abbvie

Summary of Clinical Trial Results

For Laypersons

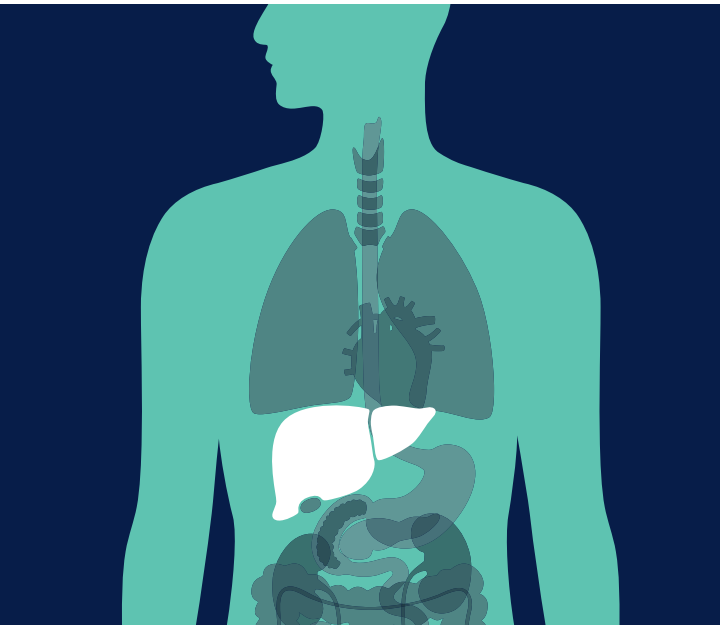
A study to learn how effective and safe a medicine containing glecaprevir and pibrentasvir works to treat adult patients with long-lasting hepatitis C genotypes 1–6 infection with scarring of the liver who have not been treated before

Overall Summary

- Hepatitis C infection is a global health problem caused by a virus in the blood stream.
- Hepatitis C can lead to liver disease, liver damage, and cancer.
- In this study, study doctors tested a medicine called glecaprevir and pibrentasvir (GLE/PIB) in patients who had long-lasting HCV genotypes 1-6 infection with scarring of the liver and had never had treatment for their HCV.
- The aim of this study was to see if 8 weeks of GLE/PIB gave patients the same long-term results as the standard approved 12-weeks of treatment.
- This study took place from April 2017 until November 2019 in 19 countries.
- A total of 343 adult patients joined the study.
- Across the whole study, 97.7% of patients (335 patients) had no detectable HCV in the bloodstream 12 weeks after they finished taking the study drug.
- All patients were given the same dose of GLE/PIB for 8 weeks and then response to treatment was evaluated after a further 12 weeks of follow-up. Around 46.1% of patients (158 patients) had side effects. The most common side effects related to study drug were fatigue (tiredness), itchiness, and headache.
- The results of this study may be used by researchers to further develop this medicine.
- 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 aim of this study?



Hepatitis C virus (HCV) is a virus in the blood that can cause liver disease, liver damage, and cancer. Researchers are looking for a better way to treat HCV in adult patients with HCV genotypes (different types) 1–6.

