

Hepatitis C Treatments in Current Clinical Development

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To locate clinical trials go to www.clinicaltrials.gov – type in HCV or hepatitis C and drill down to studies that are listed by this resource.

Terms Used

Dosing:

- BID = Taken twice a day
- QD = Taken once a day
- TID = Taken three times a day (every 7 to 9 hours)

Response:

- RVR (Rapid virological response)= No virus detected at week 4
- eRVR(Extended rapid virological response) = No virus detected at week 4 and week 12
- EVR (Early Virological Response) — 2 log drop of HCV RNA after 12 weeks.
- cEVR = Complete Early Virological Response — No virus detected after 12 Weeks.
- SVR12 (Sustained virological response) = No virus detected at 12 weeks after completion of treatment.
- SVR24 = No virus detected at 24 weeks after completion of treatment.

Quick Reference Guide

Phase I		
Drug Name	Drug Category	Company
ALS-2158	Polymerase Inhibitor	Alios
ALS-2200	Polymerase Inhibitor	Alios
ABT-072	Polymerase Inhibitor	Abbott
ABT-333	Polymerase Inhibitor	Abbott
ACH-2684	Protease Inhibitor	Achillion
ACH-2928	NS5A Inhibitor	Achillion
AZD-7295	NS5A Inhibitor	AstraZeneca
Clemizole	NS4B Inhibitor	Eiger BioPharmaceuticals
IDX719	NS5A Inhibitor	Idenix
ITX-5061	Entry Inhibitor	iTherX
MK-3281	Polymerase Inhibitor	Merck
PPI-461	NS5A Inhibitor	Presidio
PPI-688	NS5A Inhibitor	Presidio
TMC649128	Polymerase Inhibitor	Medivir / Tibotec

Note: Only drugs that have advanced into phase 2 and 3 studies will include comments

DAA Combinations			
Drug Name/ Category	Drug Name/ Category	Company	Phase / Updated
ABT-450 Protease Inhibitor	ABT-072 Polymerase Inhibitor	Abbott / Enanta	Phase II Apr 25, 2012
ABT-450 Protease Inhibitor	ABT-267 Cytochrome P450 Inhibitor	Abbott / Enanta	Phase II Feb 7, 2012
ABT-450 Protease Inhibitor	ABT-267 Cytochrome P450 Inhibitor and/or ABT-333 Polymerase Inhibitor	Abbott / Enanta	Phase II Apr 6, 2012

ABT-450 Protease Inhibitor	ABT-333 Polymerase Inhibitor	Abbott / Enanta	Phase II Apr 6, 2012
BI 201335 Protease Inhibitor	BI 207127 Polymerase Inhibitor	Boehringer Ingelheim Pharma	Phase II Apr 25, 2012
BMS-790052 (Daclatasvir) (NS5a Inhibitor)	BMS-650032 (Asunaprevir) (Protease Inhibitor)	Bristol-Myers Squibb	Phase II Jan 21, 2012
BMS-790052 (Daclatasvir) (NS5a Inhibitor)	GS-7977 (Polymerase Inhibitor)	Bristol-Myers Squibb / Gilead	Phase II Apr 25, 2012
BMS-790052 (Daclatasvir) (NS5a Inhibitor)	TMC435 (Protease Inhibitor)	Bristol-Myers Squibb / Tibotec	Phase II Apr 25, 2012
Boceprevir Protease Inhibitor	Mericitabine Polymerase Inhibitor	Merck / Genentech	Phase II Dec 16, 2011
GS-9256	GS-9190 (Tegobuvir)	Gilead	Phase II Sep 22, 2011
GS-7977 Polymerase Inhibitor	TMC435 NS3/4A Inhibitor	Gilead/ Tibotec	Phase II July 10, 2011
RG7128 (Polymerase Inhibitor)	RG7227(Danoprevir) Protease Inhibitor	Genentech	Phase II Apr 5, 2011
Telaprevir (Protease Inhibitor)	VX-222 (Polymerase Inhibitor)	Vertex	Phase II Mar 5, 2012

Phase 2			
Drug Name	Drug Category	Company	Updated
ABT-450	Protease Inhibitor	Abbott / Enanta	Oct 22, 2011
ACH-1625	Protease Inhibitor	Achillion	Apr 25, 2012
ANA598 (Setrobuvir)	Polymerase Inhibitor	Anadys / Genentech	Oct 20, 2011
BI 207127	Polymerase Inhibitor	Boehringer Ingelheim Pharma	Jun 29, 2010

BIT225	p7 Inhibitor	Biotron	Oct 12, 2011
BMS-650032 (Asunaprevir)	Protease Inhibitor	Bristol-Myers Squibb	Aug 5, 2011
BMS-791325	Protease Inhibitor	Bristol-Myers Squibb	Sep 30, 2010
Filibuvir	Polymerase Inhibitor	Pfizer	Jun 30, 2010
GS 9190 (Tegobuvir)	Polymerase Inhibitor	Gilead	Nov 11, 2010
GS-9256	Protease Inhibitor	Gilead	Nov 11, 2010
IDX184	Polymerase Inhibitor	Idenix	Apr 25, 2012
INX-189	Polymerase Inhibitor	Inhibitex / Bristol-Myers Squibb	Jan 9, 2012
MK-5172	Protease Inhibitor	Merck	Nov 9, 2011
GS-938	Polymerase Inhibitor	Gilead	Dec 16, 2011
RG7128 (Mericitabine)	Polymerase Inhibitor	Gilead/ Genentech	Nov 7, 2011
RG7227 (Danoprevir)	Protease Inhibitor	InterMune / Genentech	Nov 7, 2011
Vaniprevir (MK-7009)	Protease Inhibitor	Merck	Nov 11, 2010
VX-222	Polymerase Inhibitor	Vertex	Nov 23, 2010
VX-759	Polymerase Inhibitor	Vertex	Mar 12, 2009

Phase 3			
Drug Name	Drug Category	Company	Updated
BI 201335	Protease Inhibitor	Boehringer Ingelheim Pharma	Nov 7, 2011
BMS-790052 (Daclatasvir)	NS5A Inhibitor	Bristol-Myers Squibb	Nov 9, 2011
GS-7977	Polymerase Inhibitor	Gilead	Apr 25, 2012
Telaprevir (Phase IIIb)	Protease Inhibitor	Vertex	Jan 9, 2012
TMC435	Protease Inhibitor	Medivir / Tibotec	Nov 3, 2011

Phase 4			
Drug Name	Drug Category	Company	Updated

Boceprevir	Protease Inhibitor	Merck	Nov 7, 2011
Telaprevir	Protease Inhibitor	Vertex	Jan 11, 2012

ABT-450/r HCV Protease Inhibitor (with ritonavir)	ABT-072 Polymerase Inhibitor	Abbott / Enanta	Apr 25, 2011
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Currently in Phase II Studies:

The combination of ABT-450(QD) (combined with ritonavir), ABT-072(QD) and ribavirin (without interferon) will be given to HCV genotype 1 treatment-naïve patients for 12 weeks. Patients will be followed for an additional 48 weeks after completion of study. All patients had IL28b CC genotypes.

