

RATIONALE-315: Results of a study comparing tislelizumab plus chemotherapy versus placebo plus chemotherapy as a treatment given before surgery for people with stage II-IIIa non-small cell lung cancer

FULL TITLE

Pathological response to neoadjuvant tislelizumab (TIS) plus platinum-doublet (PtDb) chemotherapy (CT) in resectable stage II-IIIa NSCLC patients (pts) in the Phase 3 (Ph3) RATIONALE-315 trial

SUMMARY DATE

October 2023

PHONETICS

How to say medical terms used in this summary

Chemotherapy

<KEE-moh-THAYR-uh-pee>

Immunotherapy

<IH-myoo-noh-THAYR-uh-pee>

Neoadjuvant

<NEE-oh-A-joo-vnt>

Placebo

<pluh-SEE-boh>

Resectable

<re-SEKT-abel>

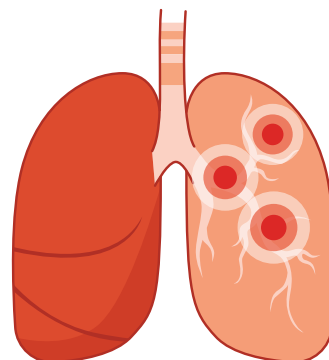
Tislelizumab

<tis-le-LIZ-ue-mab>



What is resectable stage II-IIIa non-small cell lung cancer?

- ▶ Lung cancer is the second most common type of cancer diagnosed worldwide
 - ▶ Non-small cell lung cancer (NSCLC) is the most common type of lung cancer
- ▶ Resectable means it is likely that all of the cancer in the lung and in any nearby lymph nodes can be successfully removed by surgery
 - ▶ Lymph nodes act as filters for damaged or abnormal cells
 - ▶ Cancer cells that break away from the main tumor can become trapped in lymph nodes
- ▶ Researchers use a process called staging to help decide how to treat people with NSCLC
 - ▶ The stage of NSCLC is determined by the size and location of the tumor, and whether it has spread to the lymph nodes and/or other parts of the body



Stages of NSCLC studied in RATIONALE-315

Stage IIA

The cancer is larger than 4 cm but less than 5 cm in size and has not spread anywhere else in the body

Stage IIB

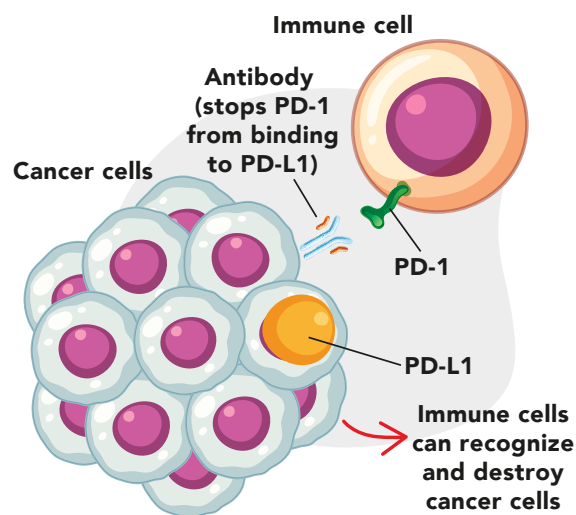
The cancer is less than 5 cm in size and has spread only to the lymph nodes in or near the lung
OR
is larger than 5 cm in size but has not spread anywhere else in the body

Stage IIIA

The cancer can vary in size and has spread to lymph nodes on the same side of the chest as the cancer

What is immunotherapy?

- ▶ Immunotherapy is a type of cancer treatment that works by helping a person's immune system recognize and kill cancer cells
 - ▶ The immune system is the body's defense system
- ▶ The immune system can find and destroy cancer cells; however, these cells have ways to avoid detection
- ▶ One way cancer cells can avoid being detected by the immune system is by producing a protein called programmed death ligand 1 (PD-L1) on their surface
- ▶ White blood cells are a type of blood cell in the immune system that scans the body for unhealthy cells. White blood cells have a protein on their surface called programmed cell death protein-1 (PD-1) that can attach to the PD-L1 on cancer cell surfaces. When the white blood cells recognize and bind to cancer cells that have PD-L1 on their surface, they are tricked into not killing the cancer cells
- ▶ Anti-PD-1 antibodies are a type of protein that stops PD-1 on white blood cells from binding to PD-L1 on the cancer cells. This removes the cancer cells' 'disguise' and allows the immune system to kill cancer cells



What is tislelizumab?

- ▶ Tislelizumab is an antibody that is designed in the laboratory. It works by binding specifically to PD-1, allowing the immune system to recognize and kill the cancer cells
 - ▶ Tislelizumab is given as an intravenous injection directly into the bloodstream
- ▶ RATIONALE-315 compared the effects of tislelizumab plus chemotherapy versus placebo plus chemotherapy
 - ▶ A placebo looks and is given like the study drug (i.e., like tislelizumab) but does not contain any active ingredients

