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Plain Language Summary of Publication

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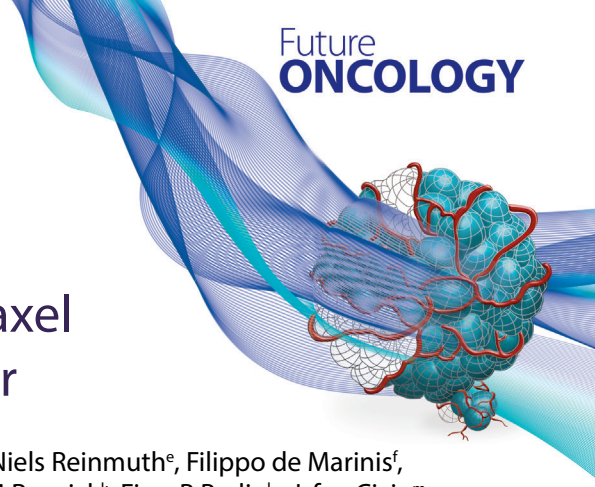

Plain language summary of the EVOKE-01 study of sacituzumab govitecan vs docetaxel in patients with non-small cell lung cancer

Luis G Paz-Ares[a], Oscar Juan-Vidal[b], Giannis S Mountzios[c], Enriqueta Felip[d], Niels Reinmuth[e], Filippo de Marinis[f], Nicolas Girard[g], Vipul M Patel[h], Takayuki Takahama[i], Scott P Owen[j], Douglas M Reznick[k], Firas B Badin[l], Irfan Cicin[m], Sabeen Mekan[n], Riddhi Patel[n], Eric Zhang[n], Divyadeep Karumanchi[n] & Marina Chiara Garassino[o]

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Where can I find the original article on which this summary is based?

In May 2024, results from the EVOKE-01 study were published in the *Journal of Clinical Oncology*. The first article is titled 'Sacituzumab Govitecan Versus Docetaxel for Previously Treated Advanced or Metastatic Non-Small Cell Lung Cancer: The Randomized, Open-Label Phase III EVOKE-01 Study'.

You can obtain a free copy of the original article at: https://ascopubs.org/doi/suppl/10.1200/JCO.24.00733

Summary

What is this summary about?

There are few treatment choices for people with non-small cell lung cancer (NSCLC) when it gets worse after prior treatments. Available treatments lead to poor survival outcomes and severe **side effects**.

This summarizes the results of a study called EVOKE-01. This study compared a newer medicine called sacituzumab govitecan (brand name: TRODELVY®) with a commonly used **chemotherapy** called docetaxel. People in the study had NSCLC that was advanced or had become **metastatic** after being treated with other medicines that contain platinum plus an **immunotherapy**.

What were the results?

After a **median** of 13 months of observation in the study, people with advanced or metastatic NSCLC who were treated with sacituzumab govitecan did not live significantly longer than those who were treated with docetaxel. However, similar to docetaxel, many people were helped by sacituzumab govitecan treatment, and patients taking sacituzumab govitecan appeared to live somewhat longer than those who were given docetaxel.

How to say (download PDF and double click sound icon to play sound)...

- **Sacituzumab govitecan:** SAH-si-TOO-zoo-mab GOH-vih-TEE-kan
- **Antibody–drug conjugate:** AN-tee-BAH-dee–druhg KON-jih-get
- **Docetaxel:** DOH-seh-TAK-sil
- **Squamous:** SKWAY-mus

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People were helped no matter what type of NSCLC they had. The positive effects of sacituzumab govitecan treatment were more obvious in people whose disease did not get better after their last immunotherapy. People given sacituzumab govitecan had fewer severe side effects. Fewer had to stop sacituzumab govitecan treatment, compared with those who were given docetaxel. People who got sacituzumab govitecan in this study had similar side effects as people who took sacituzumab govitecan in other studies. Shortness of breath is a key symptom of NSCLC. People who got sacituzumab govitecan took longer to have shortness of breath compared with people who got docetaxel. This suggests that sacituzumab govitecan controlled the disease better than docetaxel.

What do the results mean?

This study suggested that some people with advanced or metastatic NSCLC might live slightly longer when treated with sacituzumab govitecan than with docetaxel, especially those whose cancer did not respond to earlier treatment with immunotherapy. In this study, about the same number of people who got sacituzumab govitecan or docetaxel had any side effects. Fewer people had severe/life-threatening side effects or had to stop treatment because of side effects with sacituzumab govitecan than docetaxel. These results support future studies of sacituzumab govitecan as a potential treatment for people with previously treated advanced or metastatic NSCLC.

