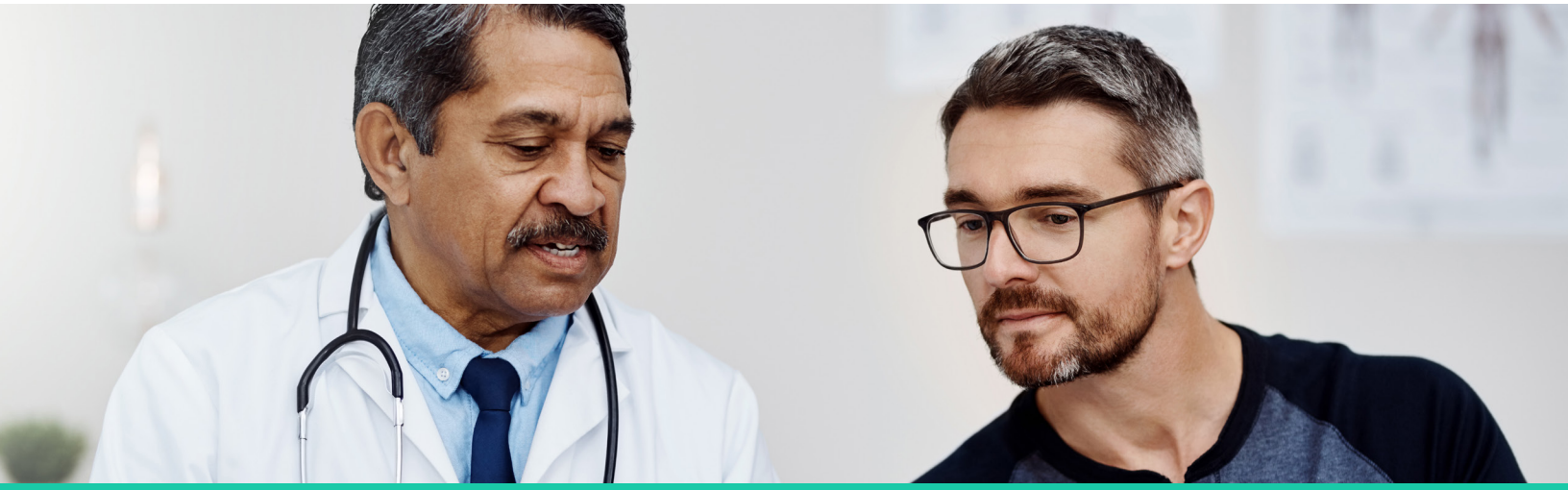
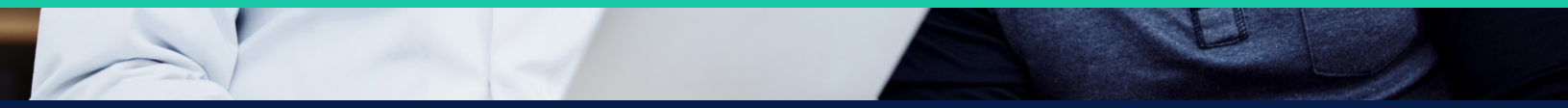
abbvie

Summary of Clinical Trial Results

For Laypersons



A study to learn if the hepatitis C virus remains undetectable in adult patients long after treatment with glecaprevir and/or pibrentasvir

