Plain Language Summary of Clinical Study Results

Bristol Myers Squibb™

Short Study Title: A Study of the Safety, Efficacy, and Biomarker Response of BMS-986165 in Participants with Moderate to Severe Ulcerative Colitis

Study Medicine: BMS-986165, also called deucravacitinib (doo-kra-va-SIT-ih-nib).

Date of Summary: 5 August 2024

Thank You!

Bristol-Myers Squibb, the sponsor, would like to thank you for taking part in this clinical study for a medicine called deucravacitinib.

With your help, we learned more about deucravacitinib and what effect it has on your ulcerative colitis.

Overview

In this study:

- About 50% of participants had a clinical response 12 weeks after taking 12 mg deucravacitinib for the first time and about 50% of participants had a clinical response 12 weeks after taking placebo for the first time.

> A **clinical response** means the patient's ulcerative colitis improved because of a treatment. Researchers and doctors use this term to show that the treatment is working.

  - Researchers could not determine if the drug was or was not effective. This is because the study only included a small number of patients.
- Researchers also learned what side effects participants might have experienced while taking the study medicine.

Why was the study done?

This study was done because researchers were looking for a better way to treat ulcerative colitis.

Ulcerative colitis (UC) is a type of inflammatory bowel disease (IBD) that makes the digestive tract swollen and causes sores (ulcers) to form. Some signs and symptoms of UC include:

- Diarrhea, often with blood or pus
- Rectal bleeding (passing a small amount of blood with stool)
- Abdominal pain and cramping
- Rectal pain
- Weight loss

- Fatigue
- Fever

Even though treatments have improved in recent years, treating UC is still difficult. This is because many current treatments don't work well enough, only help a little, or cause side effects.

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

- What percentage of participants had a clinical response after taking either 12 mg deucravacitinib or placebo for 12 weeks?
    - Some participants were initially assigned to receive 6 mg of deucravacitinib. This group was later removed from the first part of the study and was not included in the clinical response results.
- What side effects did participants have during the study?

Who took part in the study?

The study included people with ulcerative colitis (UC) who:

- Were diagnosed with UC more than three months before starting the study.
- Had moderate to severe colitis that had spread to other parts of the colon.

- In total, 22 male and 16 female participants took part in the study.
- They were between 20 and 61 years old.

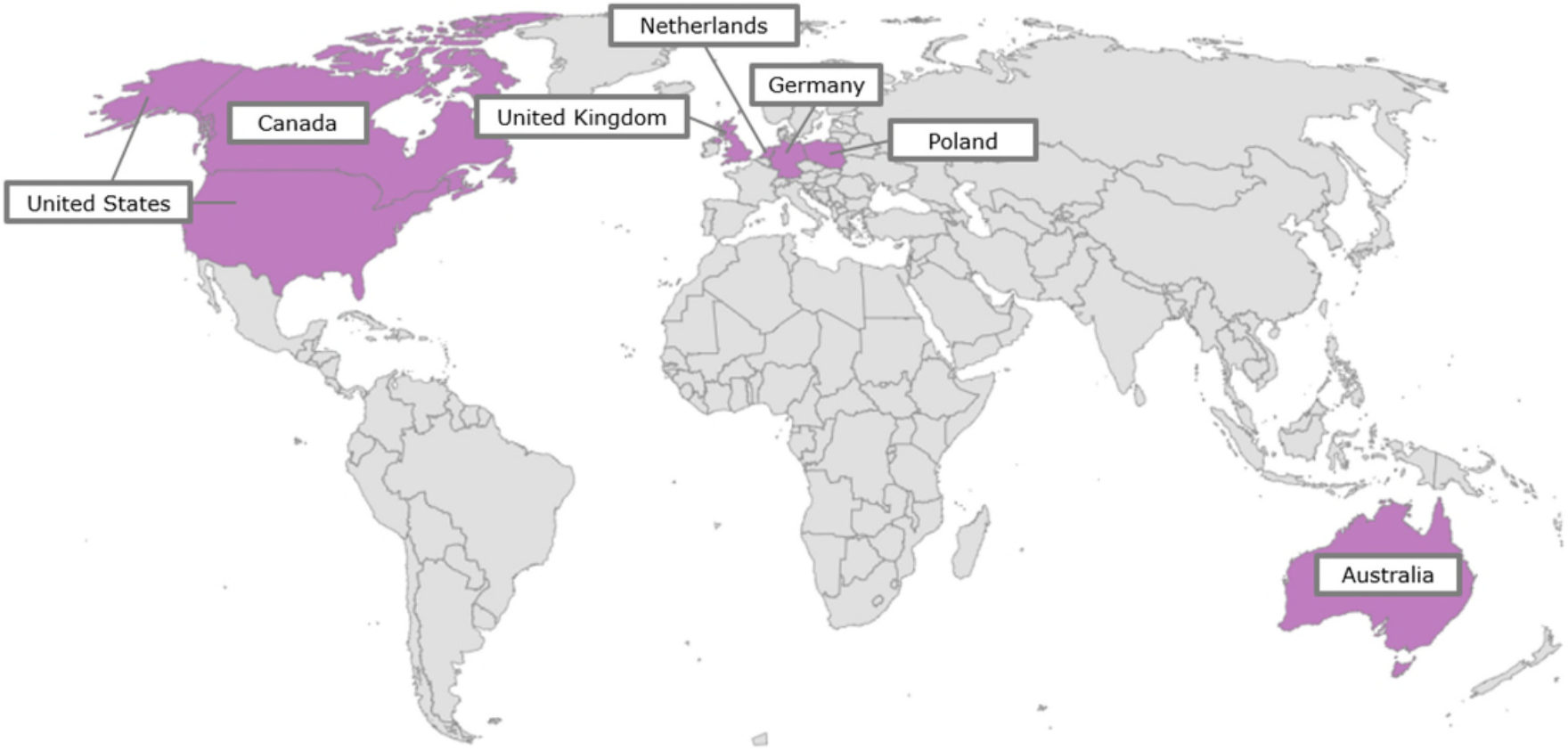
What happened during the study?