Side effects: Unwanted or harmful effects of a drug or other medical treatment.

Chemotherapy: A drug or combination of drugs used to treat cancers, either by killing them or stopping them from growing. Chemotherapy may be given alone or with other cancer treatments.

Metastatic: Cancer that has spread to other sections of the lung or parts of the body.

Immunotherapy: These drugs work by making the body's own immune system recognize and kill cancer cells.

Median: The middle value in a set of data when all values are ordered from the smallest to the largest.

What is the purpose of this plain language summary?

The purpose of this plain language summary is to explain the findings from recent research. This is a summary of the results of the EVOKE-01 study. The results of this study may be different from the results of other studies. Health professionals should make treatment decisions based on all available information, not on the results of a single study.

Who should read this article?

This summary may be helpful for people with cancer and their caregivers, patient advocates, and healthcare professionals who are interested in sacituzumab govitecan.

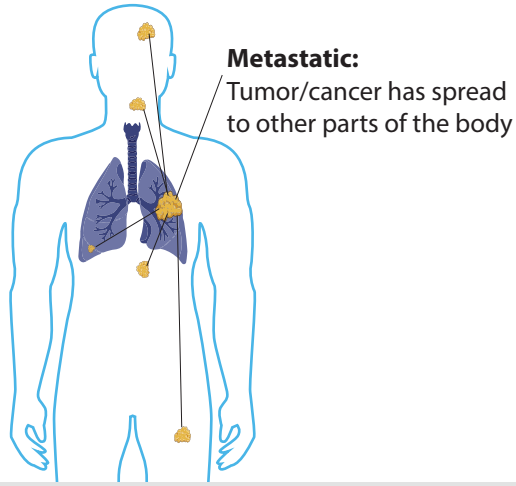
Who sponsored this study?

This study was **sponsored** by Gilead Sciences, Inc.

Sponsor: A company or organization that oversees and pays for a clinical research study. The sponsor also collects and analyzes the information from the study.

What is advanced or metastatic NSCLC and how is it normally treated?

NSCLC is the most common form of lung cancer in humans. When lung cancer cells spread from one lung to the other or to other parts of the body, the cancer is called metastatic. Lung cancer that has spread is considered advanced when it cannot be cured or controlled with available treatment. Healthcare professionals use **cancer staging** to describe how much the cancer has grown and spread. **Stage IV** lung cancer is metastatic and considered advanced. People participating in the EVOKE-01 study had stage IV NSCLC that had gotten worse after getting another treatment.



NSCLC can start from different types of cells or tissues in the lungs. Understanding which cell or tissue the cancer started from can help determine how the cancer will grow and what treatments will work best. In NSCLC, the two most common cell types are **squamous** and **nonsquamous**. Sometimes, cancerous squamous cells react differently to treatments than cancerous nonsquamous cells. Therefore, knowing the **cancer subtype** is important.

When people are diagnosed with NSCLC, they are tested for **genetic changes**. This helps to understand how their cancer will grow and what treatments might work best.

People with stage IV NSCLC that keeps growing and spreading after several treatments have limited options left. Advanced or metastatic NSCLC is usually treated with platinum-containing chemotherapy and immunotherapy that blocks a protein called **PD-1** or its partner protein **PD-L1**. If the cancer gets worse, the next treatment is usually docetaxel. However, docetaxel treatment at this stage does not usually stop the disease from getting worse, does not improve survival by much, and has severe side effects.

Cancer stage: How much cancer growth is present, and how far it has spread throughout the body. There are four (I–IV) main stages of NSCLC. Stages I–III are earlier in the disease process, and there is limited or no spread outside the chest.

Stage IV is late in the disease process and the most advanced; tumors can be any size, but there is a lot of spread throughout the body.

Squamous cell: A type of cell found in the lungs that lines the inside of the airways.

Nonsquamous cell: Any type of cell found in the lungs other than squamous cells.

Cancer subtype: The type of tissue or cell from which the cancer started. Knowing the cancer subtype can help figure out how the cancer will grow and what treatments will work best.

Genetic changes: A change in a healthy DNA sequence that can make cancers grow faster or grow even when treated.

