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# SPECIALTY PHARMACY NEWS

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## Outlook 2008

### HIV, Oncology Are Among Areas That Will See Therapeutic Impact

Although there was a limited number of specialty drugs approved in 2007, many of the therapies offer promising new approaches to a variety of patients. While some health plans may put a moratorium on coverage for drugs that have been on the market for only a short while, the apparent effectiveness of these therapies may require insurers to be more proactive in their assessment and potential reimbursement of such drugs.

With numerous therapies in the pipeline and a pair of new treatments approved in the second half of 2007, HIV is one condition that should garner attention in 2008.

On Aug. 6, the FDA approved Pfizer Inc.'s Selzentry (maraviroc) tablets, which have an annual price of about \$10,600 (*SPN 9/07, p. 6*). On Oct. 12, the agency approved Isentress (raltegravir) from Merck & Co., Inc., a tablet with an annual price of approximately \$10,000 (*SPN 11/07, p. 11*). Both drugs are first-in-class therapies and are indicated in combination with other antiretroviral agents for the treatment of HIV.

"Isentress demonstrated strong clinical results in patients that have shown resistance to other medications," says **Kevin Gorman, managing partner and founder of Putnam Associates**, a pharmaceutical and biotech consulting firm. "It was fast-tracked through the FDA and is just now making its way" across the country. Selzentry, which has some "baggage" in terms of its side-effect profile but is still an effective option, is indicated when a diagnostic test shows a patient has a particular HIV strain.

"The uptake and penetration of therapies will happen extraordinarily quickly in" the area of HIV, says Gorman.

With newer and more expensive therapies coming onto the market, plans need to be more vigilant in their attention to these drugs so that patients can have access to these therapies as soon as possible, he contends.

"Many plans have instituted a policy of 'we're not going to cover new drugs for the first six months that they are on the market,'" says Gorman. "This means it is incumbent for innovators to get to the plan...and show their therapeutic evidence of effectiveness and have economic discussions with plans.... It is good for the patient, medicine and overall outcomes for drugs to be accepted [by plans] early on."

Oncology is another area that should see new therapies approved in the next year. The FDA is expected to make a decision in March on Treanda (bendamustine

HCl). The orphan drug has fast-track status and is being considered for patients with chronic lymphocytic leukemia (CLL). If approved, it would be the first new therapy approved for this indication since 2001.

Gorman says that another CLL product that may hit the market this year is HuMax-CD20 (ofatumumab). Genmab A/S and GlaxoSmithKline PLC are co-developing the therapy, which has been fast-tracked for this indication. He expects the companies to file their application soon. "CLL is an area that needs some good new therapies," he says, "so it's likely to be acted on quickly."

#### Supplemental Indications Expected

Additional indications for already-approved therapies — many of them in oncology — are also expected in 2008, according to Gorman. A lot of these products work in multiple cancers, especially the blood cancers, says **Domenick Bertelli, a principal with Putnam Associates**. This makes it "hard for manufacturers to determine which area to prioritize. It's hard to prioritize research and development dollars," he says.

In addition to CLL, Cephalon, Inc. is also studying Treanda for approval in non-Hodgkin's lymphoma (NHL), multiple myeloma and small cell lung cancer.

Initially approved in 2005 for advanced kidney cancer, Nexavar (sorafenib) was granted approval in November for liver cancer. The drug from Bayer HealthCare AG and Onyx Pharmaceuticals, Inc. "is the first product to show promising activity in liver cancer," says Gorman, and 2008 should yield the first results in these patients.

HuMax-CD20 is also in clinical development for the treatment of NHL, rheumatoid arthritis (RA) and diffuse large B-cell lymphoma. Genentech Inc.'s Avastin (bevacizumab), already approved for colorectal and non-small cell lung cancers, is in trials for about eight to 10 indications, and breast cancer patients may be the first group to get it, perhaps in the first quarter of the year. Another Genentech product, Herceptin (trastuzumab), is in a combination trial with Avastin, says Gorman, and RA infusible Orencia (abatacept) may see a subcutaneous form. Bertelli says there are two or three RA drugs in the pipeline that are similar to some existing therapies, and they should hit the market in 2008 or 2009.

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