The study started in March 2021 and ended in November 2023.

The participants were planned to be in the study for up to 60 weeks or until their ulcerative colitis got worse, or they left the study early because of their choice or the study doctor's decision.

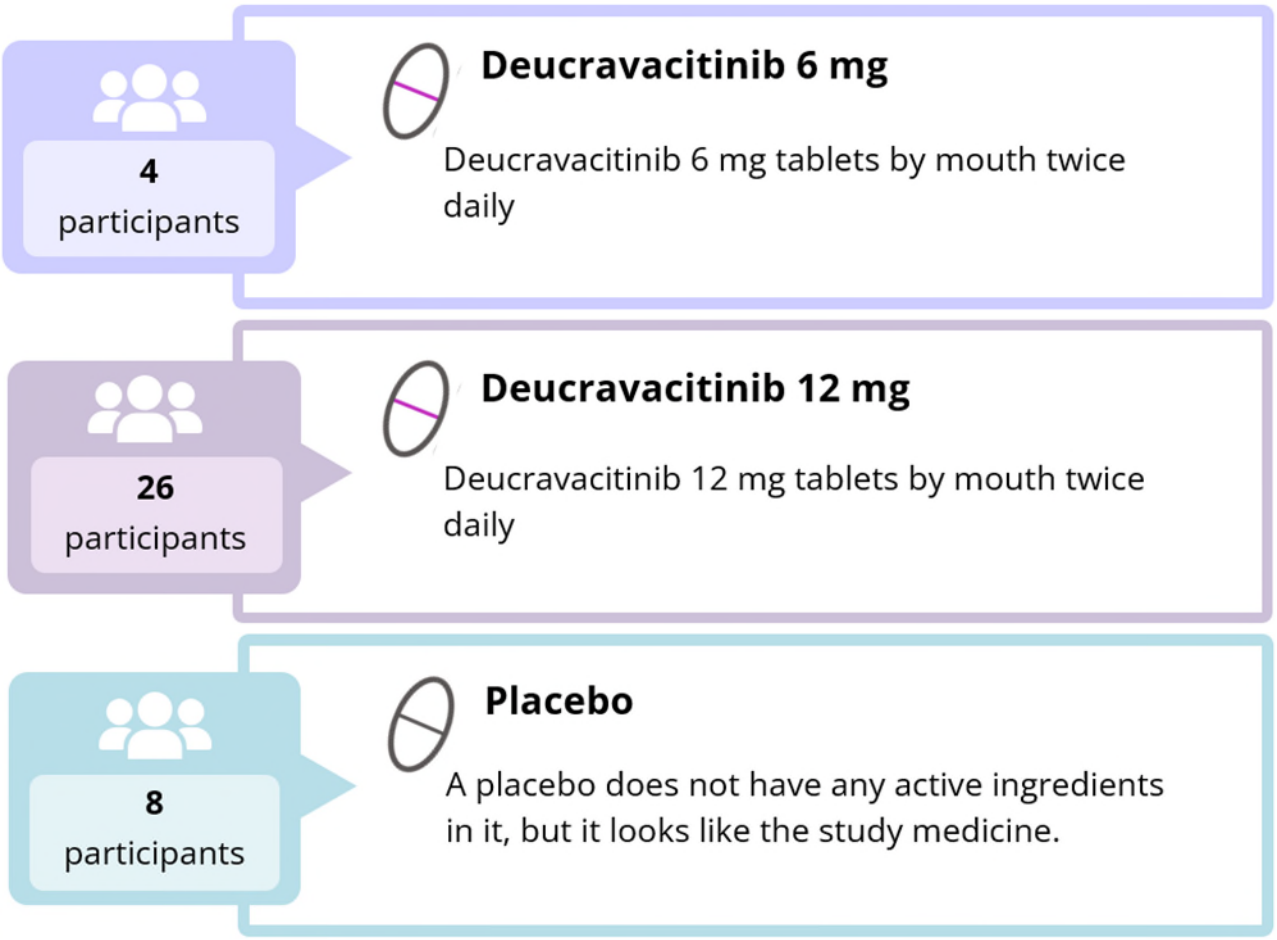
The study was ended early. This was because of a business decision and was not due to safety concerns.