PD-1: A protein found on some cells in the immune system called T cells. When attached to its partner protein, PD-L1, the T cell is unable to kill other cells, such as cancer cells. When PD-1 is prevented from binding PD-L1, T cells are able to kill other cells, including cancer cells.

PD-L1: A protein found on some healthy cells and in higher-than-normal amounts on some types of cancer cells. When PD-L1 attaches to its partner protein, PD-1, on T cells, it prevents those T cells from killing PD-L1–expressing cells, including cancer cells.

What is sacituzumab govitecan?

A common challenge in treating people with cancer is that some drugs kill cancer cells but may also kill healthy cells. This can lead to many side effects, such as tiredness, hair loss, and easy bruising and bleeding.

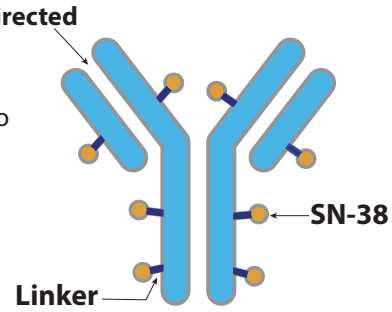
Sacituzumab govitecan is an antibody–drug conjugate (ADC). ADCs are designed to target and kill cancer cells without killing healthy cells. Sacituzumab govitecan targets cells that have Trop-2 receptors, which are found on cancer cells. Targeting cells that have Trop-2 lowers the potential for side effects.

Sacituzumab govitecan, as an ADC, has three parts:

1. An **antibody** that finds and attaches to the Trop-2 receptor.
2. SN-38, a chemotherapy drug, is known to kill cancer cells by damaging DNA, the genetic instructions for a cell's functions.
3. A **linker** that attaches the Trop-2–directed antibody to SN-38.

Sacituzumab govitecan has already been approved by the United States Food and Drug Administration (FDA) for **locally advanced** or metastatic breast cancer.

Sacituzumab govitecan is an ADC



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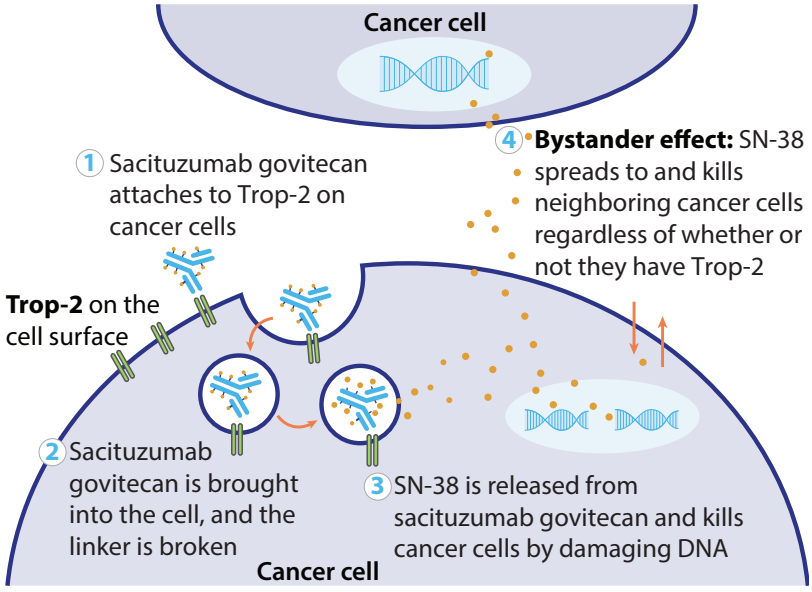
How does sacituzumab govitecan work?



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Antibody: A protein that can find and attach to other cells that contain a specific partner protein that they recognize. Antibodies are made by immune cells.

Linker: A series of amino acids (the building blocks of proteins) that enables two different proteins or two parts of a single protein to attach to one another.

Locally advanced: A cancer that has grown outside of the body part it started in but has not yet spread to other parts of the body that are farther away.

Why did the EVOKE-01 study take place?

People with advanced or metastatic NSCLC need better treatments. In an earlier study, people with previously treated metastatic NSCLC were found to benefit from sacituzumab govitecan treatment and tolerated the side effects well.

The goal of the EVOKE-01 study was to find out how well sacituzumab govitecan worked compared with docetaxel chemotherapy when used to treat people with advanced or metastatic NSCLC whose cancer got worse after treatment with platinum-containing chemotherapy plus anti–PD-1/PD-L1 immunotherapy. We will call this anti–PD-(L)1 therapy.