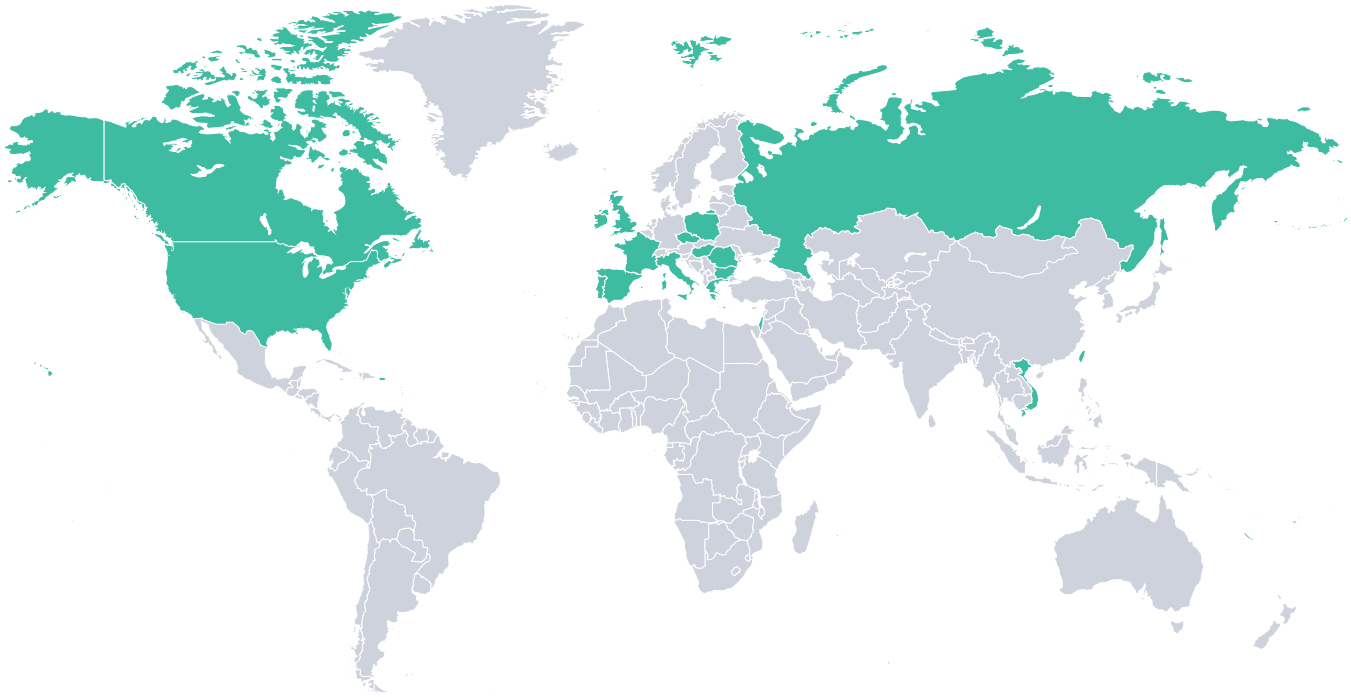
Glecaprevir and pibrentasvir (GLE/PIB) is currently approved to treat HCV in adult and adolescent patients and works to help stop the virus from multiplying. When these two drugs are taken together, they may stop all of the major genotypes (1, 2, 3, 4, 5, and 6) of HCV. At the time the study was started, standard treatment of patients with cirrhosis (scarring of the liver) who had not previously received treatment was 12 weeks of GLE/PIB. In this study, researchers wanted to see if 8 weeks of treatment is as effective as 12 weeks of treatment in treating cirrhotic patients who had not previously been treated for hepatitis C.

Researchers planned this study as a Phase 3 open-label study. Phase 3 studies test potential new treatments in a large number of patients with a condition or disease. “Open-label” means that both the patients and the study doctors knew which treatment was given. In this Phase 3 study, the study doctors looked at the benefits of taking both drugs together over 8 weeks in patients with long-lasting hepatitis C virus who had never had treatment and who had compensated liver cirrhosis (scarring of the liver with no symptoms).

The main aim of the study was to find out if the HCV was no longer found in the bloodstream of patients 12 weeks after taking the last dose of the 8-week GLE/PIB treatment. The study doctors also looked for any unwanted side effects patients may have had after starting treatment with the drugs. 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?

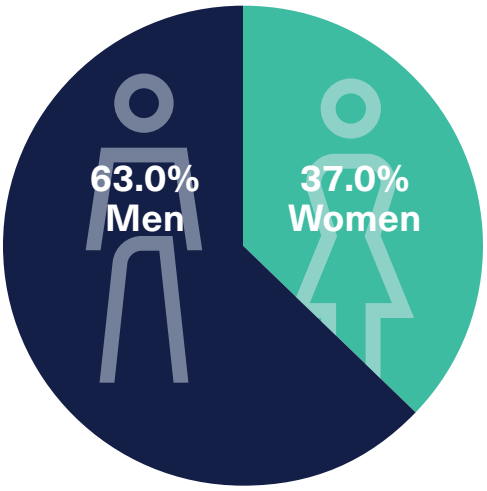
This study took place from April 2017 to November 2019 in the following countries: Bulgaria, Canada, Czech Republic, France, Greece, Hungary, Ireland, Israel, Italy, Poland, Portugal, Romania, Russia, Spain, Taiwan, United Kingdom, United States, and Vietnam.



