

# RATIONALE-309: A study comparing tislelizumab with chemotherapy versus chemotherapy alone for patients with untreated recurrent/metastatic nasopharyngeal cancer

## FULL TITLE

RATIONALE-309: Updated progression-free survival (PFS), PFS after next line of treatment, and overall survival from a phase 3 double-blind trial of tislelizumab versus placebo, plus chemotherapy, as first-line treatment for recurrent/metastatic nasopharyngeal cancer

## SUMMARY DATE

May 2022

## KEY TAKEAWAYS

After 15.5 months, more patients with untreated recurrent/metastatic nasopharyngeal cancer who received tislelizumab with chemotherapy were alive without their cancer growing or spreading compared with patients who received chemotherapy alone.

## PHONETICS

How to say medical terms used in this summary

**Immunotherapy**

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

**Leukocyte**

<loo-KO-siyt>

**Nasopharyngeal**

<NAH-zoh-fuh-RIN-jee-ul>

**Nasopharynx**

<NAY-zoh-FAYR-inx>

**Neutrophil**

<noo-TRO-fil>

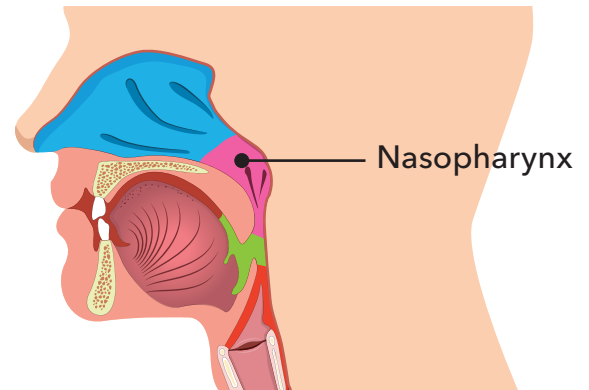
**Tislelizumab**

<tis-le-LIZ-ue-mab>



## What is recurrent/metastatic nasopharyngeal cancer?

- ▶ Nasopharyngeal cancer (NPC) occurs in the nasopharynx, which is located behind the nose and above the back of the throat
  - ▶ Recurrent NPC means that the cancer has come back after it has been treated
  - ▶ Metastatic NPC means cancer cells have moved to other areas

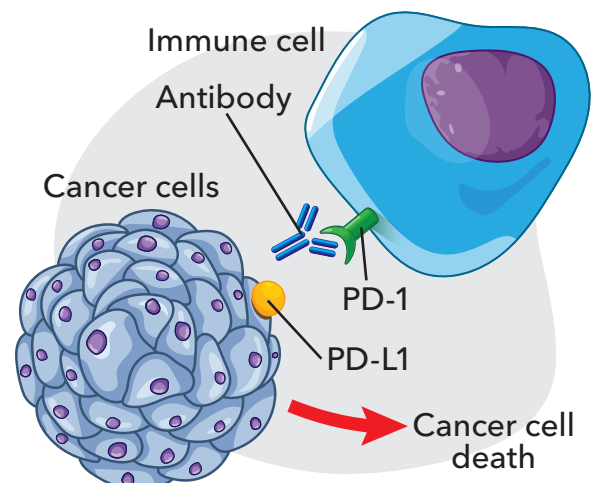


## What is immunotherapy?

- ▶ The immune system finds and destroys cancer cells; however, these cells have ways to avoid detection by the immune system
- ▶ Immunotherapy is a type of cancer treatment that works by helping the patient's immune system recognize and kill cancer cells
- ▶ Cancer cells can evade our immune system by expressing a protein called programmed death ligand 1 (PD-L1) on their surface
  - ▶ High or low levels of these proteins can affect whether the immune system can recognize and kill the cancer cells
- ▶ White blood cells, which scan the body for unhealthy cells, have a protein called programmed cell death protein-1 (PD-1) that can bind to PD-L1; when the white blood cells recognize and bind to cancer cells that express PD-L1, they are tricked into not killing the cancer cells
- ▶ Antibodies that block the binding of PD-1 to PD-L1 remove the tumor cells' 'disguise' and allow the immune system to kill tumor cells

## What is tislelizumab?

- ▶ Tislelizumab is an antibody that binds to PD-1, allowing the immune system to recognize and kill the cancer cells
- ▶ RATIONALE-309 compared the clinical effects of tislelizumab plus chemotherapy versus chemotherapy alone in patients with recurrent/metastatic NPC

