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Summary of Clinical Trial Results

For Laypersons

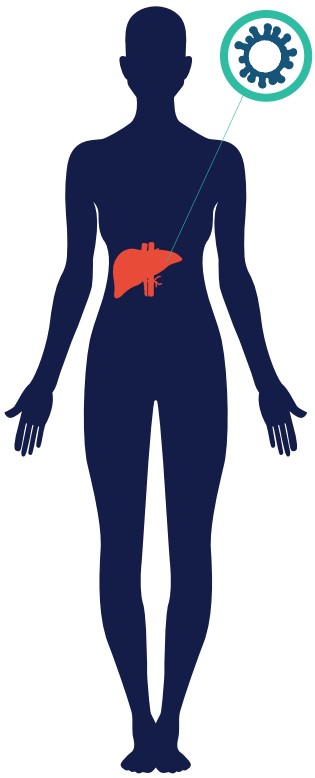
A study to learn how effective and safe a medicine containing glecaprevir and pibrentasvir works to treat Asian adult patients with long-lasting hepatitis C genotype 1 to 6 infection with compensated liver cirrhosis (scarring of the liver while the liver is still able to function)

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 infection with genotypes 1, 2, 3, 4, 5, or 6 with compensated cirrhosis (scarring of the liver while the liver is still able to function).
- The study took place from September 2017 to February 2019 in 2 countries.
- A total of 160 adult patients took part in this study and 159 completed the study.
- Patients took 3 tablets of 100 milligrams (mg) glecaprevir and 40 mg pibrentasvir with food once daily.
- A total of 99.4% of patients with hepatitis C genotype 1-6 virus did not have detectable hepatitis C virus 12 weeks after they finished taking the study drug.
- No patient had the virus come back while they were taking the study drug.
- One patient (0.6%) had the virus come back within 12 weeks after they finished taking the study drug.
- About half of the patients who experienced side effects experienced mild events as their most severe events. One patient died during the study about 24 weeks after they finished taking the study drug.
- 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 the hepatitis C virus. The doctors in this study selected Asian patients who had hepatitis C virus genotypes (different types) 1 to 6 with compensated cirrhosis (scarring of the liver while the liver is still able to function). Patients may or may not have been infected with another virus called the human immunodeficiency virus (HIV). Patients may or may not have received treatment for hepatitis C prior to this study.

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. This study was “open-label”, which means that both the patients and the study doctors knew which treatment was given.

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.

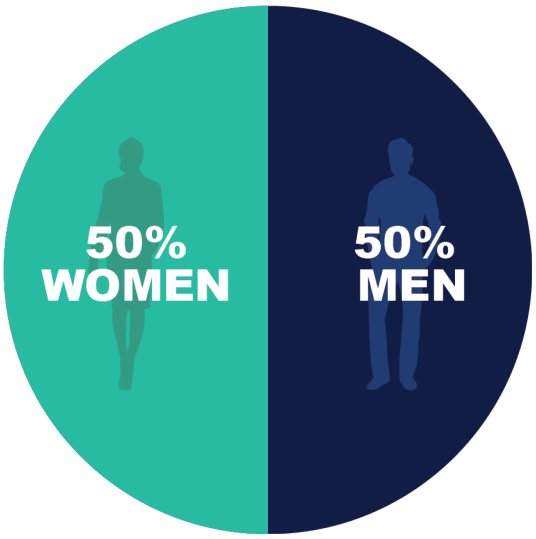
1.2 When and where was the study done?

