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The 10 Biosimilar Launches that Could Drive Big Savings by 2027

(Source: An article by Jessica Merrill for Scrip Intelligence)

Despite continued uncertainty about how exactly the U.S. biosimilar market will evolve, U.S. spending on biosimilars is poised to grow substantially from 2023 to 2027, generating billions in U.S. healthcare savings, according to a report on biosimilars by the IQVIA Institute for Human Data Science.

At least 10 molecules are expected to face biosimilar competition in the period from 2023 to 2027, which will drive growth of the U.S. biosimilars market, according to the IQVIA report released in February. Included in that list are: *Humira (adalimumab)* by Abbvie, *Stelara (ustekinumab)* by Johnson & Johnson, *Actemra (tocilizumab)* by Roche, *Eylea (aflibercept)* by Regeneron, *Prolia (denosumab)* by Amgen, *Xolair (omalizumab)* by Roche, *Perjata (pertuzumab)* by Roche, *Yervoy (ipilimumab)* by Bristol Myers Squibb, *Soliris (eculizumab)* by AstraZeneca, and *Cyramza (Ramucirumab)* by Eli Lilly. Those biosimilars will be versions of some of the biggest-selling pharmaceutical brands.

While IQVIA's outlook for the U.S. biosimilar market is encouraging for manufacturers of the copy cat entrants, the market research company's forecast incorporates a wide range of variability. Overall spending on biosimilars is expected to increase to US$20 billion from US$10 billion in 2022. The wide range takes into account various factors around pricing, access and prescribing behaviors.

At the same time, U.S. health care savings over the next five years stemming from use of the those biosimilars are projected to exceed US$80 billion, the firm said.

"Future biosimilar sales and savings will depend on a variety of market dynamics," IQVIA acknowledges in the report. For its forecast, IQVIA modeled "high, medium and low" uptake scenarios versus originator competition and price reductions from 15%-45%. IQVIA's base case scenarios used for future projections estimates a 34% biosimilar share of molecule volume is achieved after 24 months along with a 30% price reduction.

"Uncertainties remain as market events to date suggest a wide range of market outcomes are still possible," IQVIA said.

Biosimilar launches in oncology, including versions of Roche Holding AG's *Avastin (bevacizumab)*, *Herceptin (trastazumab)* and *Rituxan (rituximab)*, have outperformed most other therapeutic areas, resulting in higher volume penetration versus the original brands.

One thing that has help biosimilars gain traction in cancer is that many providers participate in oncology care models that establish treatment pathways and adopted biosimilars at higher levels, which IQVIA said shows how patient care models can impact reimbursement and potential lprovide incentives for increasing the adoption of biosimilars.

A significant test case that is currently under way is the launch

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In Brief...

- **Walgreens Boots Alliance** announced its second quarter results for fiscal 2023 with sales of US$34.9 billion, an increase of 3.3% (4.5% on a constant currency basis) year-over-year. Operating income was US$.2 billion for the quarter, compared to US$1.2 billion in the same period a year ago. Operating income for the quarter reflects a US$306 million pre-tax charge, including Summit Health acquisition costs and other costs. With the closing of **VillageMD's** acquisition of **Summit Health**, WBA is now one of the largest U.S. players in primary care, with best-in-class assets across the care continuum, according to *Rosalind Brewer*, WBA's CEO, on its Q2 earnings call.
- **McKesson Corporation** announced that it has signed an agreement in principle to extend its partnership with **CVS Health** to distribute pharmaceuticals to mail order and specialty pharmacies, retail pharmacies and distribution centers through June of 2027. "We are pleased to continue our long-standing relationship with CVS Health and value our shared commitment of improving health outcomes for all patients," said *Brian Tyler*, chief executive officer of McKesson. Separately, McKesson has opened a new state-of-the-art distribution center in Jeffersonville, Ohio, centrally located between Cincinnati and Columbus. The new facility will distribute pharmaceutical, over-the-counter and home healthcare products as well as consumer packaged goods to customers across Ohio, Indiana, Kentucky, Michigan, Pennsylvania and West Virginia.
- Japan has revised its guidelines on drone drug deliveries stating that such types of deliveries should be executed only when considered "the most appropriate method." Also, certain regulations were eased regarding target regions, emergency deliveries and powerful medicines. The guidelines were revised by the Ministry of Health, Labor and Welfare (MHLW) and the Ministry of Land, Infrastructure, Transport and Tourism.
- **Cardinal Health** announced that *Debbie Weitzman*, will become CEO of the company's pharmaceutical segment. She is the current president of pharmaceutical distribution. She

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The ChatGPT Revolution Comes to Pharma, Starting with Medical Congresses

(Source: An article by Andrew McConaughie for Scrip Intelligence)

As excitement around ChatGPT and other generative AI programs grows, one company, ZoomRx, has launched its own tool to help transform how pharma analyzes data coming out of medical congresses.

In recent months, Open AI's ChatGPT has wowed the world by generating sophisticated written responses to questions on global warming or requests to write a sonnet in the style of Shakespeare, and Google has now launched its rival, Bard AI chatbot.