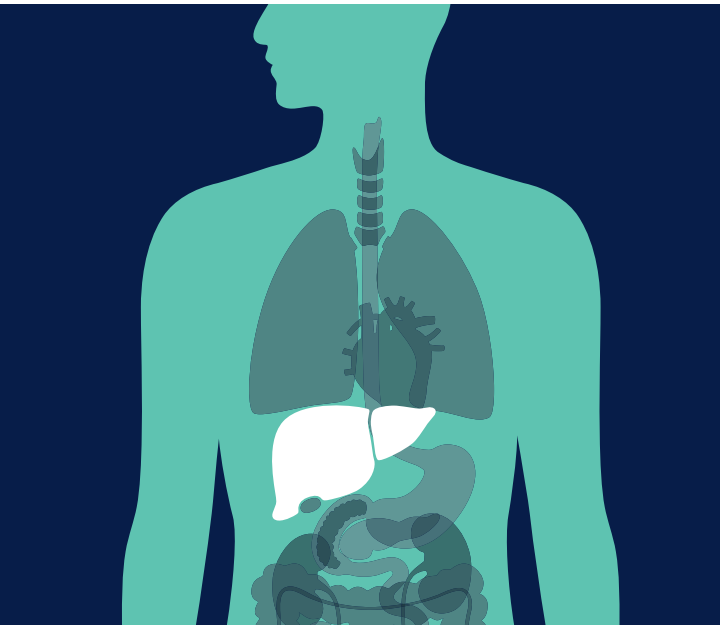


Overall Summary

- Hepatitis C infection is a global health problem caused by a virus in the blood stream.
- Hepatitis C virus (HCV) can lead to liver disease, liver damage, and cancer.
- In this study, doctors looked to see if patients who responded well to HCV treatment with glecaprevir (GLE) and/or pibrentasvir (PIB) in an earlier study maintained their response over 3 years without treatment.
- This study took place from June 2015 to October 2019 in 7 countries.
- A total of 384 adult patients enrolled in the study and 377 patients were included in the study analysis.
- All patients were given GLE and/or PIB for their HCV in an earlier study and completed the follow-up period of that study.
- No treatment was given in this study, but patients were followed for about 3 years after they finished HCV treatment in an earlier study.
- The results of this study may be used by researchers to further study treatment in patients with HCV.
- If you participated in this study and have questions about your individual care, contact the doctor or staff at your study site.

1. General information about the study

1.1. What was the main objective of this study?



Hepatitis C virus (HCV) is a virus in the blood that can cause liver disease, liver damage, and cancer.

Glecaprevir combined with pibrentasvir (GLE/PIB) is currently approved to treat HCV in adult and adolescent patients and works to help stop the virus from multiplying. When these two drugs are taken together, they may stop the virus from multiplying and may stop all of the major types (genotypes 1, 2, 3, 4, 5, and 6) of HCV.

In this study, researchers looked at patients who had taken GLE and/or PIB in an earlier study and tested to see if they maintained their response over the 3 years after finishing treatment.

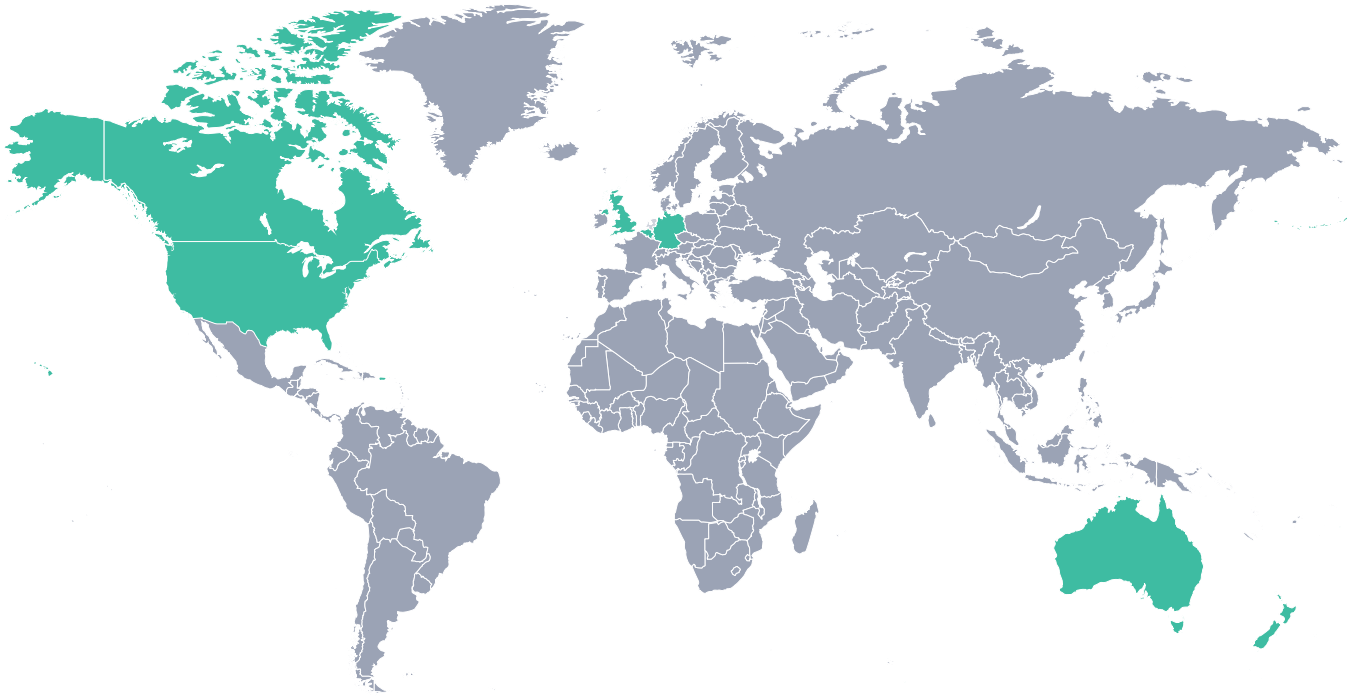
Researchers planned this study as a Phase 2/3 study. Phase 2 studies test potential new treatments in a small number of patients with a condition or disease while Phase 3 studies test potential new treatments in a larger number of patients. This study was created to follow patients who participated in earlier studies of GLE and/or PIB for a longer time.

