


Hepatitis C Treatments in Current Clinical Development

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How to use the new HCV Advocate HCV Drug Pipeline:

We have made some changes to the drug pipeline that are outlined below. If you are having problems understanding the new “Pipeline” or have suggestions to improve it, please drop me a note at alanfranciscus@hcvadvocate.org

- The current page will list only HCV Direct-Acting Antivirals (DDAS). The first section is the Quick Reference Guide. You can click on the label “Company” and it will link you directly to the company that is developing the drug. Phase I studies will not include any additional information—except for DAAs. Phase 2 and Phase 3 studies will include a short recap or comments of the clinical trial results. You can access the comments by clicking on the “Drug Name.”
- The drugs that are being developed that are **not** DAA drugs can be accessed by clicking on the “Drugs in Development – General” link below this note. We will not include comments in this section unless the drug has advanced into a Phase 3 or Phase 4 study.
- In addition we have various educational materials below to help explain some of the clinical trial processes and help with interpreting clinical trial data.

Drugs in Development - Direct-Acting Antivirals (DAA)

[Drugs in Development - General](#)

[Clinical Trial Process: Making Sense of Clinical Trials](#)

[How to Read an Abstract](#)

[Cancelled Trials](#)

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.

Quick Reference Guide

Phase I		
Drug Name	Drug Category	Company
ABT-072	Polymerase Inhibitor	Abbott
ABT-333	Polymerase Inhibitor	Abbott
ABT-450	Protease Inhibitor	Abbott / Enanta
AZD-7295	NS5A Inhibitor	AstraZeneca
BMS-824383	NS5A Inhibitor	Bristol-Myers Squibb
Clemizole	NS4B Inhibitor	Eiger BioPharmaceuticals
IDX375	Polymerase Inhibitor	Idenix
INX-189	Polymerase Inhibitor	Inhibitex
MK-3281	Polymerase Inhibitor	Merck
PPI-461	NS5A Inhibitor	Presidio
PSI-7851	Polymerase Inhibitor	Pharmasset
PSI-938	Polymerase Inhibitor	Pharmasset
VX-500	Protease Inhibitor	Vertex
VX-916	Polymerase Inhibitor	Vertex

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
PSI-7851 Polymerase Inhibitor	PSI938 Polymerase Inhibitor	Pharmasset	Phase I Dec 8, 2010
BI 201335 Protease Inhibitor	BI 207127 Polymerase Inhibitor	Boehringer Ingelheim Pharma	Phase II Nov 11, 2010
BMS 790052 (NS5a Inhibitor)	BMS 65032 (Protease Inhibitor)	Bristol-Myers Squibb	Phase II Nov 11, 2010
GS-9256	GS-9190 (Tegobuvir)	Gilead	Phase II Nov 11, 2010
RG7128 (Polymerase Inhibitor)	RG7227(Danoprevir) Protease Inhibitor	Genentech / Pharmasset	Phase II Nov 11, 2010

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Phase 2

Drug Name	Drug Category	Company	Updated
ACH-1625	Protease Inhibitor	Achillion	Oct 2 , 2010
ANA598	Polymerase Inhibitor	Anadys Pharmaceuticals	Nov 11, 2010

BI 201335	Protease Inhibitor	Boehringer Ingelheim Pharma	April 29, 2010
BI 207127	Polymerase Inhibitor	Boehringer Ingelheim Pharma	June 29, 2010
BMS 650032	Protease Inhibitor	Bristol-Myers Squibb	Nov 11, 2010
BMS 790052	NS5A Inhibitor	Bristol-Myers Squibb	Nov 11, 2010
BMS 791325	Polymerase Inhibitor	Bristol-Myers Squibb	Sep 30, 2010
Filibuvir	Polymerase Inhibitor	Pfizer	June 30, 2010
GS 9190 (Tegobuvir)	Polymerase Inhibitor	Gilead	Nov 11, 2010
GS-9256	Protease Inhibitor	Gilead	Nov 11, 2010
PSI-7977	Polymerase Inhibitor	Pharmasset	Dec 14, 2010
RG7128	Polymerase Inhibitor	Pharmasset / Genentech	Nov 11, 2010
RG7227 (Danoprevir)	Protease Inhibitor	InterMune / Genentech	Nov 11, 2010
SCH900518 (Narlaprevir)	Protease Inhibitor	Merck	June 29, 2010
TMC435	Protease Inhibitor	Medivir / Tibotec	Nov 23, 2010
Vaniprevir (MK-7009)	Protease Inhibitor	Merck	Nov 11, 2010

VX-222	Polymerase Inhibitor	Vertex	Nov 23, 2010
VX-759	Polymerase Inhibitor	Vertex	March 12, 2009

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Phase 3

Drug Name	Drug Category	Company	Updated
Boceprevir	Protease Inhibitor	Merck	Nov 11, 2010
Telaprevir	Protease Inhibitor	Vertex	Dec 22, 2010

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PSI-7851 Polymerase Inhibitor	PSI938 Polymerase Inhibitor	Pharmasset	Dec 8, 2010
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Comments:

Phase 1 combination study to evaluate once daily doses of PSI-7977 and PSI-938 in patients with HCV who have not been treated previously. The antiviral properties of the drugs (alone and in combination) will be observed for 14 days.