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How was the study carried out?

Requirements to participate:

Participants were able to take part in the study:

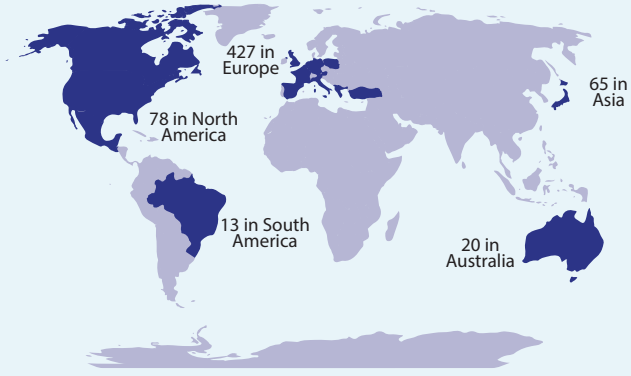
- ✓ Who were aged 18 years or older with stage IV NSCLC that could be measured using scans
- ✓ After completing tests to determine if they had squamous or nonsquamous NSCLC and if they had any genetic changes
- ✓ Who had disease that worsened after completing at least one platinum-containing chemotherapy as well as at least one anti–PD-(L)1 therapy for advanced or metastatic NSCLC
  - → If a genetic change was detected, the participant must have also completed at least one approved treatment specific for that change, if one was available, in addition to the above-described treatments
- ✓ Whose organ function and blood cell counts were considered acceptable based on established criteria and physician discretion

Participants were not able to take part in the study:

- ✗ Who had prior treatment with any anticancer drugs that specifically target Topo-1 or Trop-2
- ✗ Who had prior treatment with docetaxel chemotherapy
- ✗ Who had an additional type of cancer (other than NSCLC) that was actively getting worse

Timeframe of the EVOKE-01 study analysis:

Sites where the EVOKE-01 study took place:



Which treatment did participants receive?

Participants were randomly divided into two treatment groups:

All participants

Sacituzumab govitecan was given **intravenously** twice every 21 days

Sacituzumab govitecan 299 people

vs

Docetaxel 304 people

Docetaxel was given **intravenously** once every 21 days

People in the study kept getting the treatment until their disease got worse or they had a severe reaction to the treatment.

19 people left the study *before* getting treatment

Intravenous: When a needle is inserted into a vein and a liquid treatment is delivered straight into the bloodstream.

Who took part in the study?

49% were under 65 years old

27% had squamous NSCLC

55% received only 1 prior treatment with platinum-containing chemotherapy and anti–PD-(L)1 therapy

32% were female

73% had nonsquamous NSCLC

64% had a disease that did not respond to their prior anti–PD-(L)1 therapy

7% had gotten a prior treatment specific to a genetic change

What were the key questions answered in the EVOKE-01 study?

Researchers compared the difference between **sacituzumab govitecan** and **docetaxel** treatment:

Main question:

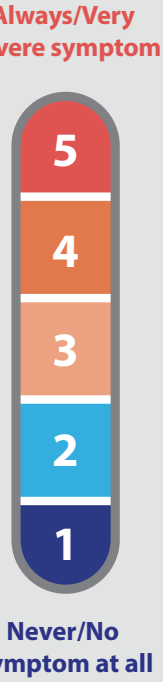
1. **Overall survival:** How long did participants live after being randomly assigned to a treatment group?

Other questions:

2. **Progression-free survival:** After being randomly assigned to a treatment group, how long did participants live before their cancer got worse (called progressive disease) or they died?
3. **Objective response rate:** What was the proportion of participants whose tumors disappeared (complete response) or got smaller (partial response)?
   a. **Duration of response:** How long did a complete or partial response last?
4. **Disease control rate:** What was the proportion of participants whose cancer either completely or partially responded to treatment or remained stable without getting worse (called stable disease)?
5. **Time to deterioration:** How long before participants started feeling that their NSCLC symptoms, especially the ability to breathe, became worse?
6. **Safety:** What were the side effects associated with each treatment?

NSCLC symptoms

1. How would you rate your **coughing** at its worst over the last 7 days?
2. How would you rate the worst **pain in your chest** over the last 7 days?
3. How would you rate the worst **pain in areas other than your chest** over the last 7 days?
4. How often did you feel **short of breath** during usual activities over the last 7 days?
5. How often did you have **low energy** over the last 7 days?
6. How often did you **tire easily** over the last 7 days?
7. How often did you have **poor appetite** over the last 7 days?



