



**Do you have squamous cell carcinoma of the head and neck that has spread to a limited number of places?**

**If so, you may be eligible to participate in this study of a potential new treatment.**

## **Combining Radiation Therapy with Immunotherapy for the Treatment of Metastatic Squamous Cell Carcinoma of the Head and Neck (HNSCC)**

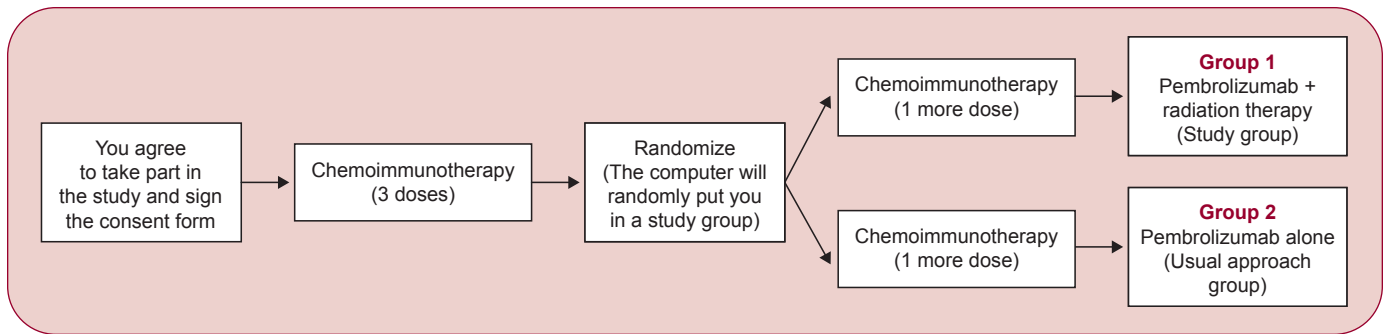
### **WHY consider participating in this study?**

- Research studies are an important way to test the effectiveness of new therapies and approaches to treating cancer.
- The usual approach (i.e., the standard treatment most patients receive) for head and neck cancer is treatment with Food and Drug Administration (FDA)-approved drugs, typically including immunotherapy drugs like pembrolizumab. Sometimes, combinations of these drugs and radiation therapy or surgery are used.
- The purpose of this study is to see if adding radiation therapy after the standard treatment of chemotherapy with pembrolizumab leads to better outcomes than treatment of chemotherapy and pembrolizumab alone for patients who have a diagnosis of squamous cell carcinoma of the head and neck that has spread to a limited number of places outside of the head and neck region.

### **WHAT does this study involve?**

If you are eligible for this study and choose to participate:

- You have already received or will receive 3 cycles of chemotherapy (given every 3 weeks) with pembrolizumab (given either once every 3 weeks [200 mg] or once every 6 weeks [400 mg]).
- After the initial 3 cycles are completed, you will be randomized (randomly assigned by a computer) to one of two treatment groups. After randomization, both groups will receive one more dose of chemotherapy and pembrolizumab.
  - **Group 1:** If your cancer is present in the head and neck, you will get 6 weeks of radiation therapy to the head and neck and metastatic sites. If your cancer is not present in the head and neck, you will get radiation over several doses to the metastatic sites only. You will continue to receive pembrolizumab (through a vein [intravenously] or through a port) on the first day of each cycle. Once radiation therapy is complete, you may receive pembrolizumab every 3–6 weeks (your schedule will be determined by your doctor) for a total of 24 months or until your disease progresses.
  - **Group 2:** You will continue to receive pembrolizumab (through a vein or port) on the first day of each cycle for 6 cycles. Once those 6 cycles are completed, you will then receive pembrolizumab every 3–6 weeks (your schedule will be determined by your doctor) for 24 months or until your disease progresses. If your disease progresses, you can also receive radiation, as needed, which will be determined by your doctor.
- There will be about 130 people in each group. You will have an equal chance of being assigned to either group.
- After you finish your study treatment, your doctor will continue to monitor your condition until 3 years after you started the study.



## WHO will take part in this study?

- Approximately 260 people diagnosed with metastatic head and neck squamous cell carcinoma will take part in EA3211.
  - The cancer must have originated in the oral cavity, larynx, oropharynx, or hypopharynx.
  - **If you have active cancer in the head and neck**, you must not have had prior head and neck radiation therapy. **If you do not have active cancer in the head and neck** (i.e., your cancer is only in the metastatic sites), previous head and neck radiation therapy must have been completed at least 6 months ago.
- You can decide to stop taking part in this study at any time, for any reason, even after you have enrolled.

## WHAT are the costs of taking part in this study?

- Just as if you were receiving the usual care for your cancer, you and/or your insurance plan will need to pay for some or all of the costs of medical care you will receive as part of this study. This includes the costs of getting the pembrolizumab and standard chemotherapy drugs ready and giving them to you.
  - Check with your insurance provider to find out what they will pay for.
- Taking part in EA3211 may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer.
- You will not be paid for taking part in this study.

## IF you would like more information:

- About the EA3211 study, talk with your doctor, or:
  - Visit [www.ecog-acrin.org](http://www.ecog-acrin.org) and search EA3211 then select the link to the EA3211 page.
    - » If you are seeking information about the locations where this study is available, scroll down the page to Locations and Contacts and click the + sign.
  - Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237).
- About clinical trials:
  - General cancer information: visit the NCI website at [www.cancer.gov](http://www.cancer.gov)
  - Insurance coverage/paying for cancer treatment: [www.cancer.gov/clinicaltrials/learningabout/payingfor](http://www.cancer.gov/clinicaltrials/learningabout/payingfor)
- About ECOG-ACRIN:
  - Visit [www.ecog-acrin.org](http://www.ecog-acrin.org)
  - For a list of patient resources and links to patient advocacy groups, visit <https://ecog-acrin.org/patients/resources>

