

Infectious Diseases

Newly launched products break ground in clearing life-threatening viruses and stanching stubborn infections. But that's only half the battle. Pharma must raise awareness levels in order to get the undiagnosed on therapy and expand access to care, reports **Noah Pines**

epatitis C (HCV) has become one of the most prolific areas of drug development. What other category boasts two new drugs with a high likelihood of cure and shorter treatment in patients infected with a common and challenging illness, as in the recently approved Victrelis (Merck) and Incivek (Vertex)?

The two novel protease inhibitors, when given with peginterferon and ribavirin, offer "far better treatment outcomes, which will most likely result in greater numbers of patients receiving treatment," predicts Derek Fetzer, director of global strategic analytics at Janssen Pharmaceutical Services. "However, aggressive screening is needed to substantially reduce the [HCV] epidemic."

Indeed, Wolters Kluwer *in*Thought says its 2015 worldwide sales estimates of \$2.7 billion for Incivek and \$2.0 billion for Victrelis could go higher, if HCV screening becomes routine.

How to accomplish this? Considering ID specialists are among the heaviest users of the web during patient consults, digital channels

are one way, says Margaret Crowley, senior director of

marketing, Optimer Pharmaceuticals, which recently received FDA approval for antibiotic Dificid, for treating Clostridium difficile–associated diarrhea (CDAD).

"There's very low awareness of the increasing incidence and severity of CDAD, and there is a problem with its recurrence, so we're focusing on disease awareness," says Crowley.

Ditto for Hepatitis B virus (HBV). While PCPs and gastroenterologists like prescribing the two guideline-recommended orals—Gilead's Viread and Bristol-Myers Squibb's Baraclude only about 5% of the 1.4-2.0 million people chronically infected are being treated, a recent study showed.

Faced with an awareness challenge in the HCV space, Merck and Vertex are doing a fair bit of disease education. A Leerink Swann survey of US hepatologists and gastroenterologists found that 39% and 45% of respondents had already prescribed Victrelis and Incivek, respectively. The brands could pave the way for newcomers. The HCV pipeline includes agents from Human Genome Sciences, Novartis, Boehringer Ingelheim and J&J.

Companies in the HIV space aren't standing still, either. Some 32 antiretroviral drugs are on the market, including several well-tolerated co-formulations. In phase III is a one-pill, once-daily combination of Gilead's Truvada and Johnson & Johnson's just-approved Edurant. Analysts anticipate it may achieve broad first-line use, despite having lower efficacy among sicker patients than the market leader, Gilead's Atripla.

Gilead's "quad pill" is also in late-stage testing, raising the possibility that the firm could face the enviable challenge of marketing three once-a-day combo pills. ViiV Healthcare is developing yet another co-formulation combining dolutegravir with Epzicom.

The next installment of MM&M's Therapeutic Focus will be October's look at oncology products

TOP 40 INFECTIOUS DISEASE PRODUCTS, 2010 Category leaders, ranked by 2010 US sales, and their media spend

