PLAIN LANGUAGE SUMMARY OF CLINICAL STUDY RESULTS

Study Sponsor: Gilead Sciences

Gilead Study Number: GS-US-548-5918

Date of Study: October 2021 to October 2024 (the study closed per Sponsor's decision)

Short Study Title: A Study of Magrolimab in People with Solid Tumors

Study Nickname: ELEVATE-Lung & UC

Date of this Plain Language Summary: March 2025

The information in this summary does not include any information available after this date.

Thank you

Thank you to the participants who contributed to the clinical study for **magrolimab**, also known as **GS-4721** or **Hu5F9-G4**.

Gilead Sciences sponsored this study. We believe it is important to share the results with study participants and the general public.

If you participated in the study and have questions about the results, please speak with a doctor or staff member at the study site.

Always talk to a doctor or a healthcare provider before making any treatment changes.

This document is a short summary of this study written for a general audience. Links to scientific summaries of this study can be found at the end of this document.

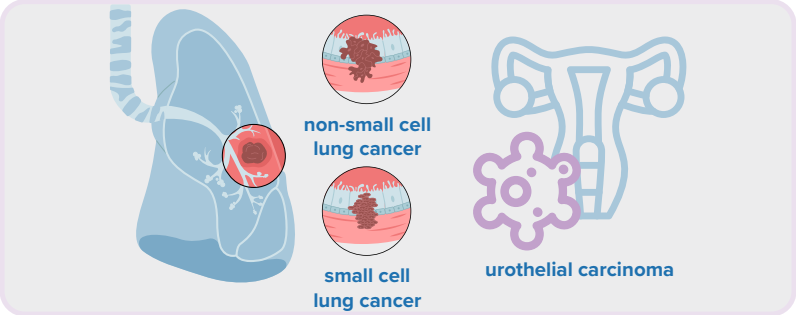
General information about the study

What are solid tumors?

Solid tumors are abnormal masses of cells that form in organs or tissues like the lungs, breast, or colon. Unlike fluid-filled cysts, these tumors consist of a solid mass of cells, which can be either cancerous or non-cancerous. Sometimes, the solid cancer becomes metastatic, which means it can spread to other parts of the body. Therefore, its early detection and treatment are important.

There are treatments available for solid tumors. However, these treatments may not always work, lose their effectiveness over time or cause side effects. Once the combination treatment fails, the people are given a single medicine as the standard of care. Single medicine may not be very effective. Therefore, there is a need for new combination treatments to treat solid tumors.

Magrolimab is a monoclonal antibody (MAb). MAbs are proteins made in a lab to help the body fight diseases like cancer. Docetaxel is a chemotherapy medicine. Chemotherapy medicines are used to treat cancers.



In this study, the researchers wanted to see if adding magrolimab to docetaxel could help people with solid tumors whose cancer has stopped responding to the standard treatment or has come back after an initial response to the treatment. They investigated this in participants with solid tumors like metastatic urothelial carcinoma **(mUC)**, metastatic non-small cell lung cancer **(mNSCLC)**, and small cell lung cancer **(SCLC)**. **UC** is a cancer of the urethra (a tube that carries urine from bladder to outside of the body). **NSCLC** is more common and grows slowly, whereas **SCLC** is aggressive and spreads fast.

What was the purpose of the study?

The purpose of this study was to find out if the recommended dose of magrolimab was safe to be given with docetaxel. It also checked how effective the treatment was in shrinking or controlling tumors in the participants with solid tumors.

The main questions the researchers wanted to answer in this study were:

For the effectiveness of the drug:

- How many participants achieved a **complete or partial response**?
  - **Complete response** means all tumors went away. **Partial response** means there was a shrink in the tumors and no new tumors appeared. **Objective response** includes both complete and partial responses, meaning the treatment is working to reduce the cancer.

For the safety of the drug:

- How many participants had unwanted medical events or abnormalities in their laboratory test results (laboratory test results were outside the normal range)?
- What side effects did participants have during the study, if any?

Who took part in the study?

- **106** participants with solid tumors were enrolled in Spain, the United States, France, Poland, and the United Kingdom in the study.

People could take part in the study if they:

- Were 18 years or older
- Had confirmed solid tumors of mUC, mNSCLC, or mSCLC
- Took treatment for solid tumors before, but it failed

The participants enrolled in the study were between the ages of **36** and **82** years.

The participants from each country are shown below (Number (%) of participants).

