

HEALTH PHARMACEUTICALS

7 New Blockbuster Drugs to Watch in 2016

by Laura Lorenzetti @lauralorenzetti MARCH 25, 2016, 8:06 AM EDT





Seven big-money drugs are expected to launch this year.

Photograph by GP Kidd--Getty Images/Cultura RF

SANOFI v. GENENTECH



Each of these new drugs could rake in \$2 billion in sales.

Blockbuster drugs, those medicines that bring in more than \$1 billion in sales every year, are the holy grail of drug development. They can make a pharmaceutical company and send them to rock-star status among investors, as evidenced by the rise of Gilead Sciences after the launch of its hepatitis C treatments. This year's slate of new drug launches features at least seven drugs expected to hit blockbuster status within the next five years, according to a study by Thomson Reuters.

The line-up also reveals key trends within the pharmaceutical industry for this year and beyond, including an increasing focus on rare diseases, the development of more convenient single-dose regimens, and more affordable treatments.

Here are the seven drugs set to launch this year and reach blockbuster status by 2020.

1. Intercept Pharmaceuticals and Sumitomo Dainippon Pharma

Drug: Obeticholic acid

Indication: Chronic liver diseases, primarily primary biliary cirrhosis

2020 Forecast Sales: \$2.62 billion

Intercept Pharmaceuticals' (ICPT 2.94%) obeticholic acid has proved very effective in treating non-alcoholic steatohepatitis, a type of liver inflammation caused by fat build-up in the organ. This condition has no approved treatment and a potentially large market, which is expected to push the drug to blockbuster status, if approved. About 2% to 3% of the global population has non-alcholoic steatohepatitis and the share will likely increase due to rising rates of pre-disposing factors like obesity and insulin resistance.

2. Gilead Sciences and Japan Tobacco



Indication: HIV-1 infection

2020 Forecast Sales: \$2 billion

Gilead's (GILD • 1.19%) two HIV-1 infection drugs in development are both expected to be big money-makers, and the company is hoping the new daily single-dosage options will be able to replace sales of its existing HIV treatments that are set to lose patent protections in 2017. The new TAF-based therapies show evidence that they are potentially a safer replacement for some current therapies, including Gilead's own Truvada.

3. Gilead Sciences and Janssen R&D

Drug: Tenofovir alafenamide and emtricitabine and rilpivirine (R/F/TAF)

Indication: HIV-1 infection

2020 Forecast Sales: \$1.57 billion

Like the No. 2 drug on this list, Gilead's secondary TAF-based combination therapy in partnership with Johnson & Johnson's (JNJ • 0.87%) Janssen unit is expected to improve renal and bone mineral density measurements compared with some existing drugs. Those results combined with the improved longevity of HIV patients and increasing numbers of those eligible for antiretroviral drugs means a large and lucrative market for the two new TAF-based drugs.



4. Merck & Co.

Drug: MK-5172A

Indication: Hepatitis C virus

2020 Forecast Sales: \$1.54 billion

Merck (MRK • 0.93%) is getting ready to enter the heated market for hepatitis C treatments, going up against Gilead's Harvoni and Abbvie's Viekira Pak. Following a significant setback when the Food and Drug Administration withdrew its "breakthrough drug" status, Merck's treatment could finally launch this year to give another safe and high-quality treatment for the disease. A recent warning by the FDA concerning Viekira Pak has dampened sales of Abbvie's drug, which could give Merck a leg up when it eventually brings its hepatitis C drug to market. It could also pursue an aggressive pricing strategy to gain market share, given the currently high price tags on current treatments.

5. Abbvie

Drug: Venetoclax

Indication: Chronic lymphocytic leukemia

2020 Forecast Sales: \$1.48 billion



a type of chronic lymphocytic leukemia that is resistant to chemotherapy. The drug was a leading therapy at last year's annual meeting of the American Society of Hematology after a clinical trial showed an overall response rate of 79.4% in patients with relapsed chronic lymphocytic leukemia. The drug is also being tested as a potential treatment for other hematological cancers like non-Hodgkin's lymphoma, as well as in combination with tamoxifen in patients with metastatic breast cancer.

6. ACADIA Pharmaceuticals

Drug: Nuplazid

Indication: Parkinson's disease psychosis

2020 Forecast Sales: \$1.41 billion

ACADIA's (ACAD • 5.79%) nuplazid could be the first and only drug on the market to help treat Parkinson's disease psychosis, which affects up to 40% of Parkinson's patients. Clinical trials have shown that the drug does not worsen motor symptoms, a vital factor for these patients, while improving night-time sleep, daytime wakefulness, and caregiver burden. Nuplazid may also work in other psychosis settings, such as schizophrenia and Alzheimer's disease psychosis. The combination of those three diseases means ACADIA's drug has a potentially massive and therefore lucrative market.

7. Nippon Shinyaku and Actelion

Drug: Uptravi

Indication: Pulmonary arterial hypertension

2020 Forecast Sales: \$1.27 billion

Nippon Shinyaky's Uptravi is able to both delay the progression of pulmonary arterial



DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