EASL 2012: 36 weeks after completion of therapy 81% were HCV RNA negative.

ABT-450/r HCV Protease Inhibitor (with ritonavir)	ABT-267 Cytochrome P450 Inhibitor	Abbott / Enanta	Feb 7, 2012
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Currently in Phase II Studies:

An open-label study in HCV treatment- naive patients with HCV genotype 1, 2 and 3. Treatment arms will include ABT-450/r and ABT-267 with and without ribavirin.

ABT-450/r HCV Protease Inhibitor (with ritonavir)	ABT-267 Cytochrome P450 Inhibitor, ABT-333 Polymerase Inhibitor with or without Ribavirin.	Abbott / Enanta	Apr 6, 2012
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Currently in Phase II Studies:

The study will evaluate the combination of the direct acting antiviral with and without ribavirin in HCV genotype 1 treatment naive and non-responders.

ABT-450/r HCV Protease Inhibitor (with ritonavir)	ABT-333 Polymerase Inhibitor	Abbott / Enanta	Apr 6, 2011
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Currently in Phase II Studies:

An open label phase II study that was launched in 2011 to study the efficacy of the combination of ABT-333, ABT-450/r and ribavirin (without interferon) to treat chronic

hepatitis C genotype 1 treatment naïve and prior non-responders with HCV genotype 1.

On Oct 21, 2011 Abbott announced preliminary results from the study in which all patients achieved early virologic response (EVR—undetectable at week 12). After 24 weeks of therapy, 9 had achieved an SVR or cure. Abbott also announced that this combination has received Fast Track status from the FDA.

On April 4, 2012 SVR12 data was released on ABT-450/r QD and ABT-333 BID plus ribavirin (various arms had different doses of ABT drugs): (a) Treatment naïve — 18 of 19 patients (95%) achieved SVR12 — 17 of the patients were genotype 1a. (b) Treatment naïve — 13 of 14 patients (93%) achieved SVR12 — 11 of the patients were genotype 1a); (c) prior non-responders — 8 of 17 patients (47%) achieved SVR12 — 16 patients were genotype 1a. Treatment duration for the three studies was 12 weeks.

BI 201335

Protease Inhibitor

BI 207127

Polymerase Inhibitor

[Boehringer Ingelheim
Pharma](#)

Apr 25 , 2011

Currently in Phase II Studies:

This combination has been designated as Fast Track Development by the Food and Drug Administration

On Oct 22 Boehringer Ingelheim announced the addition of an interferon-free regimen (SOUND-C2), to its ongoing studies (SILEN-C1 and SILEN-C2).

SOUND-C2

In SOUND-C2, 362 treatment-naïve patients with chronic genotype-1 HCV infections were randomized into five interferon-free treatment arms, each with 120mg BI 201335 once daily (QD) but with different dosing of BI 207127 and ribavirin as follows:

- a) 120 mg QD BI 201335 combined with 600 mg TID (thrice daily) BI 207127 and RBV for 16 weeks. **EASL 2012 Interim Results: 59% SVR12**
- b) 120 mg QD BI 201335 combined with 600 mg TID BI 207127 and RBV for 28 weeks. **EASL 2012 Interim Results - 61% SVR12**
- c) 120 mg QD BI 201335 combined with 600 mg TID BI 207127 and RBV for 40 weeks. **EASL 2012 Interim Results not yet available**
- d) 120 mg QD BI 201335 combined with 600 mg BID (twice daily) BI 207127 and RBV for 28 weeks. **EASL 2012 Interim Results - 68% SVR12**
- e) 120 mg QD BI 201335 combined with 600 mg TID BI 207127 for 28 weeks (no RBV). **EASL 2012 Interim Results - 39% SVR12**

BMS-790052 (Daclatasvir) NS5A Inhibitor	BMS 650032 (Asunaprevir) Protease Inhibitor	Bristol-Myers Squibb	Jan 21, 2012
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Currently in Phase II Studies:

In an important study the combination of BMS-650032 (protease inhibitor) and BMS-790052 (NS5A inhibitor) was given to genotype 1 null-responders to a prior course of therapy. Approximately 90% of patients had either the IL28B CT or TT variation which are associated with poor response to HCV therapy.

In the group (9 patients- genotype 1a; 1 patient genotype 1b) that received BMS-790052, BMS-650032 in combination with pegylated interferon plus ribavirin for 24 weeks 9 out of 10 patients achieved an SVR.

In the group that received BMS-790052 and BMS-650032 (without pegylated interferon/ribavirin) 4 out of 11 patients (2 out of 9 patients genotype 1a; 2 out of 2 patients genotype 1b) achieved an SVR. This is the first combination DAA study that achieved SVR without the use of pegylated interferon plus ribavirin.

BMS-790052 (Daclatasvir) NS5A Inhibitor	GS-7977 Polymerase Inhibitor	Bristol-Myers Squibb / Gilead	Apr 25, 2012
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Currently in Phase II Studies:

This proof of concept study will evaluate the potential to achieve sustained virologic response 24 weeks post treatment (cure) with an oral, once-daily treatment regimen in patients across HCV genotypes 1, 2 and 3. Specifically, the study will assess the safety, pharmacokinetics and pharmacodynamics of BMS-790052 in combination with GS-7977, with and without ribavirin, for 24 weeks in 84 treatment-naïve patients chronically infected with HCV genotypes 1, 2, and 3.

On November 4, 2011 BMS announced that the original study of 84 patients had completed enrollment and two new treatment arms with 120 HCV genotype 1 treatment-naïve patients were being added to the study. Both treatment arms will study the combination of GS-7977 400 QD and BMS-790052 60 QD with and without ribavirin for a total treatment duration of 12 weeks.

EASL 2012: It was reported that 100% of HCV genotype 1 patients were HCV RNA negative 4 weeks post treatment; 91% of genotype 2 and 3 patients were HCV RNA negative 4 weeks post treatment.

BMS-790052 (Daclatasvir) NS5A Inhibitor	TMC435 Protease Inhibitor	Bristol-Myers Squibb/ Gilead / Tibotec	Apr 25, 2012
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Currently in Phase II Studies:

It was announced on December 02, 2011 that BMS and Tibotec would begin a combination study. On April 18 it was announced that pending their phase II results that BMS and Tibotec would collaborate on a Phase III study.

Boceprevir (Victrelis) Protease Inhibitor	Mericitabine Polymerase Inhibitor	Merck / Genentech	Dec 16, 2011
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Currently in Phase II Studies:

It was announced on December 16, 2012 that a study (DYNAMO 1) will begin in 2012 that will combine boceprevir, mericitabine, ribavirin with and without Pegasys to treat HCV genotype 1 patients who had a prior null response to HCV therapy.

GS-9256 (Protease Inhibitor)	GS-9190(Tegobuvir) Polymerase Inhibitor	Gilead	Sep 22, 2011
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Currently in Phase II Studies:

In a study that included many doses and arms it was found that the combination of GS-9256 (HCV protease inhibitor) plus tegobuvir (GS-9190 – polymerase inhibitor) when combined with pegylated interferon plus ribavirin produced the best results. In the group that was given quadruple therapy for 4 weeks followed by 44 weeks of pegylated interferon plus ribavirin, 14 out of 14 patients were HCV RNA negative by day 28. There is an ongoing 4 month study of the quadruple therapy.

