

a series of fact sheets written
by experts in the field of liver
disease

HCV Treatment:

Incivek (Telaprevir)

Alan Franciscus, Editor-in-Chief

Incivek is an HCV protease inhibitor that has been approved by the Food and Drug Administration. The information in this fact sheet represents an overview of information obtained from the Food and Drug Administration (FDA) Highlights of Prescribing Information. Incivek was given in combination with pegylated interferon and ribavirin.

Incivek is a capsule that is taken every 7 to 9 hours with food.

Treatment Naïve

Trial 1 – ADVANCE:

The ADVANCE study included 1,095 HCV genotype 1 treatment-naïve patients (never been treated). Twenty percent of the patient population in the study were African American, Black, Hispanic or Latino, and 20% had advanced fibrosis or cirrhosis. The treatment was guided by the type of on-treatment response to the medicines. There was no lead-in phase—the triple combination of Incivek, pegylated interferon and ribavirin was started at day one.

The study contained three arms. The different arms and the SVR or sustained virological response rates* are listed below:

12-week Incivek arm: 12 weeks of Incivek, pegylated interferon and ribavirin followed by an additional 12 or 36 weeks of pegylated interferon and ribavirin (without Incivek) depending on the type of on-treatment response; **SVR = 79%**

Standard of care arm (SOC): 48 weeks of pegylated interferon plus ribavirin; **SVR = 46%**

In a sub analysis it was found that:

- Blacks achieved a 62% SVR
- People with cirrhosis achieved a 62% SVR

Note: The on-treatment response was guided by the following rules:

- People who were HCV RNA (viral load) undetectable (<25 IU/mL) at week 4 and week 12 were treated for a total of 24 weeks
- Patients who were not HCV RNA undetectable at week 4 or week 12, but who were undetectable by week 24 were treated for a total of 48 weeks

Trial 2 – ILLUMINATE

The ILLUMINATE study included 540 HCV genotype 1 treatment-naïve patients. The aim of this study was to find out if there was a benefit in extending the total treatment duration from 24 weeks to 48 weeks.

The use of erythropoiesis-stimulating agents (Epo-gen/Procrit) was not allowed in the study.

Overall SVR

SVR = 74% —patients who received the triple combination of Incivek, pegylated interferon, ribavirin.

The study was response guided—patients who were HCV RNA negative at weeks 4 and 12 of treatment were randomized at treatment week 20 to receive either 24 or 48 weeks total treatment duration.

In a sub analysis it was found that:

- Black patients achieved an 88% SVR
- People with cirrhosis achieved a 67% SVR in the group that was treated for a total treatment duration of 24 weeks; SVR was 92% in people who were treated for a total treatment duration of 48 weeks.

Based on the data in this study, there was no benefit seen in extending the treatment duration from 24 to 48 weeks for treatment-naïve HCV genotype 1 patients.

Treatment Experienced Study

The REALIZE study included HCV genotype 1 prior non-SVR patients—354 relapsers, 124 partial responders, and 184 null response patients.* The only data provided on the patient population was that 89% of patients had a high HCV RNA viral load (greater than or equal to 800,000 IU/mL) and 26% of the patients had cirrhosis—both are considered poor predictors of treatment response. All the patients were HCV genotype 1 evenly divided between subtypes 1a and 1b.

The use of erythropoiesis-stimulating agents (Epo-gen/Procrit) was not allowed in this study.

The SVR results by type of prior non-response are listed below.

SVR Results by Type of Prior Non-Response

Type of Prior Non-SVR	Telaprevir Containing Groups	Standard of Care Groups
Relapsers	86% SVR	22%
Partial Responders	59% SVR	15%
Null Responders	32% SVR	5%

Rash and anemia are the most serious side effects of Incivek. The side effects in all three clinical trials were similar across all treatment arms. The treatment discontinuation rates were also similar between all the arms in all three studies including the arms that did not contain Incivek.

**Definitions:*

Sustained virological response (SVR): is defined as undetectable HCV RNA (viral load) 24 weeks after the last dose of medicine was taken.

Relapser: a person who was undetectable at the completion of at least 42 weeks of therapy but who became detectable during the 24 week follow-up period.

Partial responder: a person who achieved at least a 2 log₁₀ reduction in HCV RNA (viral load) at week 12, but who was never HCV RNA undetectable by week 24 of treatment.

Null responder: a person who achieved LESS than a 2 log₁₀ reduction in HCV RNA by week 12.

Example: 2 log drop = 15,000,000 IU/ml to 150,000 IU/mL; a viral load that starts at 15,000,000 IU/mL and does not decrease to 150,000 IU/mL or lower.

¹Triple combination (Incivek, pegylated interferon, ribavirin). Incivek was not given for more than 12 weeks.

Vertex Patient Assistance:

1-888-552-2494

www.vrtx.com/patients.html

For more information about hepatitis C, hepatitis B and HCV coinfections, please visit www.hcvadvocate.org.

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The information in this fact sheet is designed to help you understand and manage HCV and is not intended as medical advice. All persons with HCV should consult a medical practitioner for diagnosis and treatment of HCV.

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