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Avalanche of Specialty Drugs Predicted

By David Wild

Boston—There is no sign of slowing in the specialty drug development market, according to a presentation by an Express Scripts expert at the Academy of Managed Care Pharmacy's Managed Care & Specialty Pharmacy annual meeting.

"We're seeing greater and greater competition among specialty pharmaceuticals, particularly as more generics and biosimilars are approved," said Aimee Tharaldson, PharmD, a senior clinical consultant on emerging therapeutics at Express Scripts.

Indeed, as 64 branded specialty drug patents expire between 2018 and 2022, their generic versions will have an opportunity to scoop up as much as they can of the \$25 billion of market share their originator products currently own. Similarly, with 71 biologics set to lose their patents through 2022, a slew of biosimilars will have access to the \$54.4 billion market those reference products currently control, Dr. Tharaldson said.



“There are significant legal hurdles that protect biologic medications, but the FDA is currently working on policies to increase competition in this space, so we’ll see if there are changes in the future,” she said, adding that Express Scripts found spending on specialty drugs grew by 11.3% in 2017, compared with a 4.3% drop in spending on traditional drugs last year.

Uptake of some approved biosimilars has been slower than hoped for, Dr. Tharaldson said. “Zarxio [filgrastim- sndz, Sandoz] has been able to capture about 36% of the filgrastim market, but Remicade [Janssen] still maintains 97% of the infliximab market,” she pointed out.

What’s Up Ahead?

Cancer and orphan drugs will likely see the greatest number of specialty drug approvals in the near term, Dr. Tharaldson said, with multiple cancer treatments, including several immunotherapies, slated to receive approval as early as late-summer 2018.

Migraines are another disease poised for significant product launches, Dr. Tharaldson noted. “About 3.5 million Americans take preventive migraine treatments, but up to 80% of these discontinue treatment within one year, so

there's definitely a need for new preventive treatment options," she said, adding that five new calcitonin gene-related peptide inhibitors are set for approval in 2018 to 2019, and several others are in the pipeline for later approvals.

Near-term approvals for multiple sclerosis drugs, a handful of new HIV treatments combining different mechanisms of action, and one treatment for hemophilia A also could receive FDA approval this year, she said.

Expert insight like Dr. Tharaldson's provides an important snapshot of the state of specialty drug development, said Grant Knowles, PharmD, the vice president of business development and operations at Ardon Health, a specialty pharmacy provider located in Portland, Ore. However, he said, "it's kind of a guessing game in terms of when these drugs may actually come to market.

"A couple of years ago, NASH [non-alcoholic steatohepatitis] was the next big blockbuster category on the immediate horizon, but approvals and projects got pushed," said Dr. Knowles, who moderated the session during which Dr. Tharaldson spoke. "Alzheimer's treatment breakthroughs have been looming but also didn't follow their anticipated approval projections."