How did participants know if their NSCLC symptoms, especially breathing, were getting worse?

- Participants completed a NSCLC Symptom Assessment Questionnaire (NSCLC-SAQ) just before having any study procedure or getting their first treatment, then once every 21-day treatment cycle, and at the end of treatment visit.
- NSCLC-SAQ asks participants to rate symptoms related to cough, pain, shortness of breath, fatigue, and appetite.
- Participants rated each question on a scale ranging from 1 (no symptom or never) to 5 (very severe symptom or always). If the total score for all questions worsened by at least 2 points or the score for question 4 (shortness of breath) worsened by at least 1 point since treatment started, the participant's symptoms were said to have gotten worse.

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What were the overall results of the EVOKE-01 study?

Participants were monitored for a median of 13 months after being randomly assigned to a treatment group.

1 Which treatment group lived longer?

There was no significant difference between sacituzumab govitecan and docetaxel treatments in how long people lived overall (main question).

Median overall survival

Sacituzumab govitecan: **11 months**

Docetaxel: **10 months**

Participants alive after 12 months (overall survival)

Sacituzumab govitecan: **47%**

Docetaxel: **37%**

Sacituzumab govitecan treatment compared with **docetaxel** treatment also did not significantly prolong life when specifically looking at participants with squamous or nonsquamous NSCLC.

Median overall survival

Squamous NSCLC

Sacituzumab govitecan: **10 months**

Docetaxel: **9 months**

Nonsquamous NSCLC

Sacituzumab govitecan: **11 months**

Docetaxel: **10 months**

Participants with NSCLC who did not respond well to prior anti–PD-(L)1 therapy appeared to live longer with **sacituzumab govitecan** treatment than with **docetaxel**. In participants with NSCLC that completely or partially responded to prior anti–PD-(L)1 therapy, there was only a small difference in overall survival between the two treatments.

Median overall survival

Stable/Progressive NSCLC after prior anti–PD-(L)1 therapy

Sacituzumab govitecan: **12 months**

Docetaxel: **8 months**

Complete/Partial response after prior anti–PD-(L)1 therapy

Sacituzumab govitecan: **10 months**

Docetaxel: **11 months**

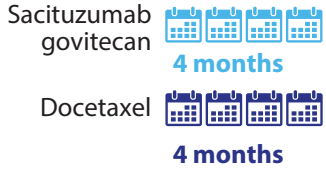
Why is the type of response to the prior anti–PD-(L)1 therapy important when considering further treatment?

Response to anti–PD-(L)1 therapy has been shown to impact the predicted overall survival of a person with NSCLC. People with advanced or metastatic NSCLC that remains stable or gets worse (progresses) on or after anti–PD-(L)1 therapy tend to have worse overall survival than those who have a complete or partial response.

2 Which treatment group lived longer without their cancer getting worse?

The length of time participants lived before their cancer came back or became worse was similar between **sacituzumab govitecan** and **docetaxel** treatments.

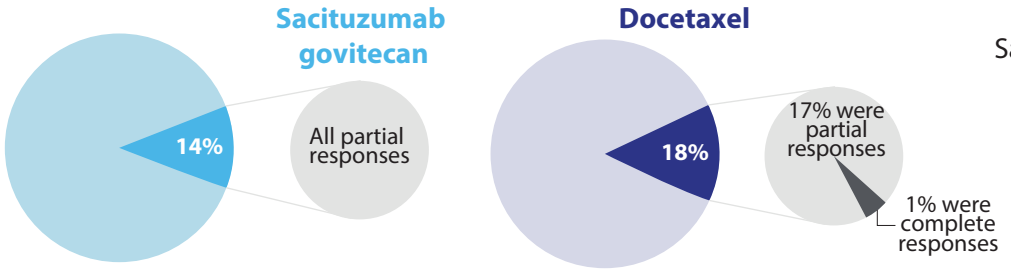
Median progression-free survival



3 Which treatment produced a better objective response?

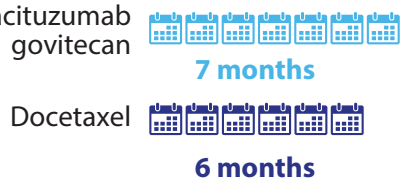
The objective response rates of NSCLC in participants treated with **sacituzumab govitecan** and **docetaxel** treatments was similar.