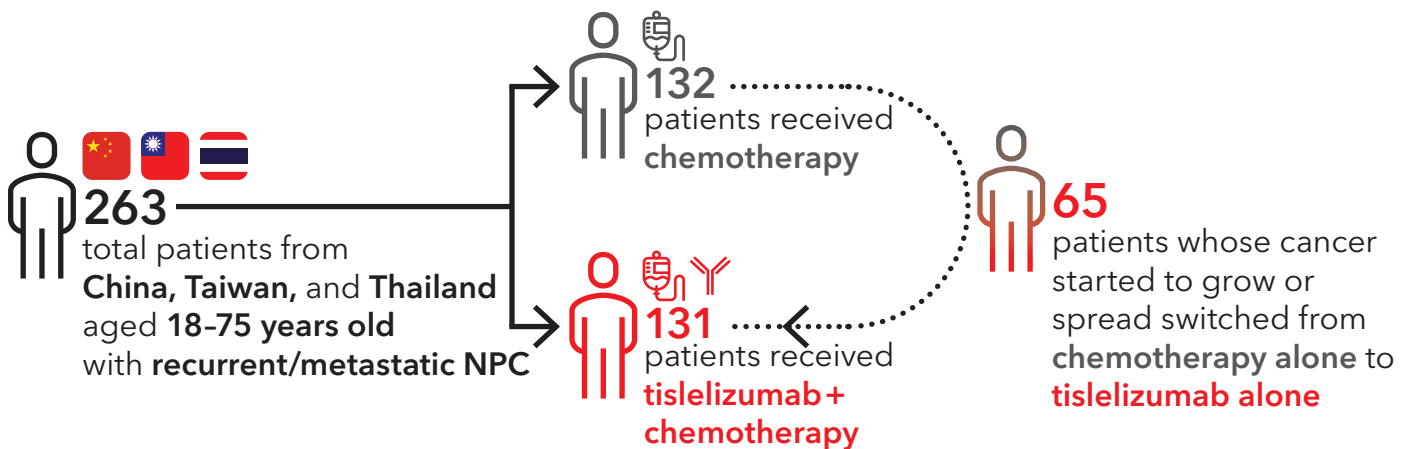


## What does this summary describe?

- ▶ This summary describes the clinical effects of tislelizumab with chemotherapy versus chemotherapy alone in patients with recurrent/metastatic NPC, such as:
  - ▶ Which treatment gave patients a lower chance of the cancer growing or spreading over time
  - ▶ Whether the amount of PD-L1 protein on tumor cells affected clinical effects
  - ▶ What side effects were common with each treatment
  - ▶ Side effects are graded on a scale from 1 to 5; the higher the grade, the more severe they are
    - Grade 3 side effects are severe or medically significant but not life-threatening, Grade 4 side effects are life-threatening, and Grade 5 side effects are fatal