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BI 201335 Protease Inhibitor	BI 207127 Polymerase Inhibitor	Boehringer Ingelheim	Nov 11, 2010
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		Pharma	
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Comments:

AASLD 2010: In a study (without interferon) the triple regime of BI 201335 (protease inhibitor) plus BI 207127 (polymerase inhibitor) and ribavirin to treat HCV genotype 1 treatment-naïve patients was found to provide strong antiviral activity—additional studies with longer durations are planned to evaluate sustained virological response rates.

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BMS 790052 NS5A Inhibitor	BMS 65032 Protease Inhibitor	Bristol-Myers Squibb	Nov 11, 2010
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Comments:

In an important study the combination of BMS-650032 (protease inhibitor) and BMS-790052 was given to genotype 1 null-responders to a prior course of therapy. The interim results at 12 weeks (total study duration is 24 weeks) produced early antiviral activity, but 6 out of the 11 people treated had viral breakthrough indicating that pegylated interferon and/or ribavirin will be needed to completely suppress the virus at least in this study. When the combination was combined with pegylated interferon and ribavirin 9 out of 10 patients became HCV RNA undetectable by week 12.

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GS-9256 (Protease Inhibitor)	GS-9190(Tegobuvir) Polymerase Inhibitor	Gilead	Oct 11, 2010
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Comments: 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.

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RG7128 (Polymerase Inhibitor)	RG7227 (ITMN-191) (Danoprevir) Protease Inhibitor	Genentech / Pharmasset	Oct 11, 2010
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Comments:

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.

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ACH-1625	Protease Inhibitor	Achillion	Oct 2, 2010
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Comments:

Results from two small studies (9 pts and 8 pts) treated with 200 or 600 mg for 5 days had a 3.86 and 3.81 log₁₀ viral load decline respectively. Adverse events were classified as mild to moderate.

Recently, Achillion announced a placebo-controlled phase IIa study to evaluate the safety, tolerability and antiviral activity of ACH-1625 in conjunction with pegylated interferon alfa-2a and ribavirin. The study will evaluate HCV genotype 1 patients after 4 and 12 weeks of dosing. The results from the 4 week study are expected in the first quarter of 2011, and the 12 week study results are anticipated by the end of 2011.

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ANA598	Polymerase Inhibitor	Anadys Pharmaceuticals	Nov 11, 2010
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Comments:

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.

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BI 201335	Protease Inhibitor	Boehringer Ingelheim Pharma	April 29, 2010
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Comments:

EASL 2010: The results from the SILEN-C2 study of 280 HCV genotype 1 patients who were prior non-responders treated for 24 weeks with either 240mg BI 201335 (once-a-day), 240 mg BI 201335 (once-a-day) after a 3-day lead-in of PEG/RBV or 240 BI 201335 (twice-a-day) 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. Interim results found at week 12 reported that 54 to 59% were HCV RNA undetectable (less than 10 IU/mL). The majority of people who discontinued treatment were in the BI twice- a-day group (24%) compared to 4% in the once-a-day groups. *The combination of BI 201335 and BI 20127 is being studied (see DDA combinations).*

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BI 207127	Polymerase Inhibitor	Boehringer Ingelheim Pharma	June 29, 2010
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Comments:

In a 5-day monotherapy study of HCV genotype 1 patients reported a median 3.8 log₁₀ viral load decrease. *The combination of BI 201335 and 20127 is being studied (see DDA combinations).*

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BMS 650032	Protease Inhibitor	Bristol-Myers Squibb	Nov 11, 2010
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Comments:

AASLD 2010: In a study (without interferon) the triple regime of BI 201335 (protease inhibitor) plus BI 207127 (polymerase inhibitor) and ribavirin to treat HCV genotype 1 treatment-naïve patients was found to provide strong antiviral activity—additional studies with longer durations are planned to evaluate sustained virological response rates.

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

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BMS 790052	NS5A Inhibitor	Bristol-Myers Squibb	Sep 30, 2010
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Comments:

BMS 790052 is being given once a day 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, non-response and treatment-intolerant patients.