Objective response rate



Objective responses seen with **sacituzumab govitecan** and **docetaxel** treatments lasted a similar amount of time.

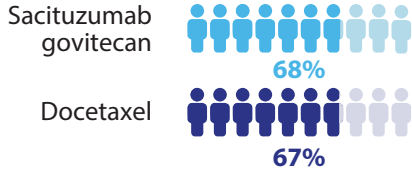
Duration of response



4 Which treatment prevented or better controlled the growth and spread of NSCLC to other parts of the body?

Sacituzumab govitecan treatment controlled the growth or spread of the cancer equally to **docetaxel** treatment.

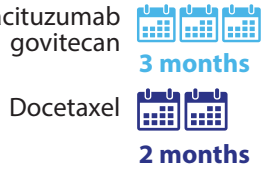
Disease control rate



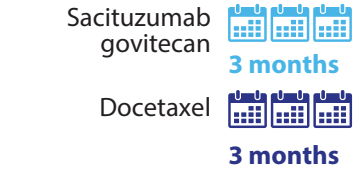
5 Which treatment prevented NSCLC symptoms from getting worse longer?

Based on the NSCLC-SAQ results, it took longer for participants to report that shortness of breath worsened when treated with **sacituzumab govitecan** compared with those treated with **docetaxel**. However, it took about the same amount of time for all NSCLC symptoms to worsen with **sacituzumab govitecan** and **docetaxel** treatments.

Median time till shortness of breath worsened



Median time till all NSCLC symptoms worsened



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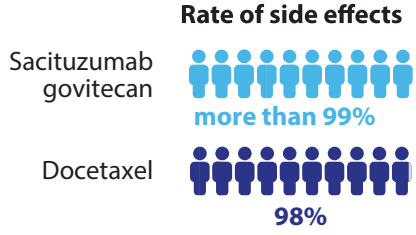
6 What were the side effects associated with each treatment?

The safety of each drug was evaluated in participants who received at least one dose of their assigned treatment. Nineteen people quit the study before receiving treatment; therefore, treatment safety was assessed in the remaining participants:

