



*Advancing Research. Improving Lives.™*

August 9, 2021

Dear Study Participant:

You are participating in the research study conducted by NRG Oncology called NRG-HN004, “Randomized Phase II/III Trial of Radiotherapy with Concurrent MEDI4736 (Durvalumab) vs. Radiotherapy with Concurrent Cetuximab in Patients with Locoregionally Advanced Head and Neck Cancer with a Contraindication to Cisplatin.” The purpose of this letter is to inform you of the decision by NRG Oncology to temporarily stop adding new patients to the study on July 30, 2021.

An early analysis of the study’s current data showed that patients receiving durvalumab on the study (Group 2; “study group”) did not live longer without cancer progression compared with patients receiving cetuximab on the study (Group 1; “usual approach group”). However, there is still a chance that with longer follow-up, the results may show that patients receiving durvalumab do live longer without cancer progression. In order to determine if that is the case, all study procedures and data collection will continue for patients already enrolled and another analysis will occur in approximately one year.

The study team has been closely monitoring the adverse events due to a higher early death rate on the durvalumab arm compared to the cetuximab arm. The difference may be real or it may be due to chance. The adverse events will continue to be monitored carefully. No other unexpected side effects have been seen.

#### Patients receiving durvalumab on NRG-HN004

You and your study doctor will discuss your choices. If you are tolerating durvalumab and you and your doctor, think you are benefiting from it and believe it is an appropriate medical intervention for you, you may continue to receive it on NRG-HN004. If you and your study doctor decide that another treatment option is appropriate, then you could go off study treatment and receive the most appropriate care decided between you and your doctor. All study procedures and data collection will continue. Your study doctor will continue to follow your progress and manage your care.

#### Patients receiving the usual treatment on NRG-HN004

If you are currently receiving the usual care consisting of cetuximab, your treatment will continue uninterrupted. All study procedures and data collection will continue. Your study doctor will continue to follow your progress and manage your care.

NRG Oncology recognizes the value of and thanks you for your participation in NRG-HN004. Your participation in an NCI-sponsored clinical trial has a valuable impact on the current and future treatment and care in head and neck cancer.

If you have any questions or concerns, please contact your study doctor.