The map below shows where study participants were from:



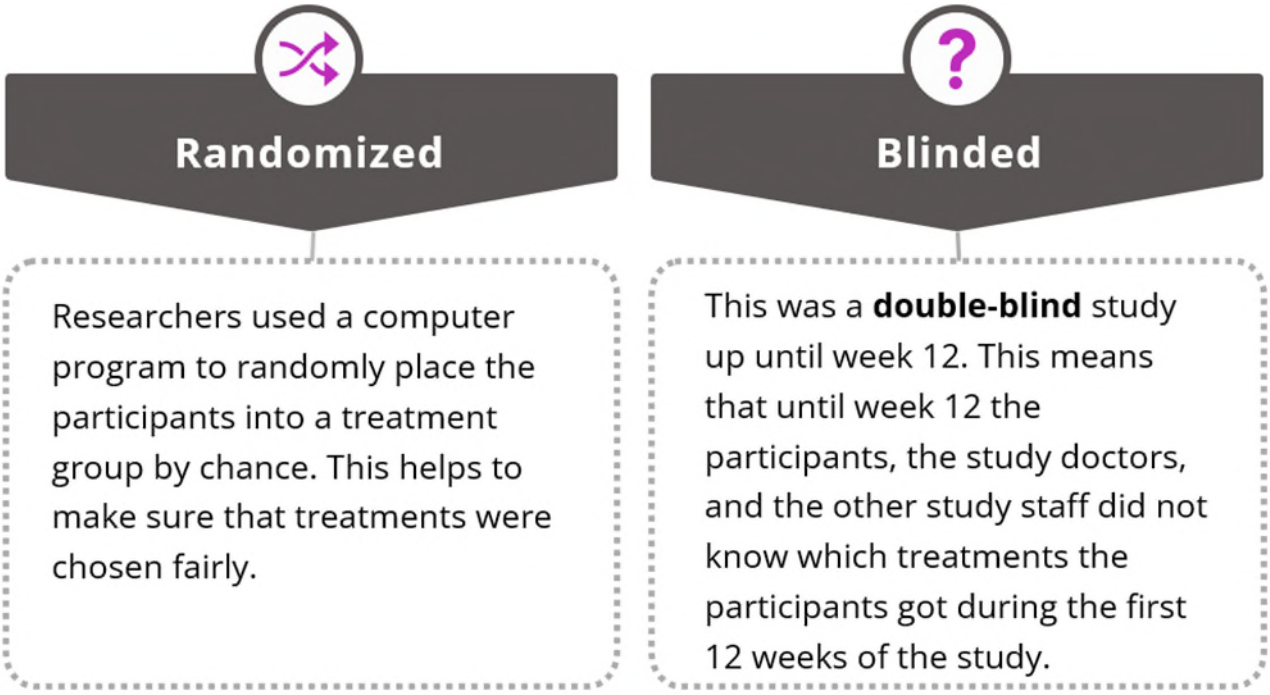
What treatments were studied?