No treatment was given in this study, but study doctors collected blood samples throughout the 3 years after patients finished GLE and/or PIB treatment in an earlier study to see how long the patient's response to treatment continued after stopping the drug and if patients who failed treatment in the prior study continued to have resistance (changes in the virus that make treatment less effective).

This summary only includes the results of this study, which may be different from the results of other studies.

1.2. When and where was the study done?

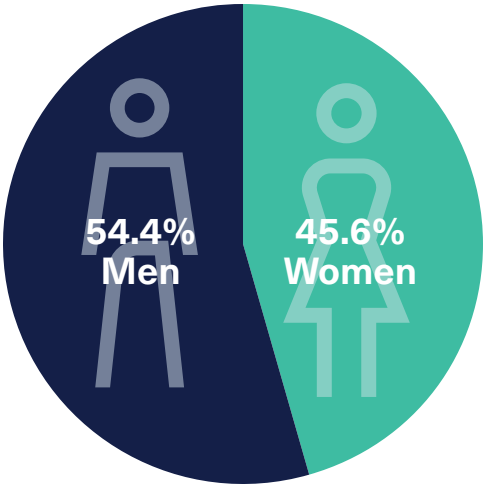
This study took place from June 2015 to October 2019 in the following countries: Australia, Belgium, Canada, Germany, New Zealand, United Kingdom, and the United States.



2. What patients were included in this study?

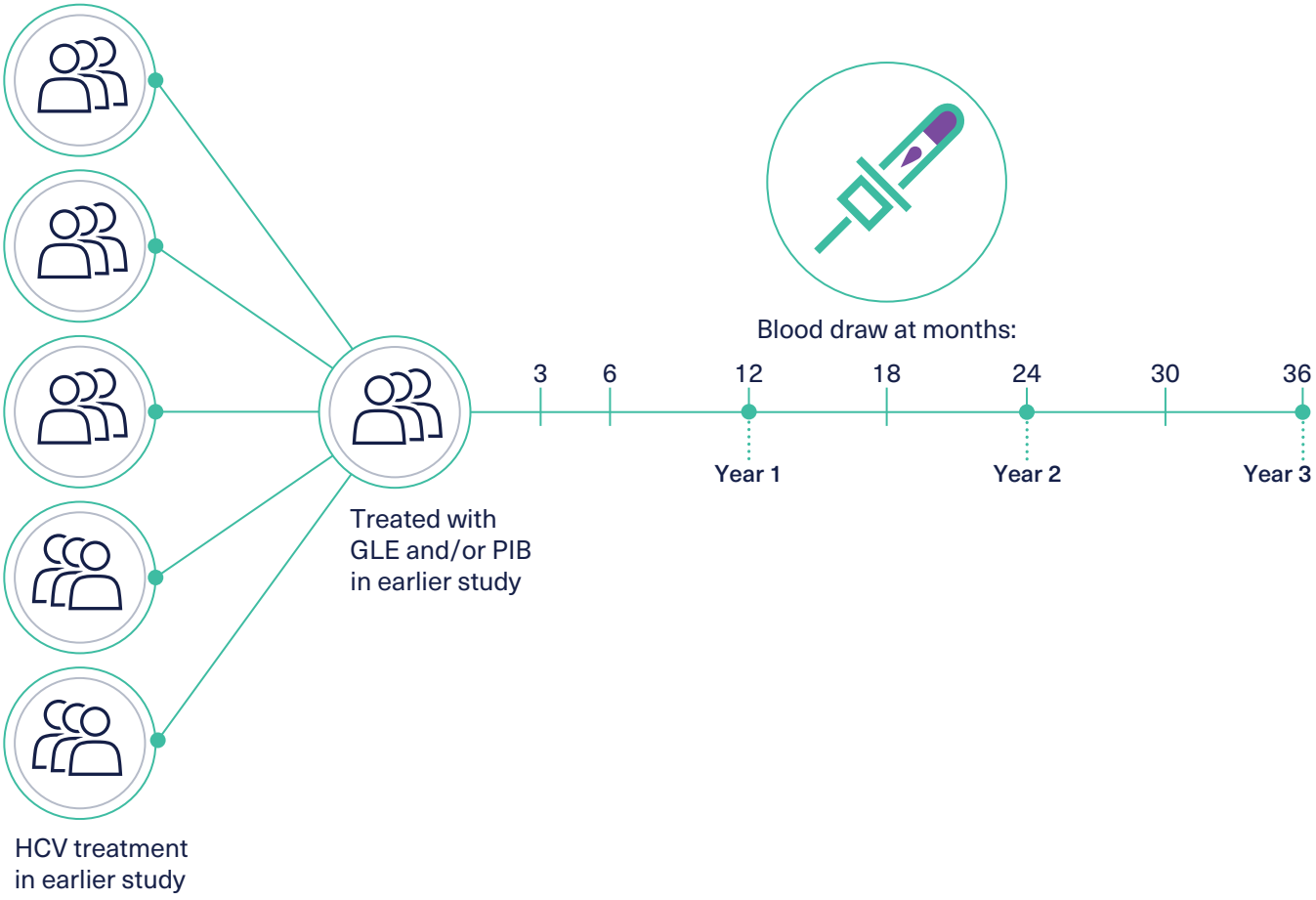
A total of 384 adult patients with hepatitis C joined this study. 377 patients who finished treatment with GLE and/or PIB within the 2 years before joining this study were eligible to participate. 7 patients who joined the study were not included in the study analysis because they were treated with different HCV medicine in the earlier study or given another treatment before joining this study.

