

# Summary of Clinical Trial Results

## *For Laypersons*



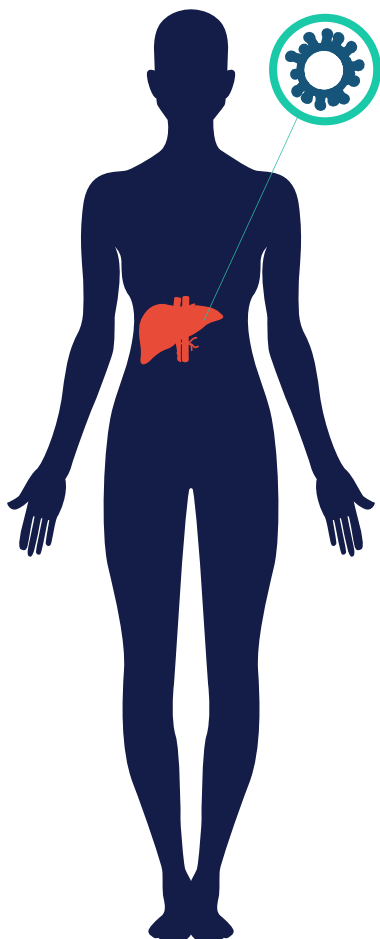
**A study to learn how effective and safe a medicine containing glecaprevir and pibrentasvir works to treat adult patients with long-lasting hepatitis C infection who had never been treated before and had no liver cirrhosis (scarring of the liver) based on the result of the APRI blood test**

### Overall Summary

- Hepatitis C infection is a global health problem caused by a virus (a small agent that infects living organisms), which may cause disease and liver damage.
- In this study, study doctors tested a medicine made up of glecaprevir and pibrentasvir taken for 8 weeks in patients who had long-lasting hepatitis C infection who had never been treated before and had not been diagnosed with liver cirrhosis (scarring of the liver), as shown by the result of a simple blood test called APRI.
- The study took place from August 2017 to August 2018 in 10 countries.
- A total of 230 adult patients took part in the study; of these, 226 patients completed taking the study drug and 223 patients completed the study.
- Patients took 3 tablets of 100 milligrams (mg) glecaprevir and 40 mg pibrentasvir.
- None of the patients had detectable hepatitis C virus while they were taking the medicine.
- None of the patients had the virus come back after they finished taking the medicine during the study, achieving virologic cure.
- None of the patients had detectable hepatitis C virus within 12 weeks after they finished taking the medicine.
- Most of the side effects were mild. Two patients (0.9% of patients) had a serious side effect related to the study drug. Two patients (0.9% of patients) stopped taking the study drug early due to side effects related to the study drug. No patients died during the study.
- The study results showed that the APRI blood test is helpful when assessing patients with hepatitis C who are treated with the combined medicine made of glecaprevir and pibrentasvir.
- The results of the study may be used by researchers to further develop this medicine. If you participated in this study and wish to see your results, 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?



Researchers are looking for a better and shorter way to treat a liver disease called hepatitis C, which is caused by a virus. The doctors in this study selected patients who had hepatitis C virus genotypes (different types) 1 to 6.

Patients were tested for cirrhosis using a simple, widely-available blood test called the aspartate aminotransferase to platelet ratio index (APRI). Patients must have had a result of 1 or less on the APRI test, which means they likely did not have cirrhosis. The doctors wanted to see if the APRI test could help identify which patients could receive shorter treatment (8 weeks) by using this simple blood test, instead of the usual tests used (a special ultrasound or liver sample), which can be difficult to perform in some locations.

In this study, the researchers wanted to find out how well glecaprevir and pibrentasvir would benefit patients when given together. Glecaprevir and pibrentasvir are two drugs that may stop the hepatitis C virus from multiplying. When taken together, these drugs may stop any of the six major genotypes of the hepatitis C virus.

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. The study was “open-label”, which means that both the patients and the study doctors knew which treatments were given. In this Phase 3b study, the study doctors looked at the benefits of taking both drugs together for 8 weeks in patients with long-lasting hepatitis C infection without cirrhosis, as shown by the result of a simple blood test (APRI). The study doctors also reported any side effects the patients may have had during and after treatment with the study drug.