A study of 48 HCV genotype 1 treatment-naïve patients treated with various doses of BMS 790052 in combination with pegylated interferon plus ribavirin for 48 weeks has been completed and data is expected to be released in 2010-2011. *BMS 790052 is also being studied in combination with BMS 65032 (see DAA combination above).*

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BMS 791325	Polymerase Inhibitor	Bristol-Myers Squibb	September 30, 2010
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Comments:

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 (4 to 48 weeks) will be guided by on-treatment response.

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Filibuvir	Polymerase Inhibitor	Pfizer	June 30, 2010
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Comments:

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.

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GS 9190 (Tegobuvir)	Polymerase Inhibitor	Gilead	Nov 11, 2010
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Comments:

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*).

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GS 9256	Protease Inhibitor	Gilead	Nov 11,
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Comments:

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 dependant 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)*.

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PSI-7977	Polymerase Inhibitor	Pharmasset	Dec 14, 2010
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Comments:

AASLD 2010: PSI-7977, a polymerase inhibitor, dosed once a day (100, 200 and 400 mg) combined with pegylated interferon plus ribavirin for 28 days produced 4 week RVRs of 88 to 94% compared to 21% in the pegylated interferon plus ribavirin group (without PSI-7977). At week 12 the cEVR (complete early virological response) was highest in the 200 mg QD (94%) and 400 (87%) compared to 64% cEVR in the pegylated interferon plus ribavirin (placebo) group. Based on these results a 12 week study is being planned. In addition PSI-7977 appears to work against different genotypes.

On December 14, Pharmasset announced the commencement of an exploratory study, The trial will evaluate PSI-7977 400mg QD in combination with ribavirin , with 0, 4, 8, or 12 weeks of pegylated interferon alfa 2a in treatment-naïve patients infected with HCV genotype 2 or 3. About 40 patients infected with HCV genotype 2 or 3, not been previously treated are expected to be enrolled. The primary endpoint of the trial will be the assessment of safety and tolerability of PSI-7977 400mg QD and RBV for 12 weeks, administered with or without pegylated interferon in treatment naïve patients with HCV genotypes 2 or 3.

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RG7128	Polymerase Inhibitor	Pharmasset / Genentech	Nov 11, 2010
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Comments:

AASLD 2010: RG7128 (500 or 1000 mg - BID) combined with pegylated interferon plus ribavirin was given in different doses and time lines based on response and it was found that RG7128 was safe and well-tolerated in HCV genotype 1 and 4 treatment-naïve patients with and without cirrhosis. The group that received the 8 or the 12 week regime of 1000 mg BID achieved the highest declines in HCV RNA (viral load) levels. RG7128 appears to have a high barrier to drug resistance.

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RG7227 (Danoprevir)	Protease Inhibitor	InterMune / Genentech	Nov 11, 2010
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Comments:

AASLD 2010: Interim results using various doses of danoprevir combined with pegylated interferon plus ribavirin found that 88 to 92% were HCV RNA negative by week 12 compared to 43% in the placebo group. More studies are planned including a study using ritonavir as a boosting agent.

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SCH900518 (Narlaprevir)	Protease Inhibitor	Merck	June 29, 2010
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Comments:

EASL 2009: A study of 40 genotype 1 patients (treatment- naïve; treatment-experienced) who received ritonavir-boosted nralaprevir, pegylated interferon/ ribavirin or placebo (with pegylated interferon/ribavirin) found an 81% SVR in the treatment- naïve group; the SVR results in the treatment-experienced were similar between the nralaprevir and placebo groups.

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TMC435	Protease Inhibitor	Medivir / Tibotec	Nov 23, 2010
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Comments:

AASLD 2010: Interim results from a study of TMC435 (75 and 150 mg QD (once a day)) combined with pegylated interferon plus ribavirin given to HCV genotype 1 treatment-naïve patients for up to 24 weeks showed that TMC435 produced significant viral load reductions. In patients who completed 24 weeks treatment or stopped treatment for any reason by week 24 the SVR results ranged from 88 to 97% (119 out of 130 patients). So far there is a low rate of viral breakthrough.

Interim 24 week results from a study of prior HCV genotype 1 treatment experienced patients found that 78 to 94% were HCV RNA undetectable. Tibotec is expected to begin phase III clinical trials in the first half of 2011.

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Vaniprevir (MK-7009)	Protease Inhibitor	Merck	Nov 11, 2010
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Comments:

AASLD 2010: A study of 45 HCV genotype 1 treatment-naïve patients who were administered 1 of 5 regimens—placebo, 300 mg BID (twice a day), 600 mg BID, 600 mg QD (once a day) or 800QD 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.