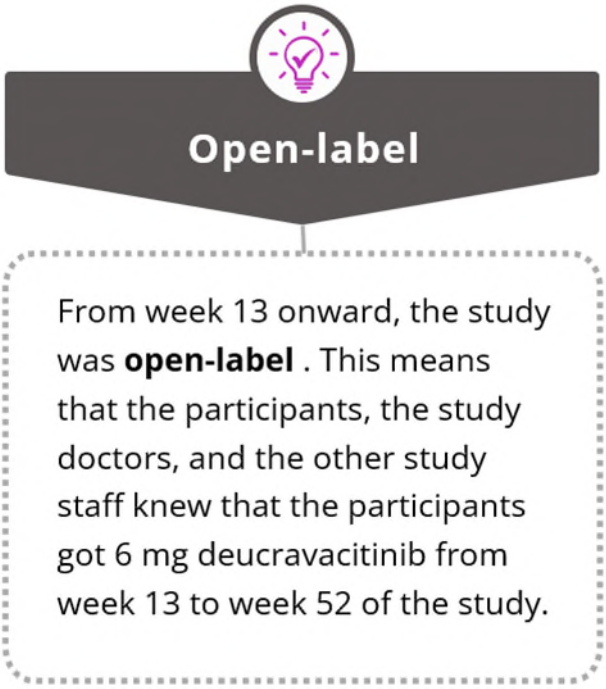
For the first 12 weeks of the study, participants were randomly assigned to one of the treatment groups below. After week 12, all participants received 6 mg of deucravacitinib.



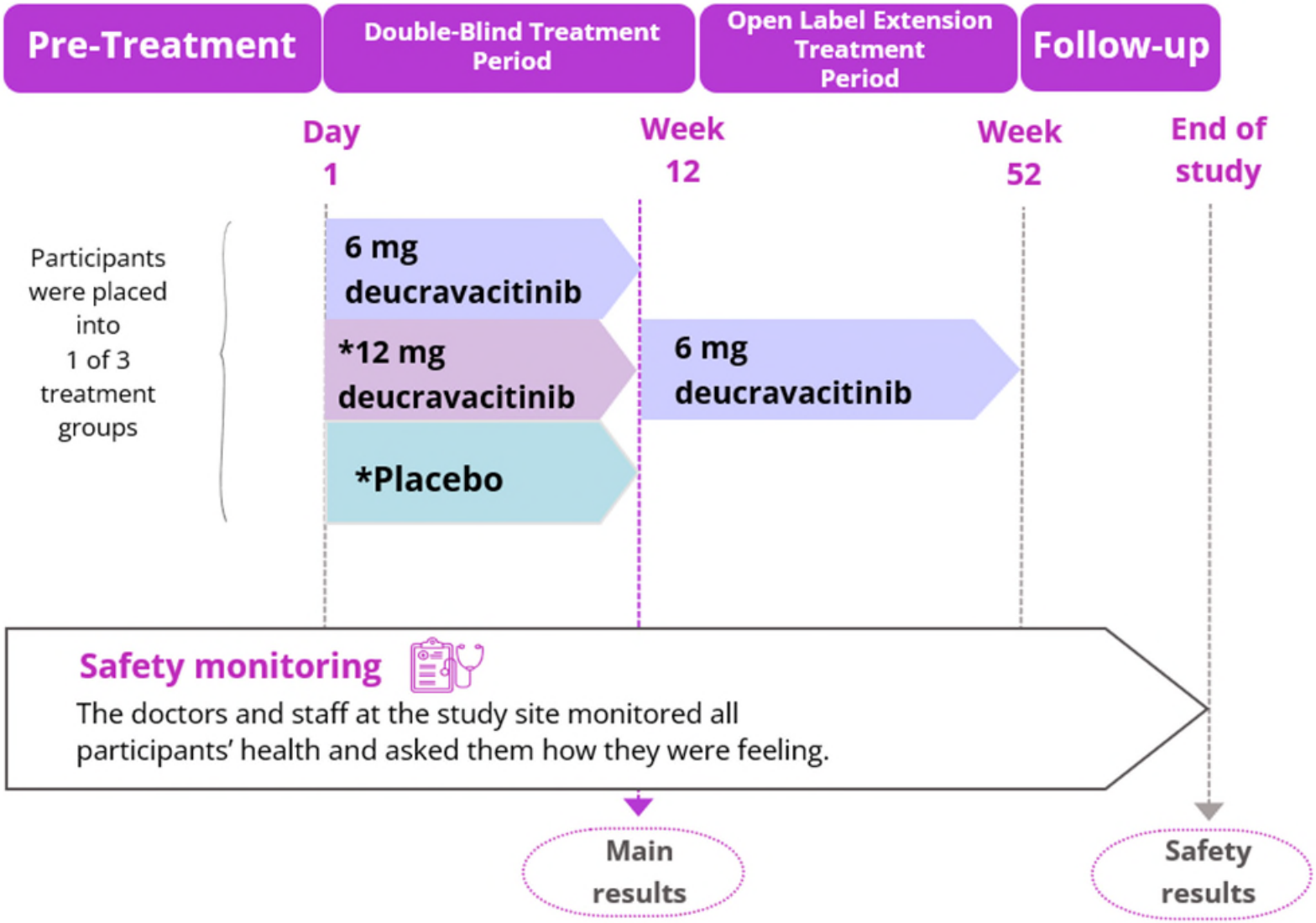
How was the study done?

