

# Clinical trial summary (S2101)

## Testing Biomarkers and Immunotherapy Drugs for People with Advanced Melanoma or Squamous-Cell Head and Neck Cancer



### What is the purpose of this clinical trial?

The purpose of this study is to find out if specific biomarkers can reveal how cancer responds to a combination of 2 immunotherapy drugs.

- A *biomarker* is any molecule in your body that can be measured. Doctors look at biomarkers to learn what is happening in your body. Knowing about certain biomarkers of your tumor can give your doctor more information about what is causing the cancer to grow and how to treat it.
- *Immunotherapy* is a type of treatment that helps the immune system fight cancer.

In this trial, researchers will test immunotherapy treatment and measure biomarkers in people who have advanced melanoma or squamous-cell head and neck cancer.

#### This trial is set up to find out:

- If treatment with 2 immunotherapy drugs can help shrink or control advanced melanoma and squamous-cell head and neck cancer
- How people with different biomarkers respond to treatment with the study drugs



### Why is this trial important?

The Food and Drug Administration (FDA) has approved the study drugs, cabozantinib and nivolumab, to treat other cancers. This study will help find out if combining the drugs can benefit people with advanced melanoma or head and neck cancer. Using the drugs together for these cancers has not yet been approved by the FDA.

The study will also help researchers learn if this combination of drugs is more likely to work for people with certain biomarkers. This could help doctors choose the best treatments for their patients and help more patients benefit from immunotherapy.



### Who can be in this trial?

This trial is for adults, age 18 or older, with advanced melanoma or squamous-cell head and neck cancer.

#### This trial is for people who:

- Have cancer that has gotten worse or spread to other parts of the body after immune checkpoint inhibitor therapy

#### This trial is not for people who:

- Have a primary tumor of the nasopharynx (the top part of the throat, behind the nose)
- Have an active infection of HIV, hepatitis B, or hepatitis C
- Have heart problems or poor organ function that may make it unsafe to get treatment in this study
- Are pregnant

Talk with your doctor to learn more about who can join this study.



## What can I expect during the trial?

This trial has 2 parts. If you join the trial, you will be in either Part 1 or Part 2, but not both.

### Part 1

#### **Biomarker Testing**

Researchers will test your tumor for 2 specific biomarkers. If your clinic does not already have a sample of your tumor, you will need to have a biopsy to remove a small sample of your tumor for testing.



#### **Treatment**

You will start treatment right away with a combination of 2 immunotherapy drugs, cabozantinib and nivolumab.

### Part 2

#### **Biomarker Testing**

Researchers will test your tumor for 2 specific biomarkers. If your clinic does not already have a sample of your tumor, you will need to have a biopsy to remove a small sample of your tumor for testing.



#### **Wait For Test Results**

Part 2 is set up to include only 30 people with each type of result from biomarker testing. Your test results determine whether you receive treatment in this study.



#### **Treatment**

If space is still available for people with your type of result from biomarker testing, you will get a combination of 2 immunotherapy drugs, cabozantinib and nivolumab.

If space is not available for people with your type of result, your part in the study ends after biomarker testing. Your study doctor will discuss other treatment options with you.



## How long will I be in the trial?

If you get the study treatment, you will be in the study for 3 years. Your study doctor will closely watch you for side effects and watch how your cancer responds to the treatment.

If the treatment keeps helping you, you may continue it for up to 2 years. You may choose to stop treatment at any time for any reason.

After treatment, you will have follow-up visits with the study team until you have been in the study for 3 years total.



## Are there costs? Will I get paid?

The study drugs, cabozantinib and nivolumab, are provided free to you. The study also covers the costs of the biopsy for biomarker testing.

You will not be paid for joining the study. Check with your health care provider and insurance provider to find out what costs will and won't be covered in this study.



## Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and search using the national clinical trial number: **05136196**



## Key information *This trial is for adults 18 years or older being*

**Full trial title:** Biomarker Stratified Cabozantinib (NSC#761968) and Nivolumab (NSC#748726) (BiCaZO) - A Phase II Study of Combining Cabozantinib and Nivolumab in Participants with Advanced Solid Tumors (IO refractory Melanoma or HNSCC) Stratified by Tumor Biomarkers – an immunoMATCH Pilot Study

**Protocol number:** S2101

**NCT number:** 05136196

**Trial sponsor:** SWOG Cancer Research Network

**Publishing date:** August 15, 2022

**Thank you!**

When you join a clinical trial,  
you're moving cancer medicine and patient care forward.