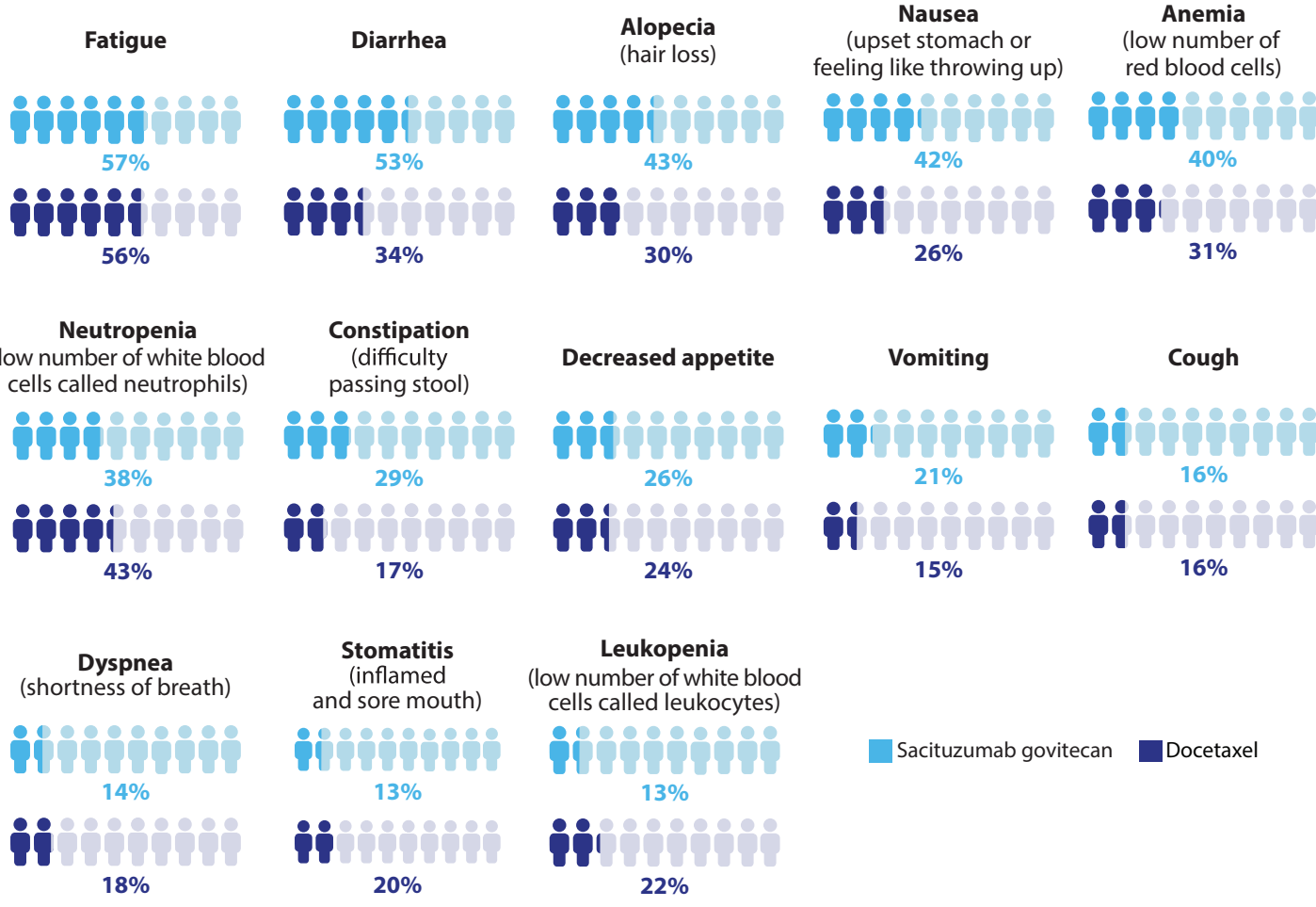
Safety population

Sacituzumab govitecan 296 people **VS** **Docetaxel** 288 people

Overall, side effects of any severity occurred at about the same rate with **sacituzumab govitecan** and **docetaxel**.

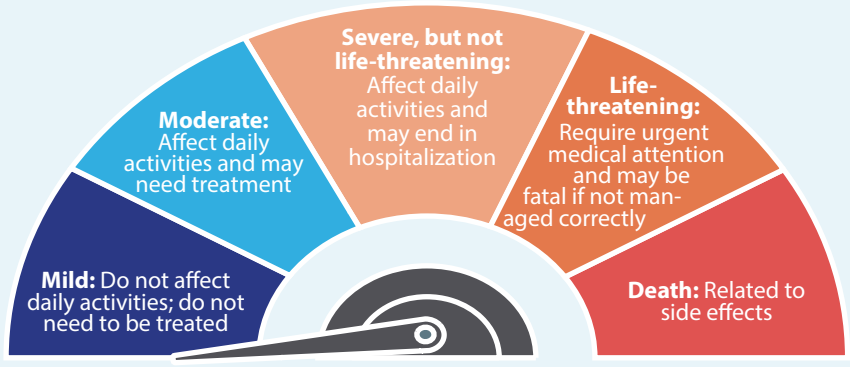


Doctors noted the side effects caused by **sacituzumab govitecan** and **docetaxel**. Some of the most common side effects are summarized here:

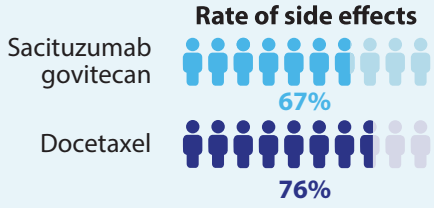


Side effects ratings

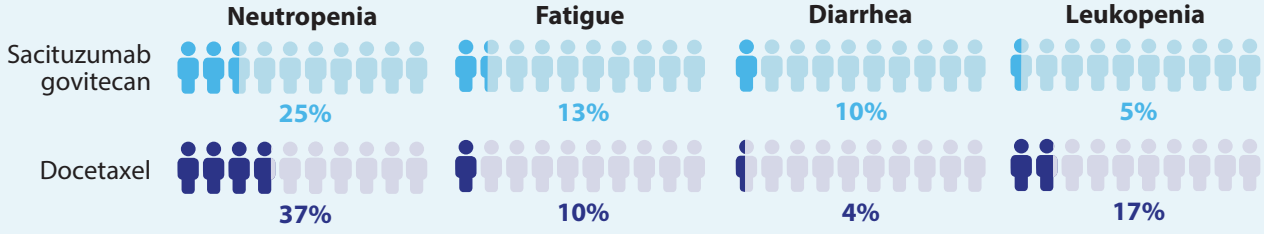
A grading system is used when measuring side effects.