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VX-222	Polymerase Inhibitor	Vertex	Nov 23, 2010
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Comments:

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 twice-a-day; 1500 mg once-a-day) 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.

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VX-759	Polymerase Inhibitor	Vertex	March 12, 2009
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Comments:

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.

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Boceprevir	Protease Inhibitor	Merck	Nov 11, 2010
Comments:			
See the HCSP Factsheet :			

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Telaprevir	Protease Inhibitor	Vertex	Dec 22, 2010
Comments:			
<p>On November 22, 2010 Vertex announced that they had completed submission of their data to the Food and Drug Administration and requested a 6 month priority review.</p>			
<p>On December 20, 2010, Janssen-Cilag (Johnson & Johnson in Europe) will seek approval from the European Medicines Agency (EMA) for a new investigational treatment for the chronic genotype 1 hepatitis C virus (HCV). JNJ owns the commercial rights to Telaprevir in Europe.</p>			

See the HCSP [Factsheet](#):

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Cancelled Trials

Drug Name	Drug Category	Company	Updated
Telaprevir (Protease Inhibitor)	VX-222 (Polymerase Inhibitor)	Vertex	Dec 21, 2010

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Drugs in Development - General

[Drugs in Development - Direct-Acting Antivirals \(DAA\)](#)

[Clinical Trial Process](#)

[How to Read an Abstract](#)

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Quick Reference Guide

Phase I		
Drug Name	Drug Category	Company
ALN-VSP	RNAi	Alnylam
ANA773	TLR Agonist	Anadys Pharmaceuticals
Bavituximab (formerly Tarvacin)	Anti-Phospholipid Therapy	Peregrine
CF102	A3AR Agonist /Anti-Liver Cancer	CAN-FITE
ChronVac-C	DNA-based Therapeutic Vaccine	Inovio / Tripep
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
TG4040	Therapeutic Vaccine	Transgene

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Phase 2

Drug Name	Drug Category	Company
4SC-201 (Resminostat)	HDAC Inhibitor	4SC AG
Alinia (nitazoxanide)	Thiazolides	Romark
Belerofon (oral)	Oral Interferon	Nautilus Biotech
BLX-883 (Locteron)	Long Acting Interferon	Biolex Therapeutics / OctoPlus
Civacir	Vaccine / Immune Globulin	NABI
CTS-1027	Anti-inflammatory	Conatus
Debio 025	Cyclophilin Inhibitor	Debio
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
IL-29 (Type III Interferon)	Long Acting Interferon	ZymoGenetics / BMS
LGD-4665	Thrombopoietin Receptor Agonist	Ligand Pharmaceuticals
Miravirsen Formerly (SPC3649-LNA-	microRNA	Santaris

antimiRTM-122)		
MitoQ (mitoquinone)	Inflammation/Fibrosis Inhibitor	Antipodean
Oglufanide disodium	Immunomodulator	Implicit Bioscience
Omega Interferon	Interferon	Intarcia Therapeutics
Oral Interferon	Oral Interferon	Amarillo Biosciences
PF-03491390 (Formerly IDN-6556)	Pancaspase Inhibitor	Pfizer
PI-88	Anti-Liver Cancer	Progen Industries
SCY-635	Cyclophilin Inhibitor	SCYNEXIS
ZIO-101	Anti-Liver Cancer (Arsenic)	ZIOPHARM Oncology

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

Phase 3			
Drug Name	Drug Category	Company	Updated
Doxorubicin (ThermoDox)	Anti-Liver Cancer	Celsion	Feb 15, 2010

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Doxorubicin (ThermoDox)	Anti-Liver Cancer	Celsion	Feb 15, 2010
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Comments: Phase one interim results found that ThermoDox (doxorubicin) – heat-activated liposome therapy – in combination with Radiofrequency Ablation of primary and metastatic tumors to the liver showed local return of cancer in only 2 of 44 tumors resulting in a 4.5% local recurrence rate. Also, 5 of the 10 evaluable patients demonstrated a complete response along with a single partial response. In June 2008 the company also announced a new phase III trial of Doxorubicin in patients with hepatocellular carcinoma (HEAT study). On December 3, 2009 Celsion reported that enrollment in this 600 patient study continues to accelerate and Celsion expects to meet its objective of completing enrollment by the middle of 2010. 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, a NDA would be submitted to the FDA before the end of 2011. On February 11, Celsion announced that the Data Monitoring Committee (DMC) had reviewed the safety data and has recommended that the study continue.

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Cancelled Trials			
Drug Name	Drug Category	Company	Updated
SCV-07	Broad Spectrum Immune Stimulator	SciClone	Dec 16, 2010

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