There are also two arms of the study that do not include interferon—one arm will study the combination of GS-9256 and GS-9190 and another arm will include GS-9256, GS-9190 and ribavirin.

GS-7977 Polymerase Inhibitor	TMC435 NS3/4A Inhibitor	Gilead / Tibotec	July 10, 2011
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Currently in Phase II Studies:

A clinical trial of the combination of GS-7977 (QD-once daily) and TMC435 (QD) with and without ribavirin (BID-twice daily), and without interferon, is expected to begin toward the

later part of 2011. The study will investigate the safety of 12 and 24 weeks of treatment.

RG7128 (Mericitabine) (Polymerase Inhibitor)	RG7227 (ITMN-191) (Danoprevir) Protease Inhibitor	Genentech	Apr 5, 2011
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Currently in Phase II Studies:

EASL 2010: A small study using ritonavir (100 mg) to boost danoprevir (200 mg) both given twice a day achieved 100% undetectable HCV RNA after 15 days and was generally well-tolerated. Based on these findings an additional two study arms of prior complete non-responders will be retreated with danoprevir, ritonavir, PEG/RBV for 12 weeks. A larger study titled INFORM-3 is being planned that will include ritonavir.

On October 7th, 2010, Genentech announced that it had purchased the full rights to Danoprevir from InterMune.

Telaprevir (Protease Inhibitor)	VX-222 (Polymerase Inhibitor)	Vertex	Mar 5, 2012
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Currently in Phase II Studies:

On March 2, 2010 Vertex announced the initiation of a phase II trial of telaprevir (1125 mg BID) & VX-222 (100 & 400 mg BID), PEG/RBV—2 arms included PEG/RBV and 2 arms were response-guided and the patients who achieved an eRVR stopped therapy at week 12, those who did not achieve an eRVR continued on therapy with PEG for additional 24 weeks.

AASLD 2011: Interim results found an SVR of 82 & 93% in the patients who received 12 weeks of quadruple therapy and 83 & 87% of those who received 24 weeks of quadruple therapy.

March 5, 2012: Interim results from an all oral regime treating HCV genotype 1a and 1b treatment-naive patients found that 83% (38 out of 46 patients) were HCV RNA negative at week 12 (<25 IU/mL). In addition 9 of 11 patients were HCV RNA negative 4 weeks post-treatment. If patients were HCV RNA undetectable at week two and eight of treatment—all treatment was stopped at week 12.

ABT-450	Protease Inhibitor	Abbott / Enanta	Apr 5, 2011
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Currently in Phase II Studies:

ABT-450 (50, 100, 200 mg- once a day— boosted with ritonavir) plus pegylated interferon and ribavirin will be given to HCV genotype 1 treatment-naïve patients for 12 weeks followed by 36 weeks of pegylated interferon plus ribavirin (without ABT-450) for a total treatment duration of 48 weeks.

Interim 12 week data found that 92% (22 of 24) of patients were HCV RNA negative.

ACH-1625

Protease Inhibitor

[Achillion](#)

Apr 25, 2012

Currently in Phase II Studies:

EASL 2012: 58 patients were enrolled in this study. ACH-1625/PEG/RBV was given for 12 weeks followed by 12 weeks PEG/RBV. 100% of those who achieved an RVR and completed the 24 weeks were HCV RNA negative -- 22 of 60 pts.

ACH-1625 has been granted Fast Track designation.

ANA598

Polymerase Inhibitor

[Anadys](#) / [Genentech](#)

Oct 20, 2011

(Setrobuvir)

Currently in Phase II Studies:

There is an ongoing study of ANA598 (in multiple doses) combined with pegylated interferon plus ribavirin. 29 HCV genotype 1 treatment-naïve patients received the triple therapy for 12 weeks and were randomized (depending of treatment response) to an additional 12 or 36 weeks. The SVR 12 results in the patients who completed 24 weeks of treatment was 73% (in eight patients). The most common side effect was rash and it was observed in 59% of the patients who received the 400 mg dose.

On January 26, 2011 Anadys began dosing ANA598 (with pegylated interferon plus ribavirin) in the Phase IIb study that is expected to enroll 275 HCV genotype 1 treatment-naïve and treatment-experienced patients.

July 10 – SVR 24 results are expected in the fourth quarter of 2011.

Oct 13, 2011 – Anadys announced positive 12-week data for setrobuvir in phase 2b study. There was a strong antiviral response in prior partial responders and relapsers, favorable safety data with an adverse effect profile comparable to control group, and a high barrier to resistance was confirmed

SVR at week 12 (cEVR) was

- 78% for treatment-naive (setrobuvir + SOC) compared to 56% (placebo + SOC);
- 76% for treatment-experienced (setrobuvir + SOC) vs 44% for placebo + SOC;
- 29% for prior null responders

On October 17, 2011 it was announced that Roche had acquired Anadys Pharmaceuticals, Inc. The acquisition of Anadys' setrobuvir enhances Roche's (Genentech's) HCV DAA pipeline and will help to accelerate their development program which may lead to a faster approval an all oral HCV treatment regime (without interferon)

BI 207127	Polymerase Inhibitor	Boehringer Ingelheim Pharma	June 29, 2010
Currently in Phase II Studies:			
In a 5-day monotherapy study of HCV genotype 1 patients reported a median 3.8 log ₁₀ viral load decrease.			
<i>The combination of BI 201335 and 20127 is being studied (see DDA combinations).</i>			

BIT225	p7 Inhibitor	Biotron	Oct 12, 2011
Currently in Phase II Studies:			
BIT225 is the first in a new class of direct-acting antiviral drugs for HCV. It specifically targets the p7 protein, a viral protein essential to virus production and replication. Twenty four patients were randomly assigned to receive either 400 mg or 200 mg BIT225, or placebo (ratio of 1:1), for the first 28 days of their standard treatment with interferon and ribavirin. All patients were infected with genotype 1 HCV.			
Preliminary analysis of Phase IIa trial data confirms that BIT225, an orally administered, small molecule drug, has good antiviral activity against HCV. Patients receiving BIT225 in combination with interferon and ribavirin (Standard of Care (SOC)) had greater reductions in HCV levels than patients receiving standard of care treatment alone.			
Patients receiving the 400 mg dose of BIT225 showed the greatest levels of virus reduction. BIT225 also inhibits HIV and studies are ongoing.			

BMS-650032 (Asunaprevir)	Protease Inhibitor	Bristol-Myers Squibb	Aug 5, 2011
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Currently in Phase II Studies:

AASLD 2010: Results found that BMS 650032 was generally safe and well tolerated. BMS 650032 is currently in combination studies with and without other DAAs, ribavirin, pegylated interferon alfa and pegylated interferon lambda.

The combination of BMS 650032 and BMS- 790052 are being studied (see DAA combinations).

BMS-791325	Protease Inhibitor	Bristol-Myers Squibb	September 30, 2010
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Currently in Phase II Studies:

A new trial will evaluate the safety, tolerability and efficacy of BMS 791325 in combination with pegylated interferon in HCV genotype 1 treatment-naïve patients. Treatment duration will be guided by type of on-treatment response.