This section describes what kind of study it was and what happened in the study.





The figure below shows what happened in the study.



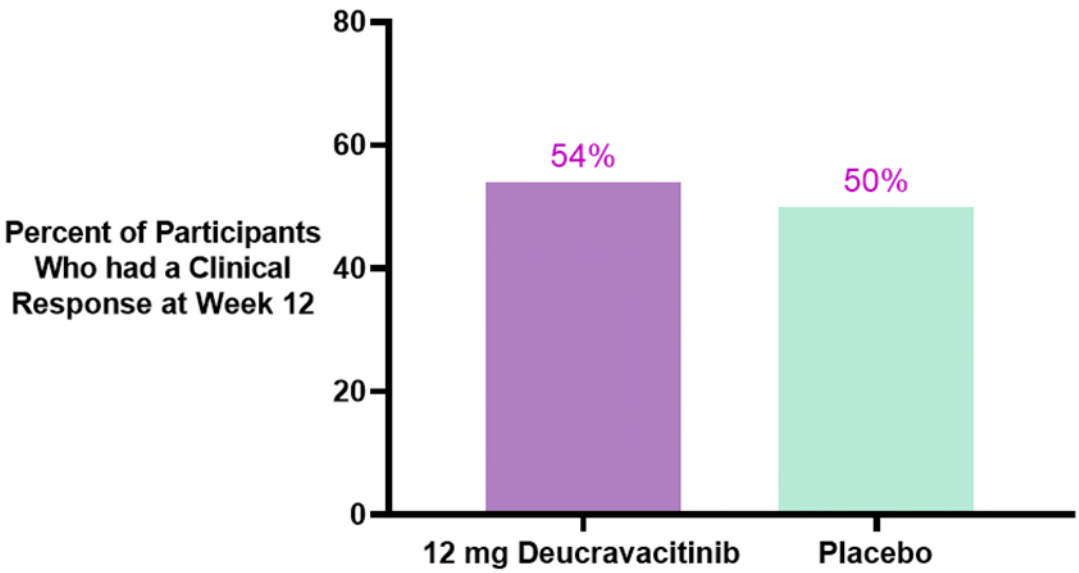
*Participants who took 12 mg deucravacitinib or placebo in the double-blind treatment period switched to take 6 mg deucravacitinib in the open label extension period.

What were the main results of the study?

This section includes the results of 34 participants who were assigned to either the 12 mg deucravacitinib group or the placebo group during the double-blind treatment period of the study. Some participants were initially assigned to receive 6 mg of deucravacitinib. This group was later removed from the first part of the study and was not included in the clinical response results.

What percentage of participants had a clinical response after taking either deucravacitinib or placebo for 12 weeks?

A **clinical response** is when a patient's symptoms get better because of a treatment. Researchers and doctors use this term to show that the treatment is working. In this study clinical response was measured using the modified Mayo score. This score is calculated based on a combination of the patient's symptoms (summarized from a daily questionnaire) and their endoscopy results at certain time points in the study. Researchers compared scores from the start of the study and 12 weeks after participants first took the study medicine. A participant had a clinical response if their Mayo score went down, and they met certain other criteria.