2. What patients were included in this study?

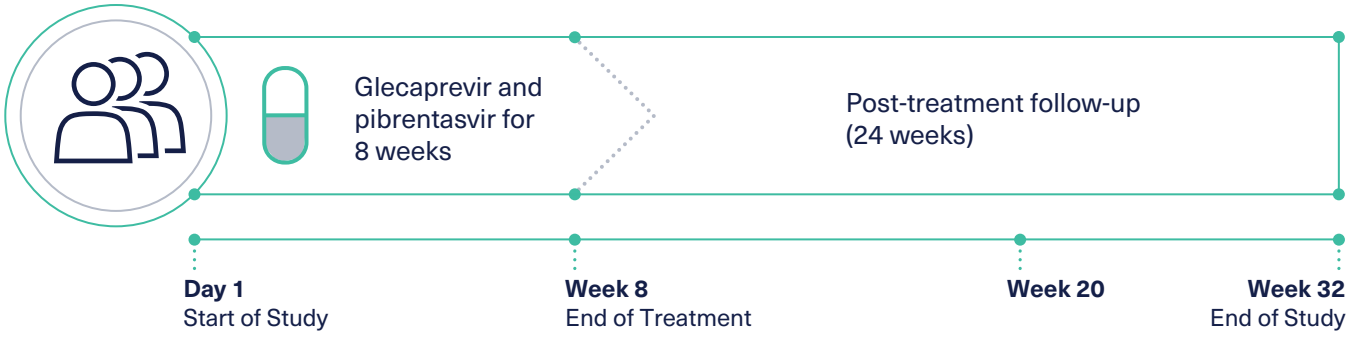
A total of 343 adult patients with long-lasting HCV with scarring of the liver took part in the study. All patients were over the age of 18, had HCV confirmed by blood test, measured scarring of the liver (without symptoms), and had never received any treatment for HCV.

There were more men (63%) than women (37%) in the study with an age range of 32 to 88 years.



3. Which medicines were studied?

The medicine in this study was the combination of two study drugs called glecaprevir and pibrentasvir. The diagram below shows how the study was organized.



The study included a treatment period and a post-treatment period. At the beginning of the study, study doctors selected patients who met the study criteria. In the treatment period, patients were given the same dose of study drug to take by mouth with food for 8 weeks. During the post-treatment period (the period after all study drugs were taken), patients gave blood samples at 12 weeks and 24 weeks after the last dose of study drug to see if the HCV continued to be stopped by the study drug.

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.

1.7% of patients (6 patients) had serious side effects during the study. No patient had serious side effects considered possibly related to the study drug.

No patient stopped taking the study drug because of side effects during the study.

No patient died during the study.

The table below shows information about the related serious side effects patients had in the study.

	GLE/PIB (343 Patients)
Number of patients with related serious side effects	0 (0.0% of patients)
Number of patients who stopped taking study drug because of related side effects	0 (0.0% of patients)
Number of related side effects leading to death	0 (0.0% of patients)

46.1% of patients (158 patients) had side effects during the study. The total number of patients that had side effects considered possibly related to the study drug was 25.7% (88 patients). The table below shows information about the common related side effects (in at least 5 or more patients) in this study. The most common related side effects were fatigue (tiredness), itchiness, and headache.

	GLE/PIB (343 Patients)
Number of patients with at least one related side effect	88 (25.7% of patients)
Common Related Side Effects (Related side effects occurring in at least 5 patients)	
• Fatigue (tiredness)	26 (7.6% of patients)
• Itchiness	23 (6.7% of patients)
• Headache	21 (6.1% of patients)
• Nausea	13 (3.8% of patients)
• Asthenia (muscle fatigue or weakness)	7 (2.0% of patients)
• Diarrhea	6 (1.7% of patients)

5. What were the overall results of the study?

The study was completed as planned. The main aim of the study was looking at patients with HCV genotypes 1, 2, 4–6. Of the 280 patients with genotypes 1, 2, 4–6, 275 patients (98.2% of patients) did not have detectable HCV in the bloodstream 12 weeks after finishing treatment.

When patients with HCV genotype 3 were added to the study analysis, 335 of 343 patients with HCV genotypes 1–6 (97.7% of patients) did not have detectable HCV in the bloodstream 12 weeks after finishing treatment.

This showed that 8 weeks of treatment with GLE/PIB was similar to 12 weeks of treatment in lowering the amount of virus in the blood.

6. How has the study helped patients and researchers?

The results of this study showed that the benefits of 8 weeks of treatment were similar to the benefits of 12 weeks of treatment with GLE/PIB for HCV patients with liver scarring who had not received prior treatment for HCV. Findings from this study may be used in other studies to learn whether patients are helped by the study drug. 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 that include the study drug glecaprevir/pibrentasvir.

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 Single Arm, Open-Label Study to Evaluate the Efficacy and Safety of Glecaprevir (GLE)/Pibrentasvir (PIB) in Treatment Naïve Adults with Chronic Hepatitis C Virus (HCV) Genotype 1-6 Infection and Compensated Cirrhosis
Protocol Number	M16-135
Clinicaltrials.gov	NCT03089944 https://clinicaltrials.gov/ct2/show/NCT03089944?term=M16-135&draw=2&rank=1
EudraCT	2016-004967-38 https://www.clinicaltrialsregister.eu/ctr-search/search?query=2016-004967-38
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!