

# Summary of Clinical Trial Results

*For Laypersons*



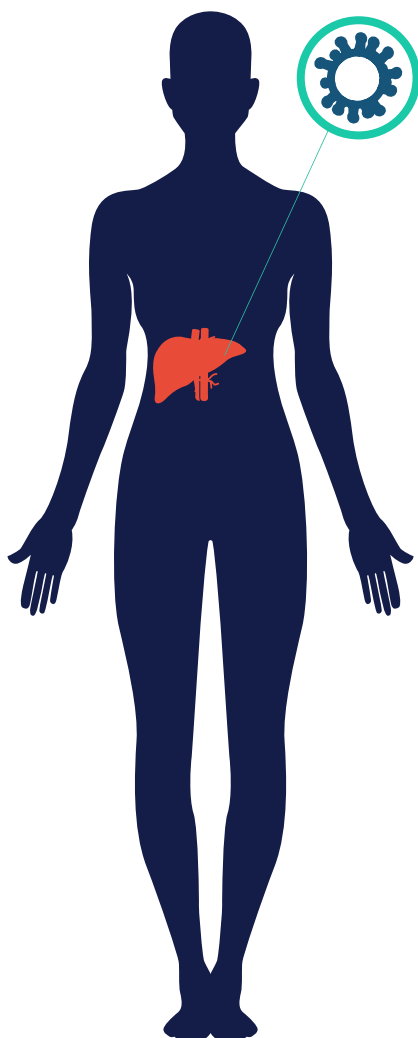
## A study to learn how effective and safe a medicine containing glecaprevir and pibrentasvir works to treat adult patients with long-lasting hepatitis-C genotype 5 or 6 infection

### 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 in patients who had long-lasting hepatitis C genotype 5 or 6 infection.
- The study took place from January 2017 to August 2018 in 9 countries.
- A total of 84 adult patients took part in the study. All of the patients completed taking the study drug and 83 patients completed the study.
- Patients took 3 tablets of 100 milligrams (mg) glecaprevir and 3 tablets of 40 mg pibrentasvir with food once a day.
- About 95.7% of patients with hepatitis C genotype 5 virus and 98.4% of patients with hepatitis C genotype 6 virus did not have detectable hepatitis C 12 weeks after they finished taking the medicine during the study.
- One patient had the virus come back while they were taking the medicine.
- One patient had the virus come back within 12 weeks after they finished taking the medicine.
- One patient had the virus come back between 12 weeks and 24 weeks after they finished taking the medicine.
- Most of the side effects were mild. No patients had serious side effects related to the study drug, no patients stopped taking the study drug early, and no patient died during the study.
- 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 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) 5 or 6, which are some of the rarest types of hepatitis C.

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 (genotypes 1, 2, 3, 4, 5, and 6) of the hepatitis C virus.