The main aim of the study was to find out if the hepatitis C virus was no longer found in the bloodstream 12 weeks after taking the combined medicine in patients who were pre-selected by the APRI test to receive only 8 weeks of treatment with the medicine. Researchers also checked if there were any unwanted side effects. 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?

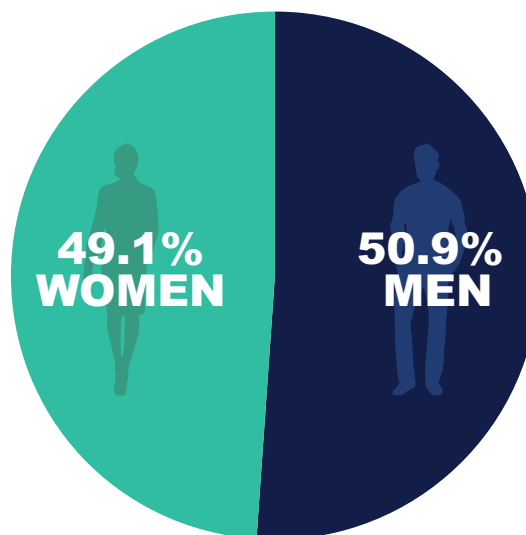
This study took place from August 2017 to August 2018 in the following locations:



## 2. What patients were included in this study?

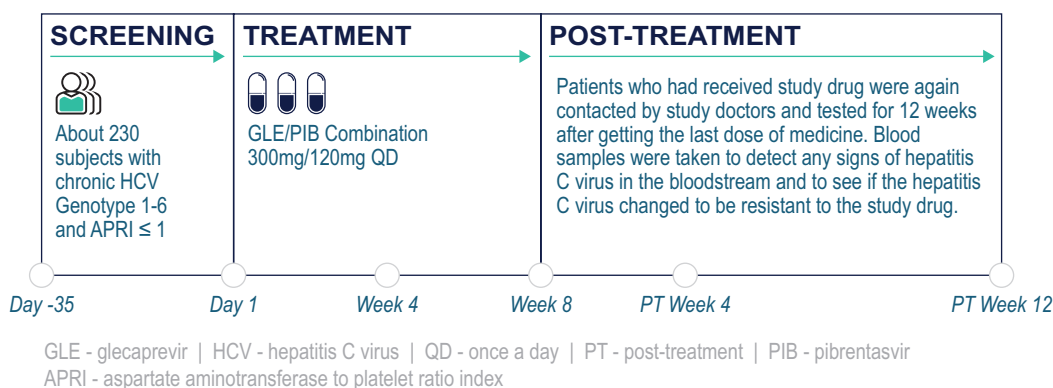
A total of 230 adult patients with long-lasting hepatitis C took part in the study. Of the 230 patients, 226 patients completed taking the study drug, 223 completed the study, and 7 did not: 1 patient left the study due to side effects, 1 patient withdrew consent to participate in the study, 4 patients were lost to follow-up (patient did not return to continue treatment or testing), and 1 patient left the study for other reasons.

About the same amount of men (50.9%) and women (49.1%) participated in the study. Study doctors selected only adults in this study. Patients ranged from 19 to 82 years of age. None of the patients had received a hepatitis C virus treatment previously and none were known to have cirrhosis.



### 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 was divided into 3 parts: the screening period, the treatment period, and the post-treatment period. At the beginning of the study, the study doctors selected patients who met all the requirements of the planned study in the screening period. In the treatment period, patients were given medicine for 8 weeks. All patients got the same dose of medicine. Patients took 3 tablets of 100 milligrams (mg) glecaprevir and 40 mg pibrentasvir with food once a day.

During the post-treatment period, patients who had received the study drug were again contacted by study doctors and tested for 12 weeks after getting the last dose of medicine. Blood samples were taken to detect any signs of hepatitis C virus in the bloodstream and to see if the hepatitis C virus changed to be resistant to 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 patient in the hospital, keeps a patient in the hospital for a long time, or causes a disability that lasts a long time.

Related side effects are side effects that were at least possibly related to the study drug.

About 1.7% of patients (4 patients) had serious side effects during the study. The total number of patients who had serious side effects considered possibly related to the study drug was 0.9% of patients (2 patients), with side effects of angioedema (swelling beneath the skin of the mouth, lips, and throat).

