Clinical trial summary (S1800D)

Combining Immunotherapy Drugs to Treat Advanced Non-Small Cell Lung Cancer

What is the purpose of this clinical trial?

Non-small cell lung cancer is the most common type of lung cancer. Many people find out they have this type of cancer when it is at an advanced stage and there are fewer treatment options.

This study will compare the usual treatment for advanced non-small cell lung cancer with treatment that combines 2 immunotherapy drugs, N-803 and pembrolizumab. This combination of immunotherapy drugs is not approved by the Food and Drug Administration (FDA) to treat advanced non-small cell lung cancer.

This trial is set up to find out:

- If treating non-small cell lung cancer with a combination of 2 immunotherapy drugs helps people live longer
- How long patients respond to the immunotherapy drugs compared to usual treatment
- Which treatment is better to lower the chance that the cancer will spread or get worse
- What side effects patients have with the different treatments

Why is this trial important?

Immunotherapy works with the immune system to fight cancer. Research on this type of treatment is expanding. By testing the use of 2 drugs together, this study will help researchers learn more about how cancer responds to immunotherapy.

This trial is part of a larger study for people with non-small cell lung cancer, called Lung-MAP. In Lung-MAP, your tumor is tested for certain genetic changes that specific treatments may target.

Who can be in this trial?

This trial is for adults, age 18 or older, with advanced non-small cell lung cancer.

This trial is for people who:

- Have cancer that has come back or grown after certain immunotherapy treatments
- Can safely receive a standard treatment for non-small cell lung cancer

This trial is not for people who:

- Have had severe side effects from immunotherapy
- Have poor liver or kidney function, or severe heart problems
- Are pregnant
- Have an uncontrolled infection or autoimmune disease
- Have another type of cancer that may affect treatment in this study

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

What treatments would I get?

A computer will randomly assign you to one of 2 study groups.

Group 1:

- You receive the usual treatment for advanced non-small cell lung cancer. You and your doctor decide which standard treatment is best for you.

Group 2:

- You receive immunotherapy treatment with 2 drugs.

Your doctor will not have control over which group you will be assigned to. This helps make sure the study results are fair and reliable.

How long will I be in the trial?

You will be in the study for 3 years. You will continue getting treatment for as long as you benefit from it. Your doctor may stop your treatment if side effects become too severe or your condition gets worse.

If you stop getting treatment, you will have follow-up visits with the study team until 3 years after you started the study.

If your condition gets worse, you may have the option to join another Lung-MAP study.

Are there costs? Will I get paid?

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** and search using the national clinical trial number: **05096663**
- Go to **lung-map.org/patients**

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

Protocol number: S1800D

NCT number: 05096663

Full trial title: A Phase II/III Study of N-803 (ALT-803) plus Pembrolizumab versus Standard of Care in Participants with Stage IV or Recurrent Non-Small Cell Lung Cancer Previously Treated with Anti-PD-1 or Anti-PD-L1 Therapy (Lung-MAP Non-Match Sub-Study)

Trial sponsor: SWOG Cancer Research Network

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Thank you!

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