your progress so that we may gather as much valuable information as possible from this study including the impact on health-related quality of life. This information will continue to help us understand and treat this condition. As with any research study, you may always decide to stop participating at any time by informing your study doctor of your choice.

Once you complete 8 weeks of treatment on the study, you will have the option of finding out whether you received dexamethasone or placebo. If you choose to find out what you were receiving before you have completed 8 weeks of treatment, no additional study drug will be provided after this time point. However, if you were receiving the dexamethasone product (as opposed to a placebo) and you and your physician thinks it is best for you to continue such, then it is clinically available by a prescription.

You have been a very important part of this study, and we wish to thank you for participating. We will use information learned from this trial to develop other studies and approaches to improve the lives of individuals living with cancer. We greatly appreciate your participation in A221701. Only through volunteers like yourself can we continue to improve cancer treatment.