About 0.9% of patients (2 patients) stopped taking the study drug because of side effects; each of these patients stopped taking the study drug because of the side effect (angioedema [swelling beneath the skin of the mouth, lips and throat]) that was considered possibly related to the study drug.

No patients died during the study.

OVERALL (n=230)	
Number of patients with related serious side effects	2 (0.9% of patients)
Serious related side effects	Angioedema (swelling beneath the skin of the mouth, lips and throat) (2 patients)
Number of patients who stopped taking study drug because of related side effects	2 (0.9% of patients)
Reason(s) for stopping	Angioedema (swelling beneath the skin of the mouth, lips and throat) (2 patients)
Number of patients with related side effects leading to death	0 (0% of patients)

About 53.9% of patients (124 patients) had side effects during the study. The total number of patients who had side effects considered possibly related to the study drug was 23.9% of patients (55 patients). The table below shows information about the most common related side effects in this study. The most common related side effects were headache and fatigue (tiredness).

OVERALL (n=230)	
Number of patients with at least one related side effect	55 (23.9% of patients)
Side Effects	
Headache	22 (9.6% of patients)
Fatigue (tiredness)	13 (5.7% of patients)
Pruritus (itchiness)	8 (3.5% of patients)
Asthenia (weakness)	6 (2.6% of patients)
Dizziness	6 (2.6% of patients)
Nausea	6 (2.6% of patients)

## 5. What were the overall results of the study?

The study was completed as planned. None of the patients who completed treatment and finished the study had detectable hepatitis C while they were taking the medicine. None of the patients had detectable hepatitis C 12 weeks after they stopped taking the medicine. None of the patients had the virus come back after they finished taking the medicine during the study. Most of the side effects were mild. Serious side effects related to study drug were uncommon.

The efficacy of hepatitis C treatment regimens are measured by the proportion of people in clinical studies achieving “virologic cure.” Virologic cure is the lack of detectable hepatitis C in the blood at certain time points after completion of hepatitis C therapy, known as sustained virologic response (SVR). SVR at 12 weeks post-treatment (SVR 12) is the standard measure of virologic cure. SVR 12 rates for the combination of glecaprevir and pibrentasvir have ranged from 91-100% across clinical studies.

## 6. How has the study helped patients and researchers?

The results of this study showed that the benefits were greater than the risks in the treatment of all hepatitis C virus genotypes (1-6) with the glecaprevir/pibrentasvir combination medicine. It also showed that patients with an APRI score of 1 or less can be treated with this medicine for the shorter treatment of 8 weeks. The results of this study may help doctors assess patients before a new treatment is started. 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. Patients should consult their physicians and/or study doctors with further questions about their individual care and should not make changes in their treatment based on the results of a single study.

## 7. Are there any plans for future studies?

There is a possibility for future studies that include the medicine that was used in this study.

## 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?

<b>Title of Study</b>	A Single Arm, Open Label, Multicenter Study to Evaluate the Efficacy and Safety of Glecaprevir(GLE)/Pibrentasvir(PIB) in Treatment Naïve Adults with Chronic Hepatitis C Virus (HCV) Genotypes 1 – 6 Infection and Aspartate aminotransferase to Platelet Ratio Index (APRI) $\leq$ 1
<b>Protocol Number</b>	M16-133
<b>ClinicalTrials.gov</b>	NCT03212521 <a href="https://clinicaltrials.gov/ct2/show/NCT03212521">https://clinicaltrials.gov/ct2/show/NCT03212521</a>
<b>EudraCT</b>	2016-004876-23 <a href="https://www.clinicaltrialsregister.eu/ctr-search/search?query=2016-004876-23">https://www.clinicaltrialsregister.eu/ctr-search/search?query=2016-004876-23</a>
<b>Study Sponsor</b>	Global Medical Services, AbbVie Phone: +1 800-633-9110 Email: <a href="mailto:abbvieclinicaltrials@abbvie.com">abbvieclinicaltrials@abbvie.com</a>

05 Sep 2019. This document includes known facts as of the time the document was finalized.

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

**Clinical study  
participants help  
advance science!**

# THANK YOU!