IFPW FOCUS
A Bi-Weekly Pharmaceutical Industry Newsletter
Vol 32 | No. 6
March 14, 2024

The Top 10 Drugs Losing Exclusivity in 2024

(Source: An article by staff writers for FiercePharma)

The passage of time serves as a reminder for pharma executives about the need for new launches to replace revenue lost to the patent cliff. That's because no matter how successful a drug is, it'll eventually fall victim to generics or biosimilars.

Below is a list of drugs expected to face the same circumstances in 2024. The drugs listed are most likely to face new generic or biosimilar competition this calendar year and are ranked by U.S. sales from last year.

There is always uncertainty stemming from legal and regulatory developments, which can affect generic and biosimilar launch timing. Documented uncertainties from company filings, conference call transcripts and outside sources were considered.

Sprycel (dasatinib)--manufactured by Bristol Myers Squibb, saw US$1.45 billion in US sales in 2023. The drug, used in the treatment of chronic myeloid leukemia is expected to face generic competition from launches by Apotex and other "undisclosed" companies by September 2024, or "earlier under certain circumstances".

Over the years, *Sprycel*—also known by its generic name *dasatinib*—has brought "tremendous innovation" to chronic myeloid leukemia (CML) field. So far, Biocon, Lupin, Dr. Reddy's Laboratories, Alebmic and Teva boast tentative FDA nods for their versions.

Tysabri (natalizumab)–manufactured by Biogen and used in the treatment of multiple sclerosis and Crohn's disease, with US$998 million in sales will face competition from generic entry the first half of 2024.

Despite Biogen's best legal efforts, it appears Sandoz is moving full steam ahead on its planned launch of a biosimilar to the multiple sclerosis blockbuster *Tysabri* later this year. Sandoz received approval for the U.S.' first—and so far only—*Tysabri* biosimilar last August, some two months after a federal court in Delaware rejected Biogen's patent infringement case against the company.

Biogen's *Tysabri* was originally approved by the U.S. FDA for multiple sclerosis in 2004 and four years later for Crohn's disease. The drug reached blockbuster status by 2009.

Myrbetriq (mirabegron)--manufactured by Astellas for the treatment of overactive bladder, saw sales in the U.S. of US$640 million. It will lose exclusivity sometime after May of 2024 and of all the drugs listed, faces the most legal uncertainty due to a ruling in U.S. District Court for the District of Delaware in June of 2023 that invalidated a key 2030 patent on the drug, prompting Astellas to publicly respond and emphasize that it still had patent protections on the drug until May 2024.

Meanwhile, Lupin and Alkem have obtained FDA approvals for generic versions of *mirabegron*, while Aurobindo's generic boasts a tentative nod, according to agency data.

Victoza (liraglutide) – manufactured by Novo Nordisk for the treatment of Type 2 diabetes, with annual US sales of US$525 million, will face generics competition beginning June of 2024.

Before there were the blockbuster GLP-1 offerings *Ozempic, Rybelsus* and *Wegovy*, there was *Victoza*. Novo Nordisk's first-generation GLP-1 diabetes med has enjoyed a smooth 14 years of exclusivity since its 2010 approval, including a period of pediatric exclusivity that extended its patent cliff into 2024. Now, generic contenders Teva, Viatris and Sandoz are eager share in Victoza's already waning sales.

Emflaza (deflazacort)—manufactured by PTC Therapeutics for the treatment of Duchenne muscular dystrophy. The drug saw 2023 US sales of US$255 million and saw generic competition in February 2024.

Emflaza is already facing new generic competition. India's Aurobindo is rolling out its generic version of the drug after scoring a final FDA approval last month. The generic's label covers its use in patients 5 and older.

PTC took over the drug in 2017 from Marathon Pharma. Marathon, for its part, scored the initial FDA approval for *Emflaza's* DMD indication a month before its handoff.

Sandostatin LAR (octreotide acetate)—manufactured by Novartis for the treatment of Acromegaly (severe diarrhea from

(continued on page 2)

In Brief...

- **Cencora Inc.** announced that *Steven H. Collis* will retire as President and Chief Executive Officer of the company and transition to the role of Executive Chair of the Cencora Board of Directors effective October 1, 2024. *Robert P. Mauch*, PharmD, Ph.D., current Chief Operating Officer of Cencora will succeed Collis as President and CEO and will also be appointed as a member of the Company's Board, effective the same date. "Steve's 30-year career at Cencora has been characterized by purpose-driven leadership, delivering phenomenal growth in domestic and international markets, diversification of the business, and the successful launch of a global brand that positions the company for even greater success," said *Mark Durcan*, one of Cencora's lead independent directors. Collis has been a member of the IFPW's board of directors since 2011. Separately, with the increasing number of cell and gene therapy (CGT) products in clinical development, Cencora's FormularyDecisions launched a new secure online platform designed to provide

(continued on page 2)

Top 10 Drugs (cont.)...

carcinoid tumors.) Sandostatin had sales of US$199 million in 2023. It will face generic competition sometime in 2024.

For Novartis, complexity in producing big-selling *Sandostatin LAR* has served the company well. The drug lost U.S. patent protections many years ago, but generics makers still have not been able to capitalize on the market opportunity. This year, though, Viatris hopes to change that.

Viatris President Rajiv Malik said this year could be "exciting" for the generics maker, citing *Sandostatin LAR* as one planned launch for the year. Viatris' *Sandostatin LAR* generic application is under review at the FDA, according to a recent corporate update .