Filibuvir	Polymerase Inhibitor	Pfizer	June 30, 2010
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Currently in Phase II Studies:

EASL 2010: Study results from 35 patients who were treated with filibuvir, pegylated interferon and ribavirin found that 75% were HCV RNA negative after 4 weeks of treatment, but there was a high relapse rate which is most likely due to the short treatment duration.

GS-938	Polymerase Inhibitor	Gilead	Dec 16, 2011
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Currently in Phase II Studies:

GS-938 has been granted Fast Track Designation by the FDA. A combination study of GS-938 and GS-7977 plus ribavirin (interferon-free regime) is expected to begin in the third quarter of 2011.

On December 16, 2011 it was announced that the arms that contained GS-938 were being discontinued due to safety concerns. The study of the combination of GS-7977 plus ribavirin will continue.

GS 9190 (Tegobuvir)	Polymerase Inhibitor	Gilead	Nov 11, 2010
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Currently in Phase II Studies:

AASLD 2010: A study of HCV genotype 1 treatment-naïve patients in single and multiple doses found HCV RNA reductions ranging for -1.22 to -1.95 log₁₀. The combination of GS 9190 and GS9256 are being studied (*see DAA Combinations above*).

GS 9256	Protease Inhibitor	Gilead	Nov 11, 2010
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Currently in Phase II Studies:

EASL 2010: Results from a three day 6-arm safety and dose-ranging study of 54 HCV genotype 1 treatment-naïve patients was released. It was found that GS-9256 was safe and generally well-tolerated and showed dose dependent antiviral activity. Phase II studies of GS-9256 with or without ribavirin are underway. (*April 29, 2010*)

The combination of GS 9190 and GS9256 are being studied (see DAA Combinations above).

IDX184	Polymerase Inhibitor	Idenix	Apr 25, 2012
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Currently in Phase II Studies:

In July 2011 it was announced that a clinical trial of 100 HCV genotype 1 treatment-naïve patients would test the efficacy and safety of a 12 week treatment regime of IDX184 (50 or 100 mg – QD--once a day) in combination with pegylated interferon and ribavirin. Interim data is expected by the end of 2011.

On January 9, 2012 Idenix announced interim results of the 31 people who received 28 days of treatment: 73% in the 100 mg arm and 63% in the 50mg arm achieved an RVR (undetectable at week 4).

On February 3, 2012 Idenix announced that the partial hold on IDX184 had been removed by the FDA, and that the study with PEG/RBV could continue.

On April 19, 2012 Idenix announced that it had completed enrollment of the study.

INX-189	Polymerase Inhibitor	Inhibitex / Bristol-Myers Squibb	Jan 9, 2012
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Currently in Phase II Studies:

On Sep 19, 2011 Inhibitex announced that it has recently commenced dosing in a 90-patient randomized, placebo controlled, treatment guided, Phase 2 clinical trial to evaluate the safety,

tolerability and antiviral activity of INX-189 in combination with pegylated interferon and ribavirin in chronic HCV-infected genotype 2 and 3 treatment naïve patients.

The trial is designed to evaluate three once-daily doses of INX-189 (25 mg, 50 mg and 100 mg) administered in combination with pegylated interferon and ribavirin for 12 weeks, plus a placebo arm with PEG/RBV. Patients that achieve an extended rapid viral response, or eRVR, will stop all therapy after 12 weeks. Those patients who do not achieve an eRVR will continue receiving pegylated interferon and ribavirin for 12 additional weeks.

The Company also announced the initiation of an additional clinical trial of INX-189 designed to evaluate higher doses of INX-189 administered as monotherapy or in combination with ribavirin for seven days. The first group in this expanded Phase 1b trial will receive 200 mg INX-189 once daily as monotherapy

AASLD 2011: a small 7-day study of INX-189 at 200 mg QD with and without ribavirin to treat HCV genotype showed a median HCV RNA reduction of $-4.25 \log_{10}$. The drug was generally well-tolerated.

On January 8, 2012 it was announced that BMS would acquire Inhibitex.

MK-5172	Protease Inhibitor	Merck	Nov 9, 2011
Currently in Phase II Studies:			
Phase I – multiple dosing trial with MK-5172 compared to placebo.			
AASLD 2011: A 7-day dosing monotherapy study of HCV genotype 1 and 3 (all males) with dosing up to 800 mg QD resulted in 75% (30 out of 40 genotype 1 pts) undetectable and 38% (9 out of 24 genotype 3 patients) achieving undetectable HCV RNA. In the genotype 1 patients who were treated with 800 mg QD, 87% (13 out of 15 patients) were HCV RNA undetectable at day 7.			
Phase II – Multiple dosing ranging study compared MK-5172 in combination with Victrelis, PegIntron and ribavirin to study the safety and efficacy compared to PegIntron plus ribavirin.			

RG7128 (Mericitabine)	Polymerase Inhibitor	Gilead / Genentech	Aug 5, 2011
Currently in Phase II Studies:			
EASL 2011: RG7128 (1000 mg - BID) combined with pegylated interferon plus ribavirin was			

given to treat HCV genotype 1 and 4 treatment naive patients and treatment-duration was guided by on-treatment response (RVR). After 24 weeks SVR12 was 91%. The medications were well-tolerated. RG7128 appears to have a high barrier to drug resistance.

Mericitabine is also being studied in combination with danoprevir. (*see DAA and interferon-free combination studies.*)

RG7227 (Danoprevir)	Protease Inhibitor	InterMune / Genentech	Nov 7, 2011
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Currently in Phase II Studies:

A study is underway that will explore the use of danoprevir with ritonavir in various combinations with and without ribavirin and Pegasys to treat chronic HCV genotype 1 patients who failed a previous course of standard therapy.

Two arms of the study will be interferon-free.

AASLD 2011: Danoprevir (with ritonavir) at 50 to 200 mg BID in combination with PEG/RBV to treat HCV genotype 1 treatment-naïve patients (Danoprevir grp 144 pts; placebo 31 pts). Patients treated for 24 weeks produced SVR rates up to 85% compared to 42% for the group that did not receive danoprevir/r.

Danoprevir is also being studied in combination with Mericitabine. (*see DAA combinations above*)

Vaniprevir (MK-7009)	Protease Inhibitor	Merck	Nov 11, 2010
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Currently in Phase II Studies:

AASLD 2010: A study of 45 HCV genotype 1 treatment-naïve patients who were administered 1 of 5 regimens—placebo, 300 mg BID, 600 mg BID, 600 mg QD or 800 mg QD in combination with pegylated interferon plus ribavirin for 4 weeks followed by an additional 44 weeks of pegylated interferon plus ribavirin resulted in SVR rates of 78 to 84% compared to 63% in the placebo (only pegylated interferon and ribavirin). Note: the high SVR rate in the placebo group is likely due to the small patient population in this group.

VX-222	Polymerase Inhibitor	Vertex	Nov 23, 2010
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Currently in Phase II Studies:

EASL 2010: The results from a small study of 32 HCV genotype 1 treatment-naïve patients treated with various doses of VX-222 (250, 500 and 750 BID; 1500 mg QD) found a viral load reduction of -3.1 to 3.4 log₁₀ IU/mL by day 4 of treatment. VX-222 was generally safe and well-tolerated. VX-222 is also being studied in combination with telaprevir (*see DAA combinations*).