## STUDY DETAILS

### Who took part in the study?



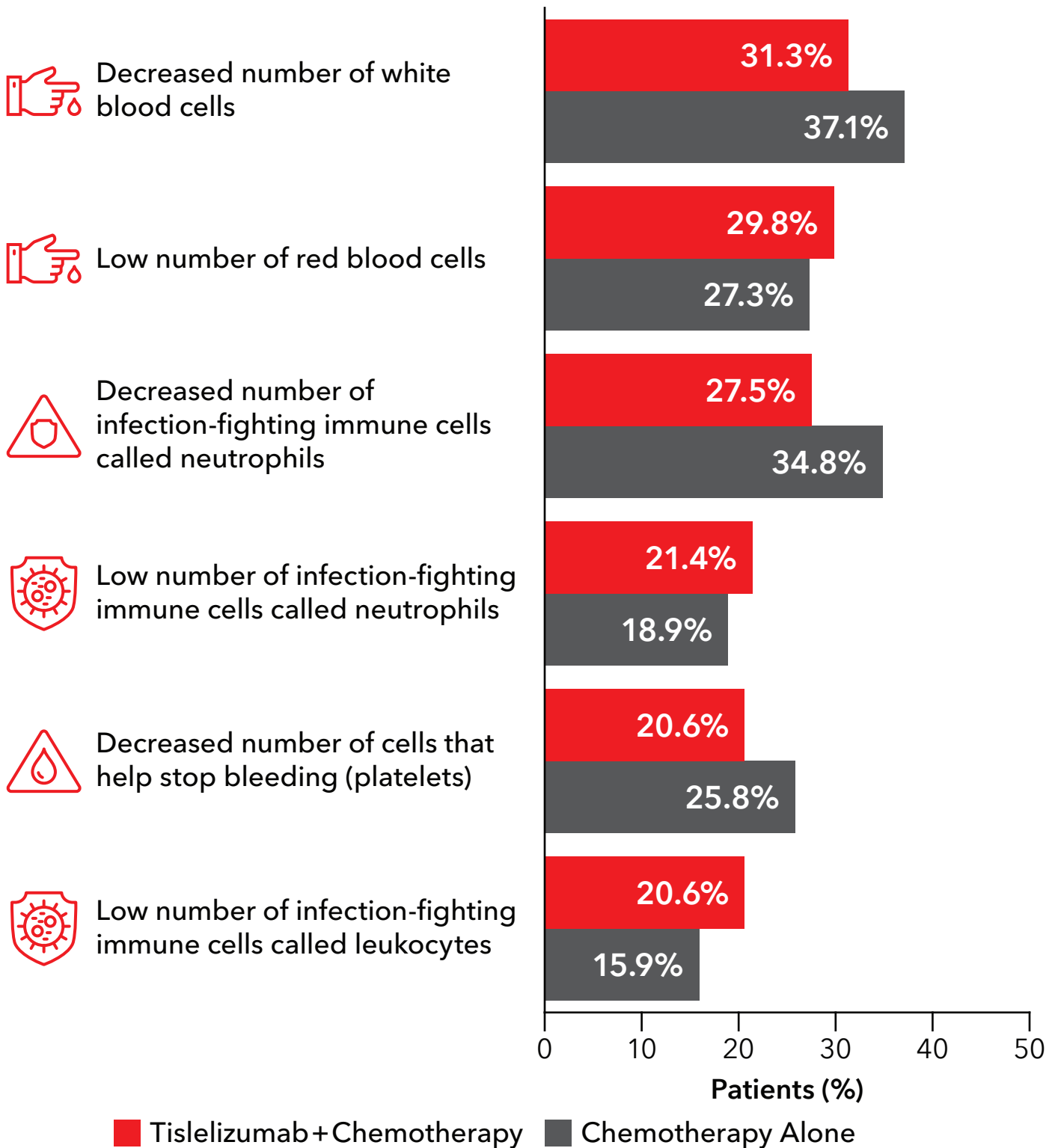
### What were the results of the study?

**50% LOWER CHANCE** After 15.5 months of follow-up, patients who received **tislelizumab with chemotherapy** had a **50% lower chance** of their cancer growing or spreading versus patients who received **chemotherapy alone**

- ▶ The **lower chance** of patients' cancer growing or spreading did not change if cancer cells expressed a little or a lot of PD-L1

## PUBLICATION PLAIN LANGUAGE SUMMARY

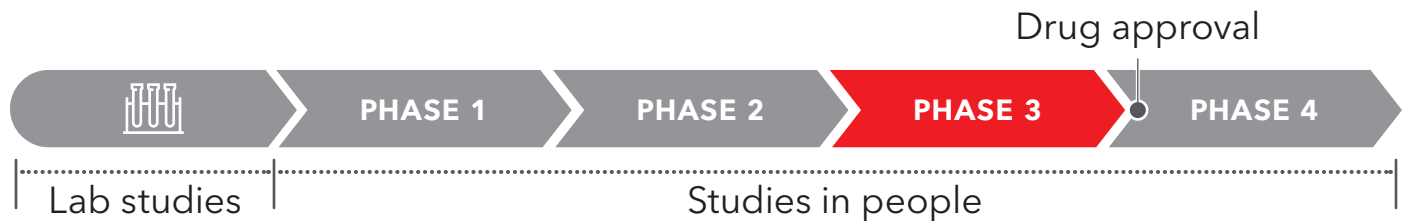
- ▶ Common side effects with the highest severity grade ( $\geq 3$ ) were reductions of different types of blood cells



## 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 patients who took part in the study. This summary was prepared by Regina Switzer, PhD (BeiGene, Ltd.).

## Where is tislelizumab in the developmental timeline?



## Are there plans for additional studies?

This study started on April 18, 2019, 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/ct2/show/NCT03924986>

For more information about scientific studies in general, go to:

<https://www.clinicaltrials.gov/ct2/about-studies/learn>

## Need additional information?

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This summary only contains information presented in the ASCO virtual plenary series: April 2022 Session, available by scanning the following QR code.