There were more men (54.4%) than women (45.6%) in the study, with an age range of 21 to 81 years.



3. Which medicines were studied?

This study did not include treatment. The diagram below shows how the study was organized.



4. What were the side effects?

Side effects are unwanted medical events that happen during a study. They may or may not be caused by the treatment in the study.

A side effect is serious if it leads to death, is life-threatening, puts a participant in the hospital, keeps a participant in the hospital for a long time, or causes a disability that lasts a long time.

Related side effects are side effects that were considered by the study doctor to be at least possibly related to study drug.

Side effects were not collected in this study because patients were not given treatment, but the study collected information about serious side effects related to study procedures (blood draws) and serious side effects considered at least possibly related to prior treatment with GLE and/or PIB in an earlier study.

No serious side effects were identified during this study.

1 patient died during this study from cancer that had spread throughout the body. This death was unrelated to HCV or prior treatment in the earlier study.

	Prior treatment with GLE and/or PIB (377 Patients)
Number of patients with related serious side effects	0 (0.0% of patients)
Number of related side effects leading to death	0 (0.0% of patients)

5. What were the overall results of the study?

The study was completed as planned. Of the 377 patients in the study analysis, 376 had no detectable hepatitis C in the blood stream 12 weeks after finishing treatment in their earlier study (sustained virologic response) while 1 patient had no detectable hepatitis C in the blood stream after finishing treatment in the earlier study but had detectable hepatitis C in the blood stream 12 weeks after finishing treatment (virologic failure).

Of the 376 patients with sustained virologic response in the earlier study, 374 (99.5% of patients) continued to have no detectable hepatitis C in the blood stream during the 3 years of follow-up after treatment in the earlier study. 1 patient had a relapse with hepatitis C detectable in the blood stream (0.3% of patients) and 1 patient had reinfection (0.3% of patients).

The 1 patient with virologic failure in the earlier study had an increase in a protein in their blood that may have caused treatment not to work in the earlier study. The patient was retreated with a different HCV medication and achieved sustained virologic response.

6. How has the study helped patients and researchers?

The results of this study showed that all but one patient had no detectable HCV levels in the blood stream after treatment with GLE and/or PIB continued to have no detectable HCV levels in the blood stream for 3 years after finishing treatment. This demonstrated extended response to earlier treatment, providing longer term benefit to patients who had no detectable HCV levels in the blood stream after finishing treatment with GLE and/or PIB in an earlier study.

This summary only shows the results from this study, which may be different from the results of other studies.

7. Are there any plans for future studies?

There is a possibility for future studies of hepatitis C virus.

8. Who sponsored this study?

This study was sponsored by AbbVie. This summary was reviewed for readability by a patient advocacy group.

9. Where can I find out more information about this study?

Title of Study	A Follow-up Study to Assess Resistance and Durability of Response to AbbVie Direct-Acting Antiviral Agent (DAA) Therapy (ABT-493 and/or ABT-530) in Subjects Who Participated in Phase 2 or 3 Clinical Studies for the Treatment of Chronic Hepatitis C Virus (HCV) Infection
Protocol Number	M13-576
Clinicaltrials.gov	NCT02441283 https://clinicaltrials.gov/ct2/show/NCT02441283?term=M13-576&draw=2&rank=1
EudraCT	2015-000452-24 https://www.clinicaltrialsregister.eu/ctr-search/search?query=2015-000452-24
Study Sponsor	AbbVie Phone: (800) 633-9110 Email: abbvieclinicaltrials@abbvie.com

Thank You

AbbVie wants to thank all the participants for their time and effort that went into making this study possible.

Clinical study participants help advance science!