VX-759	Polymerase Inhibitor	Vertex	March 12, 2009
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Currently in Phase II Studies:

In a 10 day phase I study in which 32 treatment- naïve HCV patients received different doses of VX-759 (400 mg TID, 800 mg BID, and 800 mg TID) all patients achieved a 1 log₁₀ decrease in HCV RNA but the higher dose arm of 800 mg TID achieved 2.5 log₁₀ decrease. The drug was generally well-tolerated. A Phase 2, multicenter, randomized, double-blinded, and placebo-controlled study of the antiviral activity, safety and pharmacokinetics of VX-759 is underway. Additional studies will combine VX-759 and other DAAs. VX-759 is considered to be a back-up drug to VX-222.

BI 201335	Protease Inhibitor	Boehringer Ingelheim Pharma	Nov 7, 2011
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Currently in Phase III Studies:

Data from Phase II Studies:

EASL 2011: The results from the SILEN-C2 study (Phase II) of 280 HCV genotype 1 patients who were prior non-responders treated for 24 weeks with either 240mg BI 201335 (QD), 240 mg BI 201335 (QD) after a 3-day lead-in of PEG/RBV or 240 BI 201335 (BID) after a 3-day lead-in period of PEG/RBV. After 24 weeks of treatment the participants were continued on PEG/RBV for an additional 24 weeks. The highest SVR rates were up to 50% in prior partial-responders and 35% in prior null-responders in the groups that received 240 mg QD—the dose that was selected for the phase III trials. The side effects attributed to BI 201335 were jaundice (no severe cases) and rash (severe cases—0.7 to 5.8%) and were found to be dose dependent. It was also found that a 3-day lead-in period in the phase II studies did not increase the response rates.

AASLD 2011: SILEN-C1--BI 201335 in combination with pegylated interferon plus ribavirin (treatment duration up to 48 weeks), HCV genotype 1 treatment- naïve. Patients achieved 82% to 84% SVR in HCV genotype 1a and 1b respectively.

SILEN-C3--HCV genotype 1 treatment-naïve patients treated with BI 201335 plus PEG/RBV

achieved an 80% SVR in the group that was treated for 12 weeks compared to 82% in the group that was treated for 24 weeks.

Phase III

BI 201335 (QD) in combination with pegylated interferon entered into Phase 3 studies that will include 3 arms: BI201335 in combination with pegylated interferon plus ribavirin for 12 weeks or 24 weeks of treatment compared to 48 weeks of pegylated interferon plus ribavirin (without BI 201335). The FDA has granted Fast Track designations for BI 201335 plus standard-of care (SOC), and as part of the interferon-free combination with the polymerase inhibitor, BI 207127, in chronic genotype-1 HCV patients.

On December 9, 2011, Boehringer announced that the phase III has completed enrollment.

There is also an open label study of BI 201335 in combination with pegylated interferon and ribavirin for the treatment of chronic hepatitis C in people coinfecting with HIV and hepatitis C—HCV genotype 1 treatment naïve.

The combination of BI 201335 and BI 20127 is being studied (see DDA combinations)

BMS-790052 (Daclatasvir)	NS5A Inhibitor	Bristol-Myers Squibb	Nov 9, 2011
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Currently in Phase III Studies:

Data from Phase II Studies:

BMS-790052 is being given QD for 12-24 weeks with pegylated interferon and ribavirin, or for 24 or 48 weeks guided by on-treatment response. There are various separate studies of BMS- 790052 being conducted in HCV genotype 1 treatment-naïve or treatment experienced patients.

EASL 2011: In the group that was treated for 48 weeks SVR12 rates ranged from 42% to 92% (depending on the study dose) in the BMS-790052 containing groups vs. 25% in the group that received pegylated interferon plus ribavirin (without BMS-790052). The medications were generally well-tolerated.

AASLD 2011: Interim data from HCV treatment-naïve patients found that by week 12, genotype 1—54% (157 out of 293 pts) were HCV RNA undetectable (20mg & 60mg grps) compared to 14% in the group that received PEG/RBV (w/o daclatasvir); HCV genotype 4—

58% (7 out of 12 patients in the 20mg group) and 100% (12 out of 12 pts in the 60 mg group) were HCV RNA undetectable. Side effects were similar across the treatment groups.

In a small study of Japanese HCV genotype 1 treatment-naïve and prior non-responders it was found that in the study group, for those who were HCV RNA undetectable at week 4 and 12 the SVR was 86% (7 pts) to 90% (10pts) in treatment-naïve patients and 40% (5 pts) and 67% (3 pts) SVR in prior non-responders to treatment.

Phase III:

A phase III study of BMS-790052 in combination with pegylated interferon and ribavirin to treat HCV genotype 1 treatment naïve patients is expected to begin September 2011. Treatment duration of 24 or 48 weeks will be guided by on-treatment response.

BMS-790052 is also being studied in combination with BMS-65032 and with GS-7977 (see DAA combination above).

GS-7977

Polymerase Inhibitor

[Gilead](#)

Apr 25, 2012

Currently in Phase III Studies:

Data from Phase II Studies:

Atomic Study:

The combination of GS-7977 (400 mg QD), pegylated interferon, plus ribavirin will enroll 300 HCV genotype 1 treatment naïve patients. The patients will be given GS-7977 in combination with and without PEG/RBV. An additional arm will treat 25 HCV genotype 4,5,6 patients with GS-7977 and PEG/RBV for 24 weeks. (March 2011)

Proton Study:

125 HCV genotype 1 treatment naïve non-cirrhotic patients will be treated with GS-7977 (200 and 400 mg QD) in combination with PEG/RBV. The patients will receive the triple combination for 12 weeks followed by 12 weeks of PEG/RBV and those in the group who did not achieve RVR will be treated for an additional 24 weeks with PEG/RBV.

On Sep 6, 2011, SVR results were announced from the Phase 2b PROTON study: 91% (43 of 47) treatment-naïve subjects with HCV genotype 1 achieved SVR12 following a 24-week treatment regimen incorporating 12 weeks of GS-7977 400 mg QD (Intent to treat).

EASL 2011: 25 (15 genotype 2; 10 genotype 3) treatment- naïve patients treated with GS-7977(400mg QD) plus pegylated interferon plus ribavirin for 24 weeks. All patients who completed treatment (24 out of 25 pts (one pt lost to follow-up) achieved SVR24.

Electron Study:

40 treatment naïve HCV genotype 2 or 3 patients will be enrolled. Treatment will consist of 12 weeks of GS-7977 with ribavirin (no interferon) with treatment durations of up to 12 weeks. On June 8th Pharmasset announced additional arms to the study to explore 12 weeks of GS-7977 monotherapy (without pegylated interferon and ribavirin) – one arm will explore GS-7977 plus PEG/RBV for 8 weeks in HCV genotypes 2 and 3 and one arm will explore GS-7977 plus PEG/RBV for HCV genotype 1 prior null responders.