54% of participants had a **clinical response** 12 weeks after taking **12 mg of deucravacitinib** for the first time.
This was 14 out of 26 participants.

50% of participants had a **clinical response** 12 weeks after taking **placebo** for the first time.
This was 4 out of 8 participants.

- About half of the participants in both the 12 mg deucravacitinib group and the placebo group had a clinical response after 12 weeks.
- However, researchers could not clearly tell if 12 mg twice a day deucravacitinib was working to treat ulcerative colitis. This was because the study only included a small number of participants. With fewer participants, it's harder to find out if there is a real difference or effect.

What side effects did participants have during the study?

The safety of every participant is important throughout the development and testing of study medicines. The study doctors keep a record of all signs and symptoms the participants have during the study.

Symptoms or abnormal findings that study doctors think may or may not be related to treatment are called **"side effects"**.

A side effect that is life-threatening, needs hospital care, causes death, causes birth defects, or is considered by the study doctor as medically important is called a **"serious side effect"**.

The side effects that study doctors thought may be related to the study medicine are described in this section.

This section includes the results of 30 participants who took at least 1 dose of the study medicine.

Double-Blind Period

The table below shows how many participants had side effects reported by the study doctors as related to study treatment during the double-blind period.

Overall side effects in double-blind period	12 mg deucravacitinib 26 participants	6 mg deucravacitinib 4 participants	Placebo 8 participants
	Number of participants (%)		
How many participants had any side effects related to study treatment?	14 (54%)	3 (75%)	3 (38%)
How many participants had serious side effects related to study treatment?	1 (4%)	0 (0%)	0 (0%)
How many participants stopped taking the study medicine because of side effects related to study treatment?	0 (0%)	0 (0%)	0 (0%)
How many participants died from side effects related to study treatment?	0 (0%)	0 (0%)	0 (0%)

Open-Label Period

The table below shows how many participants had side effects reported by the study doctors as related to study treatment during the open-label period. Participants are shown under their original treatment group.

Overall side effects in the open-label period	12 mg deucravacitinib 26 participants	6 mg deucravacitinib 4 participants	Placebo 8 participants
	Number of participants (%)		
How many participants had any side effects related to study treatment?	5 (19%)	3 (75%)	5 (63%)
How many participants had serious side effects related to study treatment?	0 (0%)	0 (0%)	0 (0%)
How many participants stopped taking the study medicine because of side effects related to study treatment?	0 (0%)	0 (0%)	1 (13%)
How many participants died from side effects related to study treatment?	0 (0%)	0 (0%)	0 (0%)

What were the side effects?

Listed below are the most common side effects reported by the study doctors as related to study treatment reported during the double-blind period and the open-label period.

- Acne, a skin condition that happens when hair follicles get clogged with oil and dead skin cells.
- Rash, an area of irritated or swollen skin that can be red, bumpy, scaly, or itchy.
- Mouth ulceration, painful and usually small sores that form in the mouth or at the bottom of the gums.

Symptoms or abnormal findings that study doctors think may or may not be related to treatment are called **"side effects"**.

What were the serious side effects?

The table below shows the only serious side effects reported as related to study treatment reported during the study. This side effect occurred in one participant.

- Deep vein thrombosis, a condition that occurs when a blood clot forms in one or more of the deep veins in the body, usually in the leg.

A side effect that is life-threatening, needs hospital care, causes death, causes birth defects, or is considered by the study doctor as medically important is called a **"serious side effect"**.

How has this study helped participants and researchers?

You have helped us learn more about the safety of deucravacitinib and how it works in participants with ulcerative colitis.

Researchers must look at the results of many studies to decide which treatments work and are safe.

This summary includes only the main results from this one study. Other studies may show new information or different results.

Further studies of deucravacitinib are ongoing. If you have questions about the study results or deucravacitinib, please speak with a doctor or staff member at the study site.

Always talk to a doctor before making any treatment decisions.

Where can I learn more about this study?

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

https://www.clinicaltrials.gov/study/NCT04613518?term=IM011-127&rank=1

https://www.clinicaltrialsregister.eu/ctr-search/trial/2019-004878-26/results

Full Study Title: A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Efficacy and Biomarker Response of BMS-986165 in Subjects with Moderate to Severe Ulcerative Colitis

Study Identification: IM011-127

Bristol Myers Squibb is the sponsor of this study.

For general contact information, go to the link below:

www.globalbmsmedinfo.com