Overall, **sacituzumab govitecan** treatment was associated with fewer severe or life-threatening side effects than **docetaxel** treatment.

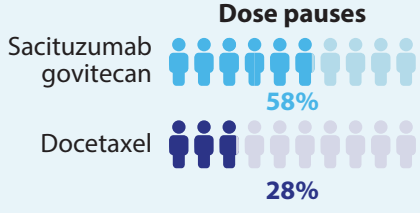


The most common severe or life-threatening side effects are summarized here:



Fewer participants had to lower the dose or completely stop use of their treatment due to side effects with **sacituzumab govitecan** compared with **docetaxel**.

More participants had to pause treatment due to side effects when taking **sacituzumab govitecan** compared with **docetaxel.**



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Did any participants die because of treatment-related side effects during the EVOKE-01 study?

Unfortunately, side effects related to study treatment led to the deaths of 4 (1.4%) participants treated with sacituzumab govitecan and 3 (1.0%) participants treated with docetaxel. The side effects leading to death that were related to sacituzumab govitecan were febrile neutropenia (fever with a low number of white blood cells), neutropenic colitis (inflammation of the large intestine associated with a low level of white blood cells called neutrophils), sepsis (serious response to infection), and septic shock (blood pressure drop to a dangerously low level after an infection). The side effects leading to death that were related to docetaxel were pneumonia (lung infection), pneumonitis (inflammation of the lungs), and an unknown cause.

What do the results of the EVOKE-01 study mean?

Although the results of this study show that participants treated with sacituzumab govitecan did not live significantly longer than those treated with docetaxel, sacituzumab govitecan was found to be an active treatment against advanced or metastatic NSCLC that allowed some participants to live a little longer. The modest improvement seen with sacituzumab govitecan treatment did not depend on the NSCLC subtype, meaning that participants received benefit from sacituzumab govitecan treatment regardless of the type of NSCLC they had. The benefit was seen in all participants. Additionally, participants with NSCLC that remained stable or became worse after their prior anti–PD-(L)1 therapy also saw a moderate survival benefit.

The quality of a person's life when living with any cancer and receiving treatment is a very important concern. The results of this study show that sacituzumab govitecan treatment had fewer severe side effects; it was also able to prevent worsening of overall NSCLC symptoms (related to cough, pain, shortness of breath, fatigue, and appetite) and, particularly, shortness of breath for a longer period than the FDA-approved and most commonly used treatment, docetaxel.

The results of this study support further investigation of sacituzumab govitecan as a potential treatment for people with previously treated advanced or metastatic NSCLC.

Significance
Although the results of the EVOKE-01 study do not show that sacituzumab govitecan treatment significantly lengthens life compared with docetaxel chemotherapy, they do suggest that sacituzumab govitecan is a possible treatment for people with previously treated advanced or metastatic NSCLC, with fewer severe side effects than docetaxel treatment. Sacituzumab govitecan needs to be studied further in people with this disease.

Where can readers find more information on the EVOKE-01 study?

The original EVOKE-01 article titled 'Sacituzumab Govitecan Versus Docetaxel for Previously Treated Advanced or Metastatic Non-Small Cell Lung Cancer: The Randomized, Open-Label Phase III EVOKE-01 Study', has the following full citation:
Paz-Ares LG, Juan-Vidal O, Mountzios GS, et al. Sacituzumab Govitecan Versus Docetaxel for Previously Treated Advanced or Metastatic Non-Small Cell Lung Cancer: The Randomized, Open-Label Phase III EVOKE-01 Study. *J Clin Oncol* 2024;42(24):2860–2872.

A free copy of the original article can be obtained here: https://ascopubs.org/doi/10.1200/JCO.24.00733

Study start date: November 17, 2021
Study recruitment ended: May 30, 2023
Study primary completion date: November 29, 2023

For more information on the EVOKE-01 study, please visit:
ClinicalTrials.gov (https://clinicaltrials.gov/study/NCT05089734)

To learn more about sacituzumab govitecan, please visit:
Drugs@FDA (https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm)
European Medicines Agency (https://www.ema.europa.eu/en/medicines/human/EPAR/trodelvy)

If you were a study participant and have questions about the results of this trial and sacituzumab govitecan (brand name TRODELVY®), please speak with the study doctor or staff at your study center.

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