Dulera (mometasone furoate / formoterol fumarate dihydrate)—manufactured by Organon for the treatment of asthma, it saw sales of US$156 million in the U.S. for 2023.

Dulera was approved for asthma in 2010, but a second application to treat chronic obstructive pulmonary disease (COPD) was rejected by the FDA in 2012.

The drug's sales peaked at US$536 million in 2015. By then, however, GSK's similar combo treatment *Breo*—which was approved for COPD and asthma—had entered the market and soon became a blockbuster.

By 2017, *Dulera's* sales had shrunk to US$287 million due to "competitive pricing pressure, as well as lower demand," Merck explained in an annual report. (Merck was the owner of the drug until it separated from Organon in a 2021 corporate split.)

This year, Organon says it still expects generic competition, even though no generics drug maker has gained approval for the therapy.

Oxtellar XR (oxcarbazepine)—manufactured by Supernus Pharmaceuticals in the treatment of epilepsy. with 2023 US sales of US$113 million. Generic competition is expected in September 2024.

While important, the loss of *Oxtellar XR's* patent protection doesn't have as much impact on the company. *Trokendi* garnered US$261 million in its final year of exclusivity, whereas *Oxtellar's* sales were less than half that in 2023.

After its approval in 2012 as an adjuvant therapy, *Oxtellar's* sales climbed slowly. In 2019, when it gained a nod as a monotherapy, Oxtellar saw a boost in sales, exceeding US$100 million in 2021.

The first generic threats for *Oxtellar* came from Actavis and TWi Pharma nearly a decade ago. Supernus prevailed in infringement cases against the generics manufacturers in 2017 and 2018, respectively, as the courts backed patents that ran through 2027.

Supernus wasn't as fortunate, however, in its 2020 infringement case against Apotex. In June of last year, the Maryland company settled with Apotex, agreeing to let the Canadian generics power begin selling *oxcarbazepine* on Sept. 1 of 2024. In July of last year, the FDA signed off on Apotex's generic.

Venofer (iron sucrose)—manufactured by CSL for the treatment of Iron deficiency anemia in patients with chronic kidney disease. US sales reached US$90 million in 2023. The drug loses exclusivity in 2024.

Venofer is another drug with no remaining patents or exclusivity, according to FDA records, but it's one that has so far been able to avoid U.S. generic competition.

Like with *Sandostatin LAR*, Viatris believes it can change that in 2024. The company's *Venofer* generic is under regulatory review and is a "first-to-market" opportunity, Viatris said in a February investor presentation.

While CSL doesn't break out the drug's sales by geography, *Venofer's* U.S. sales represented about one-half of its global sales in 2021.

Prolensa (bromfenac)—manufactured by Bausch + Lomb for postoperative eye inflammation following cataract surgery reported 2023 US sales of US$41.5 million. Generic competition entered the market this past January.

Approved by the FDA in 2013 as a treatment for postoperative inflammation in patients who have undergone cataract surgery, it was originally developed by Senju Pharmaceutical. ISTA Pharmaceuticals obtained U.S. rights to the drug in 2002, and the U.S. FDA in 2005 approved the company's *Xibrom*, or *bromfenac* 0.09%, as a twice-daily eye drop for ocular inflammation following cataract surgery. ISTA was later acquired by Bausch.

Prolensa, meanwhile, is a once-daily solution of *bromfenac* at a lower dose of 0.07%, which is enabled by a new formulation designed to improve ocular penetration. In two randomized trials, 46% of *Prolensa* takers experienced complete clearance of inflammation by Day 15, versus 20% among those on a dummy eye drop.

Prolensa made up about 1% of Bausch + Lomb's US$4.15 billion in revenues last year, according to an annual SEC filing, meaning the drug pulled down around US$41.5 million.

In Brief (cont.)

healthcare payers with centralized access to information on approved therapies and products in the pipeline. The platform provides healthcare decision-makers in the U.S. with access to evidence-based resources and facilitates information exchange between biopharma companies and payers.

- **Eli Lilly** and **Amazon** announced a partnership for home delivery of certain prescription drugs, including its popular weight loss therapy drug *Zepbound*, for patients using its direct-to-consumer service, **LillyDirect**--launched by Lilly in January in partnership with pharmacy providers such as **Truepill**-- to deliver prescribed Lilly medications, including its drugs for obesity, migraine and diabetes. Prescriptions sent to LillyDirect will be delivered to the patients' homes using either **Amazon Pharmacy** or TruePill based on factors such as insurance coverage.
- U.K.'s chancellor *Jeremy Hunt* announced that **AstraZeneca** will invest £650 million (US$827 million) in the U.K., with approximately £450 million (US$579 million) to be invested in AZ's manufacturing site in Speke, Liverpool. The remaining £200 million (US$258 million) will be used to expand AZ's presence near its global headquarters in Cambridge. The plan includes a facility that will house approximately 1,000 employees.
- The Japanese government is considering measures for restructuring the generic industry to secure stable supplies in country. An officer of the **Japan Fair Trade Commission (JFTC)** said that consolidation of similar generic products through company mergers or a consortia scheme and emergency adjustments in production volume would not likely constitute a violation to the antitrust act. *Hirohito Amada*, director of the Coordination Division under the JFTC's Economic Affairs Bureau said, "Although the situation will differ case by case, it is unlikely that such practiccces will be deemed problematic."

(Sources: Company press releases, Drug Store News, FiercePharma, and Pharma Japan)