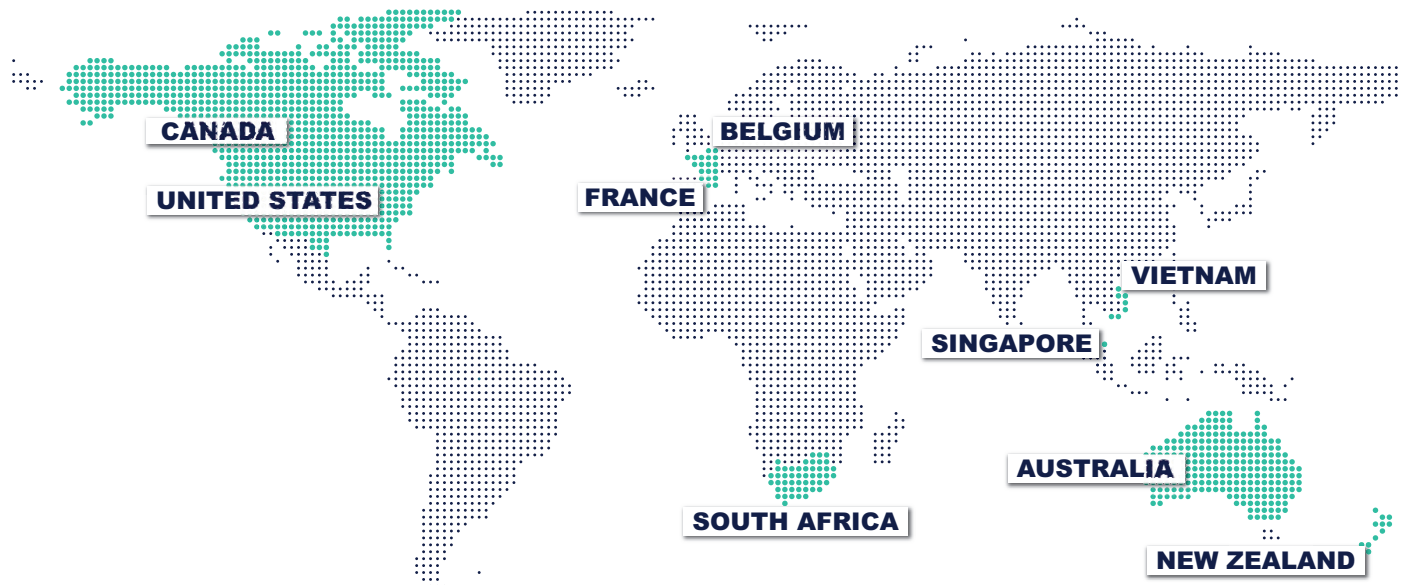
Researchers planned this study as a Phase 3 open-label study. Phase 3 studies test potential new treatments in a large number of patients with a condition or disease. The study was “open-label”, which means that both the patients and the study doctors knew which treatments were given. In this Phase 3 study, the study doctors looked at the benefits of taking both drugs together over 8 and 12 weeks in patients with long-lasting hepatitis C infection. 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 of patients 12 weeks after taking the combined 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?

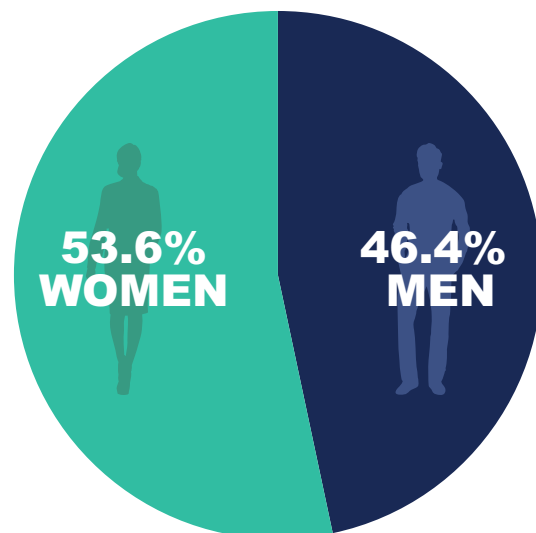
This study took place from January 2017 to August 2018 in the following locations:



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

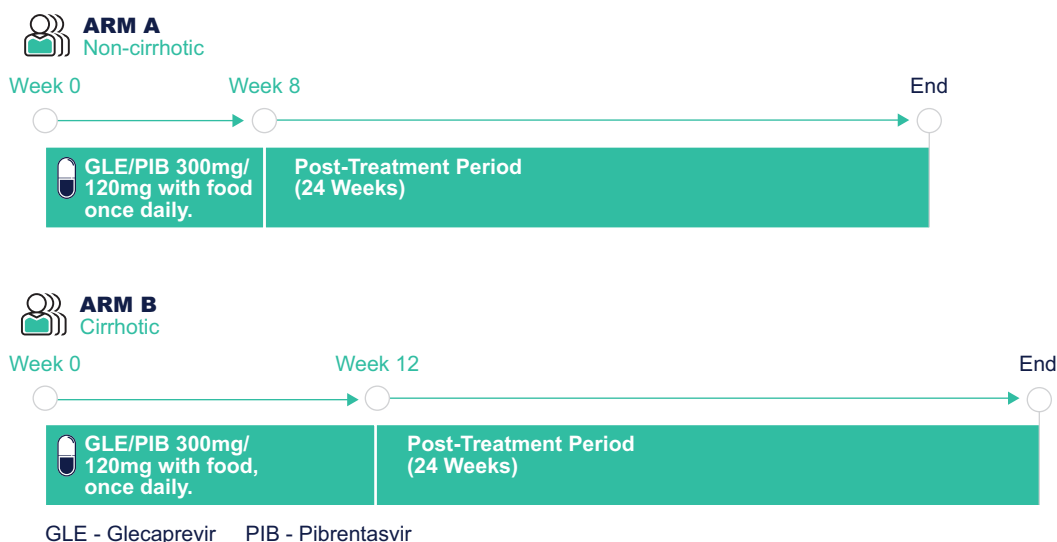
A total of 84 adult patients with long-lasting hepatitis C took part in the study. All of the 84 patients completed taking the study drug; 83 completed the study and 1 did not. This patient left the study for personal reasons not related to the study.

