

# **Hepatitis D**

### **Treatment and Clinical Trials**

# What current treatments are available for hepatitis D?

Currently there is no approved treatment for hepatitis D, but pegylated interferon (PEG-IFN) is often used in hopes of stimulating the body's immune system to fight the virus. A small percentage of patients (<30%) experience remission when injected weekly over 48 weeks. Emerging research is showing higher success rates with injections longer than 1 year. Oral nucleosides (antivirals) approved for hepatitis B have no effect on hepatitis D.

# What new drugs are in clinical trials for hepatitis D?

There are currently 7 new drugs in clinical trials being tested for effectiveness against the hepatitis D virus.

Drug	Mechanism	Company	Clinical Trial Phase	Designations
Lonafarnib	Prenylation Inhibitor	Eiger BioPharma, USA	Phase III	FDA Breakthrough Therapy Designation
				FDA Fast Track Designation
				FDA Orphan Drug Designation
				EMA Orphan Drug Designation
				EMA PRIME
Myrcludex B (Bulevirtide)	Entry Inhibitor	MYR-GmbH, Germany	Phase III	EMA PRIME
				FDA Breakthrough Therapy Designation
				FDA Orphan Drug Designation
				Promising Innovative Medicine (PIM) Designation by British MHRA
Lambda (Pegylated Interferon)	Immune Response Stimulator	Eiger BioPharma, USA	Phase II	FDA Orphan Drug Designation
interreron)	Sumulator			FDA Fast Track Designation
				FDA Breakthrough Therapy Designation
Ezetimibe	NTCP Inhibitor	Ziauddin University Hospital, Pakistan	Phase II	N/A
REP 2139	HBsAg Inhibitor	Replicor, Canada	Phase II	N/A
REP 2165				
GI-18000	Immune Response Stimulator	Globelmmune, USA	Pre-clinical	N/A
ALN-HD	RNAi Gene Silencer	Alnylam, USA	Pre-clinical	N/A
N/A	RNA Interference	Somagenetics, USA	Pre-clinical	N/A
ATI-2173	N/A	Antios Therapeutics, USA	Pre-clinical	N/A

### Lonafarnib PHASE 3

Lonafarnib is a "prenylation inhibitor", taken as a pill, that works by targeting the protein assembly process, which prevents new virus from being created. In a recent study, Lonafarnib combined with Ritonavir showed promise in reducing hepatitis D virus levels.

### Myrcludex B PHASE 3

Myrcludex B is an "entry inhibitor", taken as a pill, that that works by stopping the virus from entering and infecting hepatocytes (liver cells) and breaking the cycle of reinfection. It has shown activity against the hepatitis B virus, but is also being tested for effectiveness against hepatitis D. A recent study showed promise for Myrcludex B when combined with PEG-INF in reducing hepatitis D virus levels.



The Hepatitis B Foundation is a national nonprofit research and disease advocacy organization for hepatitis B. It established Hepatitis Delta Connect as a dedicated program in 2016 to provide information and support for those affected by hepatitis D.

### Pegylated Interferon Lambda (PEG-IFN-λ) PHASE 3

Pegylated Interferon Lambda is a type III interferon, taken as an injection, that works by activating the body's own immune system to fight the virus. A recent study showed the ability of combination therapy with ritonivir and Lonafarnib to reduce hepatitis D virus levels.

#### Ezetimibe PHASE 2

Ezetimibe is a pill currently being used as a treatment to lower cholesterol. Now being studied for effectiveness against hepatitis D, it works by inhibiting NTCP, the receptor required for hepatitis D to enter and infect liver cells.

#### Rep 2139 & 2165 PHASE 2

REP 2139 and REP 2165 are "nucleic acid-based amphipathic polymers (NAPs)", taken as a pills, that work by preventing liver cells from releasing hepatiitis B virus into infected liver cells. It is being evaluated for use in combination with PEG-IFN.

#### GI-18000 PRE-CLINICAL

GI-18000 is an "immune response stimulator", taken as a pill, that works by causing the host's T-cells to target and fight the hepatitis B and D infected liver cells.

### ALN-HDV PRE-CLINICAL

ALN-HDV is an "RNA gene silencer", taken as a pill, which works by "silencing" the viral RNA with compounds that interfere with, and cause the destruction of the virus genetics.

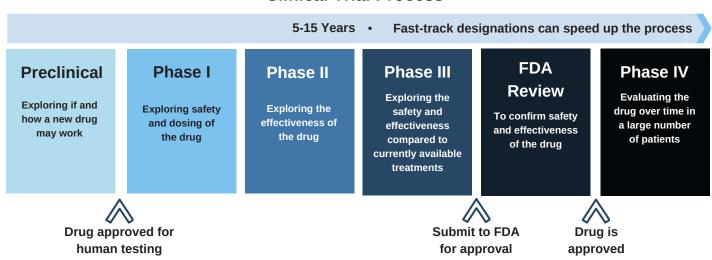
## How can patients locate clinical trial sites?

Patients can search open and upcoming clinical trials on the **Clinicaltrials.gov** website. For detailed instructions on searching and locating clinical trials, visit our helpful **guide**. Patients should also discuss with their doctors the possibility of participating, and see if their doctor can connect them with a local trial.

# How long will it take for new treatments to be available for all patients?

In the United States, new drugs must go through a multi-phase clinical trial process in order to test a drug's usefulness, safety and effectiveness before it is made available to all patients. Drugs face many obstacles during this process and not all of them may make it to the patient market. While this process can take anywhere from 5-15 years, fast-track and priority designations can speed up the process.

#### **Clinical Trial Process**





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