

Specialty drug pipeline predictions: Seven key areas to watch

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By [Bryant Furlow](#)

Biosimilars will be an increasingly important part of the specialty pharmaceuticals market, and 2017 is set to be a banner year for new cancer biologics approvals, according to Aimee Tharaldson, PharmD, senior clinical consultant, Emerging Therapeutics, at Express Scripts in Minneapolis, Missouri. Tharaldson reviewed the specialty pharmaceuticals development pipeline at the Academy of Managed Care Pharmacy (AMCP) 2017 Nexus, on October 17.

Leading specialty therapy classes include inflammatory conditions, cancer, multiple sclerosis, HIV, and Hepatitis C, she reported.

After a dip in specialty drug approvals by the FDA last year, 2017 is on track for 30 approvals—more than any previous year except 2015. Thirteen cancer drugs have already been approved this year and seven drugs for inflammatory diseases could be approved next year, she noted.

Biosimilar pipeline

Biosimilars are still a nascent field but with more than 70 biologic patent expirations by 2021, biosimilars are set to become an important part of the pharmaceuticals market, Tharaldson noted. Resolution of regulatory ambiguities and maturation of the biosimilars market, as agents that the FDA deems to be interchangeable with their reference biologics lead to more competition, will yield cost savings, she predicted.

The biosimilar naming issue has yet to be resolved, she cautioned.

The FDA released much-anticipated guidance for biosimilars naming in January, announcing that biosimilars will be named using reference biologics' generic name plus a random four-letter suffix. (Sandoz will have to rename its “filgrastim-sndz,” a biosimilar for Neupogen because sndz is a reference to the company's name rather than a random collection of letters, Tharaldson noted.)

FDA determinations of biosimilar interchangeability will be a landmark in the maturation of the biosimilars market, bringing cost savings, Tharaldson suggested. The 2010 Biologics Price Competition and Innovation Act (BPCIA) allows an abbreviated regulatory pathway for licensing biologics determined to be “interchangeable” with FDA-approved biologics.

Cancer pipeline

The cancer pipeline for 2018 includes five oral drugs for a range of tumors:

1. The nonsteroidal antiandrogen apalutamide (Janssen) for castration-resistant prostate cancer
2. Entinostat (Syndax) for estrogen receptor-positive breast cancer
3. Ivosidenib (Agiros) for acute myeloid leukemia
4. Larotrectinib (Array BioPharma) for TRK+ fusion tumors
5. Talazoparib (Pfizer), for BRCA mutation-positive breast cancers.

Other than apalutamide and entinostat, most cancer drugs in the 2018 pipeline are targeted therapies, Tharaldson noted.

Gilead's axicabtagene ciloleucel for non-Hodgkin lymphoma was approved by the FDA on October 18. Approval is also pending for AstraZeneca's MEK/BRAF inhibitor acalabrutinib for mantle cell lymphoma and Array BioPharma's binimetinib/encorafenib for BRAF-mutation-positive, advanced and metastatic melanoma.

Three antibody-drug conjugates for targeted delivery are also in the 2018 pipeline, Tharaldson said: AbbVie's depatuxizumab for glioblastoma brain tumors and rovalpituzumab for small-cell lung cancer, and Seattle Genetics' sacituzumab for triple-negative breast cancer.

Tharaldson also spotlighted the FDA's approval in August of tisagenlecleucel (Novartis' Kymriah), the first approved chimeric antigen receptor T-cell (CAR-T) cancer immunotherapy.

"It's genetically engineered and it's an immunotherapy," Tharaldson said. "It has an impressive response rate."

Tisagenlecleucel's \$475,000 price tag made headlines, she noted, but with the approval of future CAR-T therapies, competition in this space should increase to bring down costs, she suggested. Juno Therapeutics' JCAR017 for B-cell non-Hodgkin lymphoma is another anti-cancer CAR-T therapy, and may see FDA approval in 2018.

[Next: MS and HIV pipeline](#)

Multiple sclerosis and HIV pipeline

Three multiple sclerosis drugs could see approval in 2017, 2018 and 2019, Tharaldson said: Copaxone (Mylan/Sandoz/Pfizer), ozanimod (Celgene), and siponimod (Novartis).

Once-daily orals dominate HIV treatment because therapy must achieve 95% compliance to achieve effective viral suppression, Tharaldson said. The FDA is anticipated to issue a decision by December 2017 for the oral combination integrase inhibitor/non-nucleoside reverse transcriptase inhibitor (NNRTI) dolutegravir/rilpivirine (ViiV/Janssen), she noted.

Another oral HIV integrase inhibitor/NNRTI, Gilead's bicitegravir/FTC/TAF might be approved in February 2018. Merck's oral doravirine/lamivudine/TDF is also expected to see approval next year. Tharaldson anticipates FDA approval for the intravenously-administered HIV viral entry inhibitor ibalizumab (Theratechnologies) in early January 2018.

Migraine pipeline

Migraine is a debilitating condition involving severe, throbbing headache with nausea, vomiting, and light and sound sensitivity, affecting an estimated 39 million Americans, Tharaldson said. Acute treatments currently include triptans, caffeine, ergot drugs, acetaminophen, opioids and NSAIDS.

A number of subcutaneous and oral calcitonin gene-related peptide (CGRP) inhibitor biologics promise to expand treatment options in the coming four years, Tharaldson said.

Amgen and Novartis' monthly subcutaneously-administered erenumab is scheduled for possible FDA approval in May 2018; two other monthly subcutaneous biologics could also see approval next year: Teva's fremanezumab and Eli Lilly's galcanezumab.

Hemophilia pipeline

In the U.S., 20,000 people live with hemophilia; most (80%) of cases involve Hemophilia A. The hemophilia drug pipeline includes the intravenously-administered recombinant

Inhibitor eptacog beta activated (LFB S.A.) for hemophilia A or B, and two drugs for patients with Hemophilia A: the subcutaneously-administered emicizumab (Genentech), for patients with Factor VIII inhibition, and Bayer's intravenous damoctocog alpha pegol.

Nonalcoholic steatohepatitis pipeline

Nonalcoholic steatohepatitis, a fatty liver disorder that causes inflammation and liver damage, affects up to 16 million Americans for whom there are currently "limited" treatment options, Tharaldson said. Ten investigational therapies, including three undergoing Phase 3 clinical trials, could see approval in 2019 and beyond, she said.

Alzheimer's pipeline

New drugs for Alzheimer's Disease treatments are further on the horizon, with possible approvals in 2020 and 2021, and beyond, she noted.

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