On Oct 10, 2011 Pharmasset announced further expansion of the Electron trial as follows:

- Added one GS-7977 monotherapy arm in treatment-naïve patients with HCV GT1
- Added one GS-7977/RBV arm in treatment experienced patients with HCV GT2/3
- Modified a previously-announced treatment regimen in HCV GT1 prior null responders to explore a 12-week IFN-free regimen of GS-7977/RBV

AASLD 2011:

ELECTRON study of 40 HCV genotype 2 and 3 patients treated with GS-7977 & ribavirin (no interferon) –100% achieved an SVR. It was also noted that there were no cases of blood abnormalities (hemoglobin, lymphopenia, neutropenia).

Electron Null-Responder Results:

March 6, 2012: The treatment arm that treated HCV genotype 1, prior null responders—the hardest group to retreat—with GS-7977 (HCV polymerase inhibitor) plus ribavirin (no interferon) reported results for 9 of the patients. The patients were treated for 12 weeks (GS-7977/RBV). Of the nine patients who were HCV RNA undetectable at the end of treatment, eight patients relapsed within 4 weeks post treatment.

EASL 2012:

QUANTUM Study: In the genotype 1 treatment-naïve part of this study, the preliminary results from 25 patients who completed 12 weeks GS-7977 (QD)/RBV (TID) found that 88% were HCV RNA negative 4 weeks post-treatment.

GS 7977 is also being studied in combination with GS-938, BMS-790052 and TMC435 (*see DAA combination above*).

Phase III:

It was announced on Nov 1 that Pharmasset, INC would initiate three phase III studies of GS-7977 in combination with ribavirin, but WITHOUT interferon.

- **FISSION:** 500 HCV treatment naïve genotype 2 and 3 patients will be given either a) GS-7977 400 mg QD (once-a-day) with ribavirin for 12 weeks or b) pegylated interferon plus ribavirin for 24 weeks. The study will enroll more HCV genotype 3 people since current therapy (PEG/RBV) doesn't work as well compared to genotype 2. The study will also include patients with and without cirrhosis. This trial is expected to begin by the end of 2011.
- **POSITRON:** 225 HCV genotype 2 and 3 patients with and without cirrhosis who are interferon intolerant. The study will have two arms: a). GS-7977 400 mg QD with ribavirin for 12 weeks and b). placebo. This study is expected to begin in the first quarter of 2012.
- **NEUTRINO:** 280 HCV interferon-intolerant patients (all genotypes) – the study design will be based on the results from data when on-going studies are completed. This study is expected to begin mid-2012.

Pharmasset also announced that they expect to apply for marketing approval in the U.S. and European Union in 2013.

In November 2011 it was announced the Gilead would acquire Pharmasset.

Telaprevir	Protease Inhibitor	Vertex	Jan 9, 2012
Currently in Phase III Studies:			
Phase IIIb:			
Enrollment in the twice-daily dosing of telaprevir (in combination with PEG/RBV) has been completed. This trial began in 2011 to study the combination of telaprevir, PEG/RBV for a total treatment duration of 12 weeks for HCV genotype 1, CC genotype people.			
A trial of telaprevir to treat post-transplant HCV recurrence is expected to begin in the first quarter of 2012.			
In the first quarter of 2012 a trial of telaprevir/pegylated interferon and ribavirin will begin enrollment of a study in African Americans who did not respond to a prior course of treatment with PEG/RBV			

TMC435	Protease Inhibitor	Medivir / Tibotec	Nov 3, 2011
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Currently in Phase III Studies:

Phase IIb ASPIRE (C206) Study Final Results:

On November 2, 2011 final results from the ASPIRE study were released:

462 HCV genotype 1 patients who did not achieve an SVR with a prior course of pegylated interferon plus ribavirin. 62 percent (287/462) of patients had advanced liver disease fibrosis or cirrhosis (scarring of the liver) (Metavir score F2-F4). The study participants received either 75 or 150 mg QD of TMC435. There were seven treatment arms (including one placebo arm). The SVR24 or cure in the 150 mg QD (the dose that is being used in phase III studies) by type of prior response included 85% (prior relapsers), 75% (prior partial responders), and 51% (prior null responders) compared to 37%, 9% and 19% respectively in the arms that did not receive TMC435. Treatment duration for TMC435 was either 12, 24 or 48 weeks (all patients received 48 weeks of pegylated interferon plus ribavirin) The press release did not break down cure rates by treatment duration. The overall percentage of side effects was similar across all arms. Serious AEs or side effects were reported in 6.1% of the arms that received pegylated interferon plus ribavirin (without TMC435) compared to 7.8% in the group that received TMC435, pegylated interferon and ribavirin.

Phase II Interim Results: On February 22, 2011 interim results from a phase II study were released and 278 patient results were made available:

For HCV genotype 1 treatment-naïve patients using TMC435 QD (75 or 150 mg) the sustained virological response (SVR) rates were 76 to 84% in the groups that received TMC435. The study was response-guided with 83% of patients being able to stop all therapy at 24 weeks. On July 6, 2011 Medivir/Tibotec announced that the Food and Drug Administration awarded fast track designation to the phase III study.

Phase III:

Phase III Studies: Tibotec announces on February 19, 2011 that it expects to enroll 1,125 HCV genotype 1 patients in 24 countries with a total of 160 clinical trial sites worldwide to study TMC435 plus pegylated interferon plus ribavirin for 12 weeks followed by either 12 or 36 weeks of pegylated interferon plus ribavirin (without TMC435). The studies will be guided by on-treatment response. The three clinical trials are listed below:

- QUEST-1 (TMC435-C208): Treatment-naïve (never been treated) patients will receive either TMC435 (100 mg) QD (once-a day) or placebo in combination with Pegasys/ribavirin.

- QUEST-2 (TMC435-C216): Treatment-naïve patients will receive either TMC435 QD (150 mg) or placebo plus pegylated interferon and ribavirin. In this trial different treatment arms use either Pegasys or PegIntron.
- PROMISE (TMC435-C3007): Patients who had been previously treated with interferon-based therapy, but who relapsed (the viral load becomes undetectable, then detectable) during therapy will receive TMC435 QD (100 mg) or placebo plus Pegasys/ ribavirin.

TMC345 is also being studied in combination with GS-7977(*see interferon-free studies*).

Telaprevir	Protease Inhibitor	Vertex	Jan 11, 2012
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Currently in Phase IV Studies:

In the first quarter of 2012 a trial of telaprevir/pegylated interferon and ribavirin will begin enrollment to study treatment of telaprevir in African American patients who did not respond to a prior course of treatment with PEG/RBV.