There were more women (53.6%) than men (46.4%) in the study. Study doctors selected only adults in this study. Patients ranged from 24 to 79 years of age. Patients either had no cirrhosis (no scarring of the liver) or had compensated cirrhosis (scarring of the liver with no symptoms).



### 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 if they did not have cirrhosis (Arm A) and 12 weeks if they did have compensated cirrhosis (Arm B). All patients got the same dose of medicine. Patients took 3 tablets of 100 milligrams (mg) glecaprevir and 3 tablets of 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 24 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 6.0% of patients (5 patients) had serious side effects; of these, none were considered possibly related to the study drug.

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

The table below shows information about the related serious side effects patients had in the study, as well as related side effects patients had that led to the patient stopping the study drug, and related side effects leading to death.

OVERALL (n=84)	
Number of patients with related serious side effects	0 (0% of patients)
Number of patients who stopped taking study drug because of related side effects	0 (0% of patients)
Number of patients with related side effects leading to death	0 (0% of patients)

About 54.8% of patients (46 patients) had side effects during the study. The total number of patients that had side effects considered possibly related to the study drug was 31.0% (26 patients).

The table below shows information about the most common related side effects reported by at least 3 patients in this study.

The most common related side effects were fatigue (tiredness) and headache.

OVERALL (n=84)	
Number of patients with at least one related side effect	26 (31.0% of patients)
Side Effects	
Fatigue (tiredness)	10 (11.9% of patients)
Headache	9 (10.7% of patients)
Nausea	4 (4.8% of patients)
Dizziness	3 (3.6% of patients)
Pruritus (itchiness)	3 (3.6% of patients)

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

The study was completed as planned. A total of 95.7% of patients with hepatitis C genotype 5 virus and 98.4% of patients with hepatitis C genotype 6 virus did not have detectable hepatitis C 12 weeks after they finished taking the medicine during the study. One patient had the virus come back while they were taking the medicine. One patient had the virus come back within 12 weeks after they finished taking the medicine. One patient had the virus come back between 12 weeks and 24 weeks after they finished taking the medicine. Most of the side effects were mild. There were no serious side effects, study drug discontinuations, or deaths related to the study drug.

## 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 hepatitis C virus genotypes 5 and 6 with the glecaprevir/pibrentasvir combination medicine. 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 Multicenter, Open-label Study to Evaluate the Efficacy and Safety of Glecaprevir (GLE)/Pibrentasvir (PIB) in Adults With Chronic Hepatitis C Virus (HCV) Genotype 5 or 6 Infection
<b>Protocol Number</b>	M16-126
<b>ClinicalTrials.gov</b>	NCT02966795 <a href="https://clinicaltrials.gov/ct2/show/NCT02966795">https://clinicaltrials.gov/ct2/show/NCT02966795</a>
<b>EudraCT</b>	2016-003192-22 <a href="https://www.clinicaltrialsregister.eu/ctr-search/search?query=2016-003192-22">https://www.clinicaltrialsregister.eu/ctr-search/search?query=2016-003192-22</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>

06 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!