Spain	40 **(38%)**
United States	39 **(37%)**
France	18 **(17%)**
Poland	6 **(6%)**
United Kingdom	3 **(3%)**

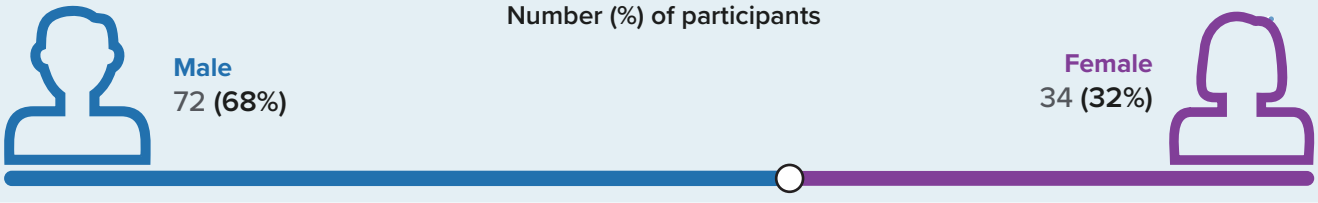
The race of participants is shown below (Number (%) of participants).

White	83 **(78%)**
Asian	3 **(3%)**
Black or African American	2 **(2%)**
Not collected	18 **(17%)**

The ethnicity of participants is shown below (Number (%) of participants).

Not Hispanic or Latino	83 **(78%)**
Not collected	19 **(18%)**
Hispanic or Latino	4 **(4%)**

Participant breakdown by sex
Number (%) of participants



What happened during the study?

This was an **open-label**, **Phase 2** study with 2 parts: **Safety Run-in** and **Phase 2**.

Phase 2 means the researchers tested magrolimab with docetaxel in a small number of people with solid tumors. **Open-label** means the participants, the study doctors, and the study staff knew what treatment the participants received in each part.

Safety Run-in

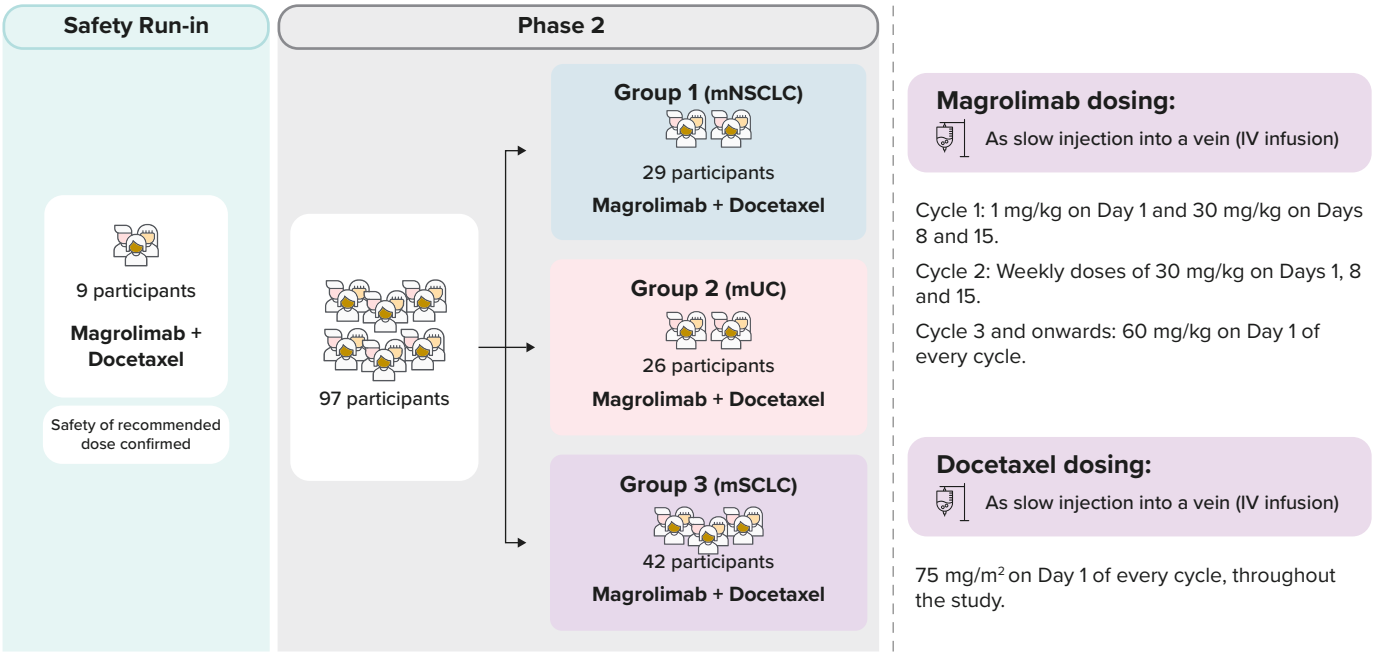
Safety Run-in checked if the recommended dose of magrolimab was safe to be given with docetaxel, in a small group of participants before giving it to the rest of the participants in Phase 2.