Interferon Free Trials			
Drug Name	Drug Name	Company	Updated
ABT-450	ABT-072	Abbott / Enanta	Jan6, 2011
ABT-450/r	ABT-267	Abbott / Enanta	Feb 7, 2012
ABT-450	ABT-333	Abbott / Enanta	Oct 22, 2011
ABT-450/r	ABT-333, ABT-267	Abbott / Enanta	Feb 7, 2012
Bavituximab (formerly Tarvacin)	Ribavirin	Peregrine	Sep 26, 2011
BI 201335	BI 207127	Boehringer Ingelheim Pharma	Oct 22, 2011
BMS-790052 (Daclatasvir)	GS-7977	Bristol-Myers Squibb / Gilead	Nov 7, 2011
Boceprevir Protease Inhibitor	Mericitabine Polymerase Inhibitor	Merck / Genentech	Phase II Dec 16, 2011
GS-9256	GS-9190 (Tegobuvir)	Gilead	Sep 22, 2011
GS-7977	Ribavirin	Gilead	Nov 7, 2011
GS-7977	TMC435	Gilead / Tibotec	July 10, 2011
RG7227 (Danoprevir)	RG7128 (Mericitabine)	InterMune / Genentech	Sep 22, 2011

No Longer Listed on clinicaltrials.gov

Drug Name	Drug Category	Company	Updated
BMS-824383	NS5A Inhibitor	Bristol-Myers Squibb	June 12, 2011

IDX375	Polymerase Inhibitor	Idenix	June 12, 2011
INX-189	Polymerase Inhibitor	Inhibitex	June 12, 2011
VX-500	Protease Inhibitor	Vertex	June 12, 2011
VX-916	Polymerase Inhibitor	Vertex	June 12, 2011

Cancelled Trials

Drug Name	Drug Category	Company	Updated
IDX320	Protease Inhibitor (Phase II)	Idenix	Feb 10, 2011
MK-3281	Polymerase Inhibitor	Merck	June 12, 2011
SCH900518	Protease Inhibitor (Phase II)	Merck	Apr 5, 2011

On Hold

Drug Name	Drug Category	Company	Updated
DEB025 (Alisporivir)	Ribavirin	Debio/ Novartis	Apr 25, 2012

Drugs in Development - General

[Cancelled Trials](#)

Quick Reference Guide

Phase I		
Drug Name	Drug Category	Company
ALN-VSP	RNAi	Alnylam
ANA773	TLR Agonist	Anadys Pharmaceuticals
CT-1011	Therapeutic Vaccine	CureTech / Teva
CYT107	Immunomodulator	Cytheris
HCV/MF59	Vaccine(s)	Chiron / Novartis
IMO-2125	TLR9 Agonist	Idera Pharmaceuticals
MBL-HCV1	Neutralizing Vaccine	MassBiologics
NOV-205	Immunomodulator	Novelos Therapeutics
PeviPROTM	Therapeutic Vaccine	Pevion Biotect
PV-10	Anti-Liver Cancer	Provectus
SD-101	TLR9 Agonist	Dynavax

Note: Only drugs that have advanced into phase 3 studies will include comments

Phase 2		
Drug Name	Drug Category	Company
4SC-201 (Resminostat)	HDAC Inhibitor	4SC AG
ABT-267	Cytochrome P450 Inhibitor	Abbott
Alinia (nitazoxanide)	Thiazolides	Romark
Bavituximab (formerly Tarvacin)	Anti-Phospholipid Therapy	Peregrine
Belerofon (oral)	Oral Interferon	Nautilus Biotech
BLX-883 (Locteron)	Long Acting Interferon	Biorex Therapeutics / OctoPlus
CF102 (Phase I/II)	A3AR Agonist /Anti-Liver Cancer	CAN-FITE
Civacir	Vaccine / Immune Globulin	NABI
ChronVac-C	DNA-based Therapeutic Vaccine	Inovio / Tripep
Doxorubicin (BA-003 Transdrug)	Anti-Liver Cancer	BioAlliance Pharma
GI-5005 (Tarmogen)	Therapeutic Vaccine	Globe Immune
GV1001 (Heptovax)	Anti-Liver Cancer	Pharmexa
IC41	Therapeutic Vaccine	Intercell
LGD-4665	Thrombopoeitin Receptor Agonist	Ligand Pharmaceuticals
Miravirsen Formerly (SPC3649-LNA-antimiRTM-122)	microRNA	Santaris
MitoQ (mitoquinone)	Inflammation/Fibrosis Inhibitor	Antipodean
Oglufanide disodium	Immunomodulator	Implicit Bioscience
Omega Interferon	Interferon	Intarcia Therapeutics
Oral Interferon	Oral Interferon	Amarillo Bisociences
PF-03491390 (Formerly IDN-6556)	Pancaspase Inhibitor	Pfizer
PI-88	Anti-Liver Cancer	Progen Industries
SCY-635	Cyclophilin Inhibitor	SCYNEXIS
TG4040	Therapeutic Vaccine	Transgene
ZIO-101	Anti-Liver Cancer (Arsenic)	ZIOPHARM Oncology

Phase 3			
Drug Name	Drug Category	Company	Updated
DEB025 (Alisporivir) (<i>on hold</i>)	Cyclophilin	Debio/ Novartis	Apr 25, 2012

	Inhibitor		
Doxorubicin (ThermoDox)	Anti-Liver Cancer	Celsion	Feb 15, 2010
PEG-Lambda (IL-29) (Type III Interferon)	Long Acting Interferon	ZymoGenetics / BMS	Apr 25, 2012

DEB025 (Alisporivir)	Cyclophilin Inhibitor	Debio/ Novartis	Apr 25, 2012
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Currently in Phase III Studies:

DEB025 (Alisporivir) is a once-a-day cyclophilin inhibitor that works by blocking a part of the replication process in the HCV NS5A region needed by the hepatitis C virus to replicate. It is not considered an HCV direct antiviral medication but may have a broad application because it works on the host rather than a specific virus. In early studies Alisporivir given alone or in combination with pegylated interferon and ribavirin was found to produce rapid reductions in HCV RNA and has a low drug resistance profile. DEB025 is being developed by Novartis.

EASL 2011: Results from a Phase II study of 300 HCV genotype 1 treatment-naïve patients who were treated with alisporivir plus pegylated interferon and ribavirin reported a 76% SVR rate in the group that was treated for 48 weeks compared to 55% in the group that received pegylated interferon plus ribavirin (without alisporivir).

Data from Phase II Studies:

AASLD 2011: In a study that included an interferon-free arm (alisporivir monotherapy & alisporivir plus ribavirin), at week 6, 49% HCV genotype 2 and 3 treatment-naïve patients were HCV RNA undetectable (the highest rates were seen in the alisporivir plus ribavirin arms).

Phase III

On Nov 3 Two phase III studies were announced of Alisporivir (DEB025):

- The triple combination of alisporivir, pegylated interferon and ribavirin in people with HCV genotype 1 treatment- naive will be compared to pegylated interferon and ribavirin, and
- The triple combination of alisporivir pegylated interferon and ribavirin to treat HCV genotype 1 treatment- naive African American patients will be compared to the treatment of boceprevir, pegylated interferon plus ribavirin.

This trial is on hold due to one patient death from pancreatitis.