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10 Biosimilars (cont.)

of Amgen Inc.'s A*mjevita* the first biosimilar version of *Humira*, which launched in January. Several other biosimilars are expected to launch later this year, beginning in June. The amount of traction these products get in the commercial market could speak volumes about the future of the U.S. biosimilar market, which has been steadily growing but continues to face headwinds.

One challenge stems from the U.S. reimbursement structure and incentives that are in place for payers to simply negotiate steep discounts for high-volume brands, essentially blocking biosimilars from the market. During a recent panel discussion on biosimilars sponsored by IQVIA and corresponding with the release of the report, panelists predicted that U.S. market dynamics could curb the early uptake of *Humira* biosimilars. Another recent biosimilar launch has also faced commercial hurdles – the first versions of Roche's *Lucentis (ranibizumab)* for wet age-related macular degeneration and diabetic eye disease. A few other biosimilars in the ophthalmology space launched last year but are off to a slow start. Some experts say the sluggish ramp is driven by uncertainty on the part of retina specialists about how to put them into practice.

Even with slower biosimilar adoption, more competitive discounting and price reductions by innovators to compete against, biosimilars still deliver savings to the U.S. health care system.

Experts say the savings are valuable to the health care system regardless, but they worry that that it might come at the expense of future investment in biosimilars if biosimilar manufacturers aren't able to recoup their return on investment.

Among the nine biologic brands that have already faced biosimilar competition in the U.S. (not including *Humira*), average sales price reductions for biosimilars have ranged from 27%-66% off the price of the originator pre-biosimilar. Brand manufacturers generally respond with their own price reductions.

Cumulative biosimilar sales over the next five years are expected to total US$129 billion at the base case, ranging from US$79-US$163 billion depending on volume uptake and price discounts IQVIA predicts. Biosimilar spending in 2027 is expected to rise to US$38.5 billion in the U.S. with scenarios ranging from US$20 billion to US$49 billion.

ChatGPT (cont.)...

US-based ZoomRx has used ChatGPT to develop its own Ferma.AI program to understand and analyze biopharma data sources, and has made a free-to-all version on its website. https://aacr23.ferma.ai/#/chat, ahead of the American Association for Cancer Research annual congress, which takes place 14-19 April in Orlando, Florida.

The FermaGPT AACR application can search all the 8,230 abstracts submitted to the congress to answer specific-text-based questions such as "List abstracts about KRAS and NSCLC" and "Summarize key discussions around racial disparities in prostate cancer."

The company has fed into the prototype version a range of pharma data sources including clinicaltrials.gov, and pharma and biotech earnings calls, in order to enrich its text-based outputs. It believes it is the first to launch an AI platform for medical conference coverage, and the first to launch a GPT-powered tool to analyze conference abstracts.

It also believes the tech can revolutionize congress monitoring for medical affairs, competitive intelligence, and business development teams, just as AI is being increasingly used to accelerate biopharma R&D.

The pharma business consultancy already has a number of big pharma clients, which it charges for access to the full version of the technology. The ZoomRx team did not want to name names when it comes to their existing pharma clients, but their wider business services roster includes companies such as Amgen, AstraZeneca, Biogen, and Merck & Co.

The company had been working on its Ferma.AI product for five years, but saw the opportunity to merge its platform with the large language model ChatGPT, paying a fee to developers of OpenAI to access its software.

Sririam Subramanian, ZoomRox's co-founder and co-CEO said early 2023 felt like a "transformative moment" in AI's role in the world, and in life sciences. "People are going to be much more empowered by having the information in an accessible way through large language models in general," he said. "It doesn't have to be ChatGPT, there's a tremendous amount of simultaneous progress going on right now."

As accuracy is most important, ZoomRx has refined ChatGPT-4 to make it less "creative" and more conservative – which includes admitting when it does not have an answer. This makes it much more optimized for accuracy. For that reason, Ferma.AI is programmed to lean towards a "don't know" to guarantee a high level of accuracy. According to Subramanian, pharma's cultural barriers to adopting new technology are likely to be greater than the technical challenges facing developers.

The company plans to create FermaGPT public access applications for many more medical conferences this year, including the American Society of Clinical Oncology, the European Society of Medical Oncology, and the American Society of Hematology congresses.

In Brief (cont.)

will replace *Victor Crawford* who leaves the position effective September 19 but will remain with he company until November 13 to assist with the transition. The role of President of Pharmaceutical Distribution will be eliminated. The company has further streamlined the pharmaceutical segment by restructuring and eliminating additional roles. As a result of these changes, the pharmaceutical and specialty distribution businesses will both report directly to Weitzman.

- **Pfizer Japan** began the commercial rollout of its oral COVID-19 treatment *Paxlovid (nirmatrelvir/ritonavir)* making it available via the normal wholesaler distribution channels in the country. The company earned special approval for the *Paxlovid* pack in February of 2022 less than one month after its filing in January that year. While the product has since been provided under the government-controlled allocation scheme, the drug maker received approval in November for its commercial versions with Japanese language packaging.

(Sources: Company Press Releases, Drug Store News, FiercePharma, Pharma Japan and World Pharma News)