Phase 2

After confirming the recommended dose of magrolimab in Safety Run-in, additional participants were enrolled in Phase 2. Participants with mUC, mNSCLC, and mSCLC were assigned to 3 separate groups based on their disease type to receive the treatment.

The participants received treatment in 21-day cycles. A cycle is the time between one round of treatment and the start of the next. Magrolimab doses were based on the participant's weight (mg/kg), while docetaxel doses followed standard clinical practice.

The below graphic shows the treatment plan in each part:



Participants were to continue the treatment until the end of the study. The treatment was stopped if their disease got worse, they had unacceptable side effects, they decided to leave the study, or they died.

The study was closed because the sponsor decided to stop developing magrolimab, both alone and in combination, as a treatment for cancer.

What were the results of the study?

This is a summary of the main results from this study. The individual results of each participant might be different and are not in this summary. A detailed presentation of the results can be found on the websites listed at the end of this summary.

How many participants achieved a complete or partial response?

The researchers assessed participants in Phase 2 groups to see if they achieved a complete or partial response. The participants had blood tests and scans during the study. Study doctors reviewed the results of these tests and scans to determine if participants met the criteria for complete or partial response. This helped researchers determine the effectiveness of the drug.

The participants who achieved a complete or partial response in the Phase 2 groups were:

- 5 out of 29 (17%) participants in Group 1 (mNSCLC: Magrolimab + Docetaxel)
- 1 out of 26 (4%) participants in Group 2 (mUC: Magrolimab + Docetaxel)
- 2 out of 42 (5%) participants in Group 3 (mSCLC: Magrolimab + Docetaxel)

Gilead decided to close the study early. The data was not sufficient for researchers to conclude if the magrolimab and docetaxel treatment was effective.

What were the safety results of the study?

How many participants had unwanted medical events or abnormalities in their laboratory test results?

To answer this question, the researchers first monitored the safety of magrolimab and docetaxel combination in the first 6 out of 9 participants in Safety Run-in to find if there are any dose-limiting toxicities (**DLTs**).

- **None of the 6 participants in Safety Run-in had any DLTs.**

DLTs were the medical events that were severe enough to stop the study doctor from giving the recommended dose of magrolimab in combination with docetaxel.

In case DLTs were observed, a lower dose of magrolimab would be studied in combination with docetaxel.

The researchers confirmed that the recommended dose of magrolimab was safe and well-tolerated to be given in combination with docetaxel, in Phase 2 part.

The recommended dose of magrolimab was an initial dose of 1 mg/kg followed by 30 mg/kg administered weekly up to Cycle 2 and 60 mg/kg on Day 1 of each cycle from Cycle 3 onwards.

The researchers also kept track of any **unwanted medical events** that the participants had during the study. They also did laboratory tests and measurements of participants before and after taking the treatment. They checked if the changes in laboratory test values were abnormal, meaning they were out of normal reference range.

An **unwanted medical** event is any unwanted sign or symptom that participants may have during the study.

The unwanted medical events or abnormalities in laboratory test **results may or may not be caused by the study treatment.**

The table below lists how many participants had unwanted medical events or abnormalities in their laboratory test results during the study.

Unwanted Medical Events or Abnormalities in Laboratory Test Results

	Safety Run-in (Magrolimab + Docetaxel) (out of 9 participants)	Phase 2		
		Group 1 (mNSCLC) (Magrolimab + Docetaxel) (out of 29 participants)	Group 2 (mUC) (Magrolimab + Docetaxel) (out of 26 participants)	Group 3 (mSCLC) (Magrolimab + Docetaxel) (out of 42 participants)
Number (%) of participants				
Participants with any unwanted medical event	9 (100%)	29 (100%)	26 (100%)	42 (100%)
Participants with any abnormalities in their laboratory test results	9 (100%)	29 (100%)	26 (100%)	42 (100%)
Participants with serious or potentially life-threating abnormalities in laboratory test results	7 (78%)	24 (83%)	24 (92%)	33 (79%)

What side effects did participants have during the study, if any?

The researchers also checked the **side effects** of magrolimab in combination with docetaxel during the entire study.

The results from several studies are usually needed to help conclude if a treatment actually causes a side effect:

Side effects are defined as unwanted medical events that the study doctors thought **might be caused by study treatment.**

A side effect is considered "serious" if it:

- results in death
- is life-threatening
- is considered by the study doctor to be medically important
- causes lasting problems
- requires hospital care
- causes a birth defect

The table below lists how many participants had side effects during the study.