Doxorubicin (ThermoDox)	Anti-Liver Cancer	Celsion	Feb 15, 2010
Currently in Phase III Studies:			
<p>In June 2008 Celsion announced a new phase III trial of Doxorubicin in patients with hepatocellular carcinoma (HEAT study). A pre-planned, un-blinded interim efficacy analysis will be performed by an independent Data Management Committee when 50% of the endpoint events, tumor recurrence, are realized in the study population. Based on an historical review of RFA cases, Celsion expects the study could be completed by the middle of 2011, and pending positive data, an NDA would be submitted to the FDA before the end of 2011.</p>			

PEG-Lambda (IL-29) (Type III Interferon)	Long Acting Interferon	ZymoGenetics / BMS	Apr 25, 2012
Currently in Phase III Studies:			
<p>The combination of PEGLambda plus ribavirin will be compared to Pegasys plus ribavirin in chronic HCV genotypes 1 and 4 treatment-naive patients. The treatment duration will be 48 weeks and the primary endpoints of the study will be the safety and efficacy. In early studies PEGLambda has been shown to be as effective as pegylated interferon, but with less side effects.</p> <p>AASLD 2011: Interim results from a study of Lambda (with ribavirin) in doses of 120 ug to 240 ug compared to Pegasys (with ribavirin) at 180 ug to treat HCV genotype 1 thru 4 treatment-naïve patients for 24 to 48 weeks is on-going. Interim results reported that Lambda/RBV was generally well-tolerated with similar response rates to Pegasys, but with less side effects and dose reductions.</p> <p>EASL 2012: Results from 118 treatment-naive HCV genotype 2 & 3 patients found that the SVR rates were similar between PEG-Lambda and Pegasys. The side effects were similar between all groups, but there were less side effects (flu-like, musculoskeletal, anemia, neutropenia, and thrombocytopenia) and fewer dose reductions in the PEG Lambda/RBV arms compared to the Pegasys arms.</p>			

Cancelled Trials			
Drug Name	Drug Category	Company	Updated
CTS-1027	Anti-inflammatory	Conatus	Oct 26, 2011
SCV-07	Broad Spectrum Immune Stimulator	SciClone	Dec 16, 2010

Drugs in Development – HIV / HCV Coinfection Studies

Quick Reference Guide

Phase I		
Drug Name	Drug Category	Company

Phase 2		
Drug Name	Drug Category	Company

Note: Only drugs that have advanced into phase 3 studies will include comments

Phase 3			
Drug Name	Drug Category	Company	Updated
BI 201225	Protease Inhibitor	Boehringer Ingelheim Pharma	Nov 7, 2011
BMS-790052	NS5a Inhibitor	Bristol-Myers Squibb	Jan 18, 2012
Boceprevir	Protease Inhibitor	Merck	Jan 18, 2012
Telaprevir	Protease Inhibitor	Vertex / Tibotec	Mar 6, 2011
TMC435	Protease Inhibitor	Tibotec	Jan 18, 2012
Telaprevir	Protease Inhibitor	Vertex / Tibotec	Nov 7, 2011

Phase 4			
Drug Name	Drug Category	Company	Updated
Boceprevir	Protease Inhibitor	Merck	Nov 7, 2011

BI 201335	Protease Inhibitor	Boehringer Ingelheim Pharma	Nov 7, 2011
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Currently in Phase III Studies: HIV/HCV Coinfection

The study will include HCV genotype 1 patients (treatment naïve and relapsers) who are coinfecting with HIV-1. The study is open label and will contain 2 arms: a) BI201335 QD for 12 week and PEG/RBV for 48 weeks) and b) BI201335 QD for 24 weeks and PEG/RBV for 48 weeks. Enrollment started 10/11.

BMS-790052	NS5a Inhibitor	Bristol-Myers Squibb	Jan 18, 2012
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Currently in Phase III Studies: HIV/HCV Coinfection

This is an open label trail to test the safety and efficacy of BMS-790052 plus PEG/RBV for the treatment of HCV Genotype 1 treatment-naive patients who are also infected with HIV-1

Boceprevir	Protease Inhibitor	Merck	Jan 18, 2012
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Currently in Phase III Studies: HIV/HCV Coinfection

This is an open label (all subjects receive study drugs) study to test the safety and efficacy of boceprevir plus PEG/RBV for the treatment of hepatitis C in genotype 1 treatment-naive and treatment-experienced people who are also infected with HIV-1.

Telaprevir	Protease Inhibitor	Vertex / Tibotec	Mar 6, 2012
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Currently in Phase III Studies: HIV/HCV Coinfection

Phase II:

March 6, 2012: The results from a phase 2 study that included two arms (patients who were treated with the triple HCV therapy (telaprevir, PEG/RBV) or PEG/RBV only. Part A: No HIV ART and Part B: People who were on an ART therapy (Atripla or Reyatax-based treatment regime for HIV). Telaprevir, pegylated interferon and ribavirin were given for 12 weeks followed by pegylated interferon plus ribavirin (without telaprevir) for 36 weeks. The SVR12 results found that 74% (28 of 38 patients) who received the triple therapy were HCV RNA undetectable 12 weeks post-treatment compared to 45% (10 of 22 patients) of the group that did not receive telaprevir.

Phase III:

Two studies are underway:

1. HCV genotype 1 treatment experienced patients will receive either 750mg TID (those who are being treated with HIV medications-atazanavir or raltegravir) or 1125 mg mg TID (those who are being treated with HIV medication efavirez) in combination with pegylated interferon plus ribavirin for either 48 or 72 weeks. This is an open label trial.
2. HCV genotype 1 treatment naïve patients will receive either placebo or 750 mg TID for 12 weeks or 1125 mg TID for 12 weeks and pegylated interferon plus rigbavirin for 48 weeks. The ribavirin dose will either be fixed at 800mg BID or weight based 1000-1200 mg BID.

AASLD 2011: Interim results from a study of 60 patients who were treated with telaprevir, PEG/RBV reached treatment week 24 (total treatment duration is 48 weeks) found that 74% (28 out of 38 pts) were HCV RNA negative compared to 55% (12 out of 22 pts) in the group that received PEG/RBV (w/o telaprevir). 16 patients discontinued treatment.

It was announced on 11/5/2011 that Vertex will initiate a triple combination response guided study of telaprevir, PEG/RBV for either 24 or 48 weeks that will include HCV genotype 1 treatment naïve and experience people. The trial is expected to begin towards the end of 2011.

TMC435	Protease Inhibitor	Tibotec	Jan 18, 2012
Currently in Phase III Studies: HIV/HCV Coinfection			
This is an open label trial to test the safety and effectiveness of TMC435 plus PEG/RBV for the treatment of HCV genotype 1 people who are also infected with HIV-1.			

Boceprevir	Protease Inhibitor	Vertex	Jan 11, 2012
Currently in Phase IV Studies: HIV/HCV Coinfection			
The study will include HCV genotype 1 treatment naïve patients with and without HIV. This is an open label trial that will contain two study arms (one arm will only include people mono-infected with HCV and the other arm will only include people coinfectd with HIV and hepatitis C. All patients will receive the boceprevir and PEG/RBV.			
Interim results from an on-going study of 98 HIV-1/HCV coinfectd HCV treatment naïve patients who will be treated with a 4-week lead-in of PEG/RBV followed by 44 weeks of boceprevir and PEG/RBV was released. The results released were from the patients who received 24 weeks of treatment. There was a 70.5% (43 of 61 patients) who were HCV RNA undetectable compared to 34.4% (11 of 32 patients) of the patients who received PEG/RBV (without boceprevir).			