

Date, 2019

Dear Research Participant (or name):

You are receiving this letter because you are currently participating or recently participated in the research study called Alliance A091401, “Randomized phase II study of nivolumab with or without ipilimumab in patients with metastatic or unresectable sarcoma.” We are writing to notify of the study progress.

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

This research study was being done to test any good effects of the treatment on the tumor and possible side effects of the study drugs called nivolumab and ipilimumab.

### **WHAT HAS HAPPENED?**

A group of cancer research specialists including patient advocates, not directly involved in the study, regularly look at the results from all participants who joined this research study. They look to see if information is available to answer the study question for participants in your situation. They found that the study had enough information to answer the study question and no new patients should be enrolled. Your doctor will talk to you about the responses that were seen in some types of cancer that were treated on the trial. After discussing this with your doctor, if you and your doctor believe that the treatment is benefiting you, then you can continue on with the treatment as outlined in the protocol. The experts did not see increased side effects that would lead to stopping treatment in any arms of the study.

### **TALK TO YOUR DOCTOR**

You can continue participation in the research study and continue on therapy as long as your cancer is not getting worse and your doctor feels it is safe for you to do so:

1. If you are taking nivolumab alone you may continue nivolumab. Nivolumab will continue to be provided free-of-charge by the National Cancer Institute.
2. If you are taking nivolumab plus ipilimumab followed by nivolumab alone you may continue on this therapy. Nivolumab and ipilimumab will continue to be provided free-of-charge by the National Cancer Institute.
3. If you were receiving nivolumab alone and your disease worsens, your doctor can discuss the option of either receiving therapy with nivolumab plus ipilimumab or discontinuing treatment on this study.

If you want to stop the research study, you and your doctor together will decide which further treatment you will receive going forward. Choices regarding further treatment will be an individual medical decision between you and your doctor.

As in any research study, you may always decide to stop participating at any time by informing your study doctor of your wishes. Regardless of the treatment option that you choose, we will continue to collect information about your progress so that we can get as

much valuable information as possible from this research study. This information will help us to continue to understand and treat this disease.

You have been a very important part of this research study, and we thank you for participating. We will use lessons learned from this trial to develop other research studies and approaches to improve the lives of patients living with sarcoma. We greatly appreciate your participation in Alliance A091401.