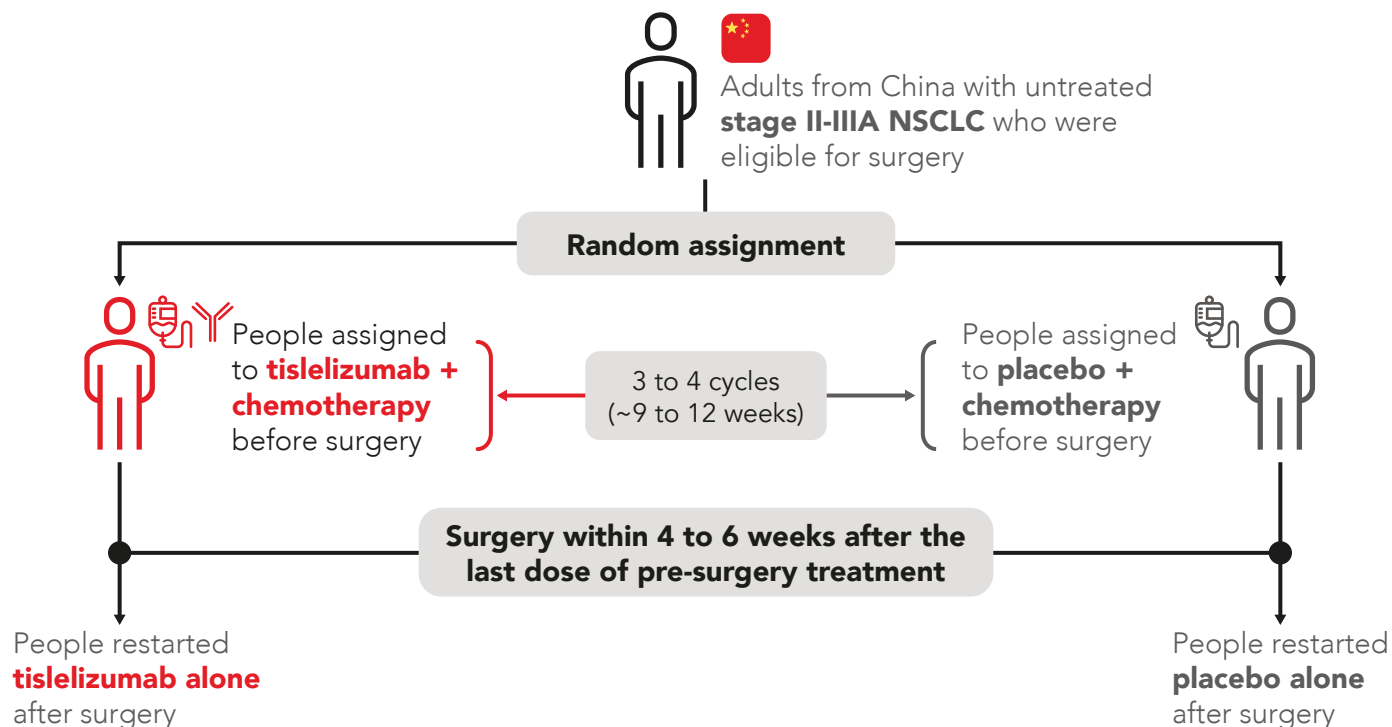
PUBLICATION PLAIN LANGUAGE SUMMARY

What does this summary describe?

- ▶ This summary describes how researchers compared the effects of receiving tislelizumab plus chemotherapy with placebo plus chemotherapy before surgery in people with resectable stage II-IIIa NSCLC
- ▶ In the study, researchers looked at:
 - ▶ The ability of treatments to kill cancer cells before surgery, measured by the proportion of living cancer cells in the tumor after surgery
 - The proportion of people whose tumor had less than 10% of cancer cells alive after surgery, called a major pathological response
 - The proportion of people whose tumor had no cancer cells alive after surgery, called a pathological complete response
 - ▶ What side effects were common with each treatment
 - A side effect is something that people feel is caused by the treatment they take

STUDY DETAILS

Who took part in the study?



What results from the study are expected to be presented?

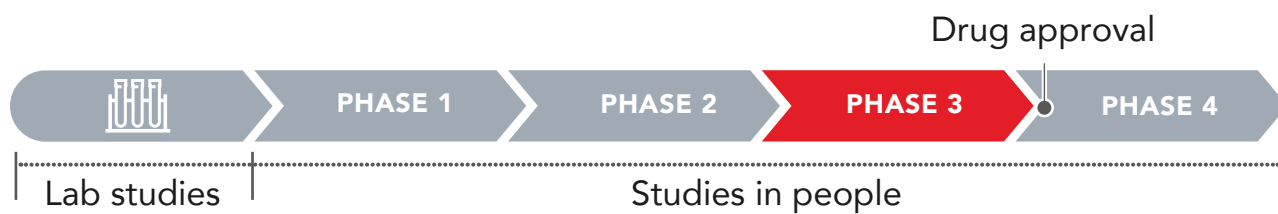
- ▶ The results of this study will be presented at the European Society for Medical Oncology (ESMO) scientific congress, October 20–24, 2023
- ▶ Researchers will report how well tislelizumab plus chemotherapy worked compared with placebo plus chemotherapy as a treatment given before surgery in people with stage II-IIIa lung cancer
- ▶ Researchers will also report how safe tislelizumab was and whether the side effects reported were considered to be manageable

PUBLICATION PLAIN LANGUAGE SUMMARY

Who sponsored the study?

This study was sponsored by BeiGene Ltd. BeiGene would like to thank the trial investigators, site support staff, and especially the people who took part in the study. This summary was prepared by Steven Moore, PhD, CMPP, and Smitha Reddy, PhD, of Envision Pharma Group and was funded by BeiGene Ltd.

Whereabouts is tislelizumab in the drug development timeline?



Are there plans for additional studies?

This study started on May 29, 2020, is ongoing, and has not yet been completed. Other tislelizumab studies are currently ongoing and can be viewed by going to <https://www.beigene.com/our-science-and-medicines/pipeline>

Additional study information

For detailed study information, go to:
<https://clinicaltrials.gov/study/NCT0437963>

For more information about scientific studies done by specialist doctors in clinics and hospitals on new medicines in general, go to:
<https://www.clinicaltrials.gov/ct2/about-studies/learn>

Need additional information?

Email: info@beigene.com

Website: <https://www.beigene.com>

Address: BeiGene, USA
1900 Powell Street, Suite 500
Emeryville, CA 94608
Phone: 1 (877) 828-5568