Overall Side Effects

	Safety Run-in (Magrolimab + Docetaxel) (out of 9 participants)	Phase 2			Total (out of 106 participants)
		Group 1 (mNSCLC) (Magrolimab + Docetaxel) (out of 29 participants)	Group 2 (mUC) (Magrolimab + Docetaxel) (out of 26 participants)	Group 3 (mSCLC) (Magrolimab + Docetaxel) (out of 42 participants)	
	Number (%) of participants				
Side effects	9 (100%)	29 (100%)	25 (96%)	42 (100%)	105 (99%)
Serious side effects	2 (22%)	10 (34%)	8 (31%)	12 (29%)	32 (30%)
Side effects that caused participants to stop treatment	0	6 (21%)	0	7 (17%)	13 (12%)

1 out of 42 (2%) participants died in Group 3 due to a side effect. The side effect was bleeding in parts of the brain (brain hemorrhage). The cancer already spread to participant's brain (brain metastasis).

What were the serious side effects?

The table below lists serious side effects that occurred in more than 1 participant during the study.

Serious Side Effects

Serious side effects	Safety Run-in (Magrolimab + Docetaxel) (out of 9 participants)	Phase 2			Total (out of 106 participants)
		Group 1 (mNSCLC) (Magrolimab + Docetaxel) (out of 29 participants)	Group 2 (mUC) (Magrolimab + Docetaxel) (out of 26 participants)	Group 3 (mSCLC) (Magrolimab + Docetaxel) (out of 42 participants)	
	Number (%) of participants				
Fever with low number of white blood cells (Febrile neutropenia)	0	3 (10%)	4 (15%)	3 (7%)	10 (9%)
Low number of red blood cells (Anemia)	0	3 (10%)	2 (8%)	3 (7%)	8 (8%)
Low number of white blood cells (Neutropenia)	0	2 (7%)	1 (4%)	1 (2%)	4 (4%)
Reaction during or after taking a drug as injection into a vein (Infusion) (Infusion related reaction)	0	1 (3%)	0	2 (5%)	3 (3%)
The body's response to an infection leading to severe illness (Sepsis)	0	0	0	3 (7%)	3 (3%)
Inflammation of lung tissue (Pneumonitis)	0	0	0	2 (5%)	2 (2%)

What were the non-serious side effects?

The table below lists the **most common non-serious side effects** that occurred in at least 25% of the study participants. These side effects were not serious in nature and did not meet the definition of 'serious side effects' mentioned in the section above in this summary.

Non-Serious Side Effects

Non-serious side effects	Safety Run-in (Magrolimab + Docetaxel) (out of 9 participants)	Phase 2			Total (out of 106 participants)
		Group 1 (mNSCLC) (Magrolimab + Docetaxel) (out of 29 participants)	Group 2 (mUC) (Magrolimab + Docetaxel) (out of 26 participants)	Group 3 (mSCLC) (Magrolimab + Docetaxel) (out of 42 participants)	
	Number (%) of participants				
Low number of red blood cells (Anemia)	5 (56%)	20 (69%)	14 (54%)	26 (62%)	65 (61%)
Abnormal physical weakness (Asthenia)	1 (11%)	14 (48%)	9 (35%)	17 (40%)	41 (39%)
Low number of white blood cells (Neutropenia)	0	13 (45%)	13 (50%)	15 (36%)	41 (39%)
Diarrhea	2 (22%)	13 (45%)	6 (23%)	16 (38%)	37 (35%)
Extreme tiredness (Fatigue)	6 (67%)	6 (21%)	4 (15%)	11 (26%)	27 (25%)

There were other serious and non-serious side effects, but those occurred in fewer participants. Some participants may have had more than 1 serious or non-serious side effect.

How has this study helped researchers?

The researchers learned more about the safety and effectiveness of magrolimab and docetaxel combination and how it works in people living with solid tumors.

The results from several studies are needed to help decide which treatments work and are safe. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Gilead Sciences does not plan to have further clinical studies with magrolimab alone or in combination.

Where can I learn more about this study?

You can find more information about this study on the websites listed below.

Organization (Website)	Study Identifier
European Medicines Agency (www.clinicaltrialsregister.eu)	EudraCT number: 2020-005265-14
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	ClinicalTrials.gov ID: NCT04827576
www.gileadclinicaltrials.com	GS-US-548-5918

Please note that information on this/these websites may be presented in a different way from this summary.

Full Study Title: A Phase 2, Multi-Arm Study of Magrolimab in Patients With Solid Tumors

To learn more about clinical trials in general,
please visit this page on www.clinicaltrials.gov website

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Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

GILEAD