This study took place from September 2017 to February 2019 in China and South Korea:

2. What patients were included in this study?

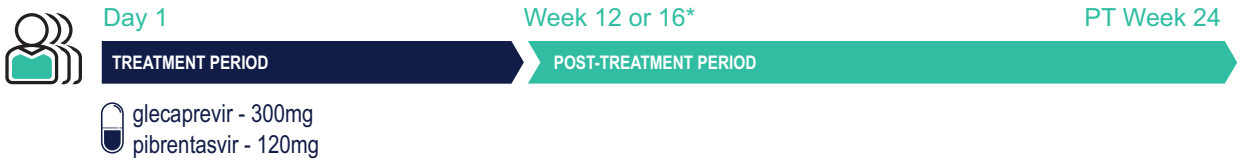
A total of 160 Asian adult patients with long-lasting hepatitis C and compensated cirrhosis took part in the study. Of these, 159 patients completed the study and 1 patient did not. This patient left the study due to side effects.

The same number of men (50%) and women (50%) participated in the study. Study doctors selected only adults in this study. Patients ranged from 29 to 87 years of age. No patient was infected with HIV. A total of 110 patients (68.8% of patients) were receiving hepatitis C treatment for the first time in this study, and 50 patients (31.3% of patients) had received hepatitis C treatment previously.



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.



KEY: PT = Post-Treatment and GT=genotype
*16 weeks for treatment-experienced GT3-infected patients

The study was divided into two parts: 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.

All of the patients were given the combined glecaprevir and pibrentasvir study drug for 12 weeks or 16 weeks. Treatment duration depended on hepatitis C genotype and past hepatitis C treatment experience. 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 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 3.1% of patients (5 patients) had serious side effects. One patient (0.6% of patients) had a serious side effect considered possibly related to the study drug.

One patient (0.6% of patients) stopped taking the study drug because of a side effect which was considered not related to the study drug. One patient died during the study about 24 weeks after they finished taking the study drug, as a result of a gastrointestinal hemorrhage which was not considered related to the study drug.

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=160 patients
Number of patients with related serious side effects	1 (0.6% of patients)
Serious side effect(s)	Gastrointestinal hemorrhage
Number of patients who stopped taking study drug because of related side effects	0 (0.0% of patients)
Number of patients with related side effects leading to death	0 (0.0% of patients)

About 55% of patients (88 patients) had side effects. The total number of patients that had side effects considered possibly related to the study drug was 11.3% of patients (18 patients).

The table below shows information about the most common related side effects (in at least 2 or more patients) in this study. The most common related side effect was blood bilirubin increased (higher levels of a blood component called bilirubin).

	Overall n=160 patients
Number of patients with at least one related side effect	18 (11.3% of patients)
Most common side effects in 2 or more patients	
Blood bilirubin increased (higher levels of a blood component called bilirubin)	3 (1.9% of patients)
Anemia (low red blood cell count)	2 (1.3% of patients)
Diarrhea	2 (1.3% of patients)
Dyspepsia (indigestion)	2 (1.3% of patients)
Flatulence (passing gas)	2 (1.3% of patients)

5. What were the overall results of the study?

The study was completed as planned. A total of 99.4% of patients with hepatitis C genotypes 1-6 virus did not have detectable hepatitis C virus 12 weeks after they finished taking the study drug. No patient had the virus come back while they were taking the study drug. One patient (0.6% of patients) had the virus come back within 12 weeks after they finished taking the study drug. About half of the patients who experienced side effects experienced mild events as their most severe events. One patient died during the study about 24 weeks after they finished taking 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 (1-6) 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 of 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?

Title of Study	An Open-Label Study to Evaluate the Efficacy and Safety of ABT-493/ABT-530 in Treatment-Naïve and Treatment-Experienced Asian Adults With Chronic Hepatitis C Virus Genotype (GT) 1 to GT6 Infection With Compensated Cirrhosis and With or Without Human Immunodeficiency Virus Co-Infection (VOYAGE-2)
Protocol Number	M15-593
ClinicalTrials.gov	NCT03235349 https://clinicaltrials.gov/ct2/show/NCT03222583?term=NCT03222583&rank=1
Study Sponsor	Global Medical Services, AbbVie Phone: +1 800-633-9110 Email: abbvieclinicaltrials@abbvie.com

01 Jan 2020. 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!