Rank	Product	Manufacturer	US sales dollars (millions)*	% change vs. prior I2 mos.	TRx count (thousands)	TRx % change vs. prior 12 mos.	US media spend dollars (thousands)**	Media spend % change vs. prior 12 mos.
1	Atripla	BMS/Gilead	\$2,198.0	23.3%	959.2	14.9%	\$1,529.0	-33.7%
2	Levaquin	Johnson & Johnson	\$2,062.9	-1.5%	9,256.1	-18.2%	\$1,176.0	410.5%
3	Truvada	Gilead	\$1,694.8	21.5%	1,148.9	14.0%	\$228.0	-79.9%
4	Azithromycin	Generic	\$1,064.8	-8.3%	51,616.3	-3.0%	\$0.0	N/A
5	Zosyn	Pfizer	\$861.0	-4.5%	2.0	-21.6%	\$130.0	-57.5%
6	Reyataz	Bristol-Myers Squibb	\$754.0†	4.0%	643.1	4.0%	\$1,443.0	-40.7%
7	Solodyn	Medicis	\$748.2	31.9%	1,268.8	13.7%	\$101.0	110.4%
8	Amoxicillin tr./clavulanate	Generic	\$723.5	-0.6%	21,468.1	-0.1%	\$20.0	N/A
9	Zyvox	Pfizer	\$681.1	-2.0%	139.4	-7.4%	\$1,028.0	-0.1%
10	Prevnar 13	Pfizer	\$645.5	N/A	0.1	N/A	\$8,350.0	N/A
11	Ciprofloxacin HCI	Generic	\$611.1	1.5%	22,531.8	3.7%	\$0.0	N/A
12	Isentress	Merck	\$591.4	60.4%	451.2	50.8%	\$1,243.0	20.1%
13	Pegasys	Roche	\$553.9	3.6%	192.0	-5.1%	\$0.0	N/A
14	Norvir	Abbott	\$503.6	10.3%	1,011.3	13.5%	\$0.0	N/A
15	Cubicin	Cubist	\$468.9	9.3%	2.6	3.1%	\$239.0	-75.0%
16	Prezista	Johnson & Johnson	\$460.6	59.4%	342.2	48.2%	\$417.0	-36.8%
17	Epzicom	ViiV Healthcare	\$452.3	10.7%	359.2	2.7%	\$424.0	-10.7%
18	Kaletra	Abbott	\$407.1	-13.1%	403.3	-11.1%	\$523.0	142.6%
19	Cefdinir	Generic	\$401.6	-5.7%	9,000.3	-0.3%	\$0.0	N/A
20	Avelox	Bayer HealthCare	\$392.9	-11.1%	2,721.2	-20.7%	\$0.0	N/A
21	Doryx	Warner Chilcott	\$392.9	29.2%	961.8	10.0%	\$0.0	N/A
22	Viread	Gilead	\$379.8	18.4%	459.7	13.9%	\$104.0	-79.7%
23	Amoxicillin	Generic	\$338.8	0.1%	53,680.9	-2.6%	\$0.0	N/A
24	Combivir	ViiV Healthcare	\$312.3	-8.0%	277.3	-13.5%	\$0.0	N/A
25	Vancomycin HCI	Generic	\$310.5	8.7%	33.2	15.6%	\$0.0	-100.0%
26	Vancocin HCI	ViroPharma	\$265.8	21.6%	153.9	1.1%	\$0.0	-100.0%
27	Cephalexin	Generic	\$254.4	1.1%	22,285.1	-0.3%	\$0.0	N/A
28	Engerix-B	GlaxoSmithKline	\$251.8	2.2%	43.9	14.9%	\$0.0	N/A
29	Fluvirin	Novartis	\$244.5	71.1%	8,846.1	47.5%	\$0.0	N/A
30	Oracea	Galderma	\$230.1	61.4%	724.0	23.1%	\$7,995.0	-61.5%
31	Tobi	Novartis	\$208.0	8.1%	40.0	-5.3%	\$0.0	N/A
32	Minocycline HCI	Generic	\$202.9	-6.1%	3,822.7	-4.5%	\$0.0	N/A
33	Co-trimoxazole	Generic	\$197.0	3.4%	22,282.3	3.1%	\$0.0	N/A
34	Invanz	Merck	\$196.0	16.5%	3.6	18.6%	\$0.0	N/A
35	Sustiva	Bristol-Myers Squibb	\$194.1	-10.3%	248.1	-13.1%	\$182.0	-49.3%
36	Clindamycin HCl	Generic	\$189.3	2.2%	7,761.8	3.3%	\$0.0	N/A
37	Pneumovax 23	Merck	\$185.3	21.3%	288.1	61.3%	\$0.0	N/A
38	Primaxin	Merck	\$180.6	-6.5%	1.1	3.3%	\$0.0	N/A
39	Merrem	AstraZeneca	\$178.4	-28.7%	0.8	-6.2%	\$50.0	>999
40	Tygacil	Pfizer	\$168.8	-2.5%	1.2	5.0%	\$2,339.0	25.0%

*Integrated wholesale acquisition cost sales, unless noted
**DTC/journal spend
Note: TRX count includes retail only. List includes products FDA indicates as approved for treating AIDS, hepatitis B/C and bacterial infections, as well as vaccines and other antivirals.

Sources: Sales/TRx, Wolters Kluwer Pharma Solutions, company reports; media spend, SDl/Kantar Media † Company reported sales