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Bayer Sharpens US Focus As Pressure Tightens On Drug Makers

US To Account For More Than Half Of New Product Sales

by Mandy Jackson

The German company's two top sellers are marketed by partners in the US, but Bayer will pocket all US sales from its four newest products, at a time when pressures are mounting at home and abroad.

Bayer AG is "really doubling down on expanding our presence in the United States," president of pharmaceuticals for the Americas region Sebastian Guth said in an interview with *Scrip*, with a commitment to spend $1bn on research and development in the US in 2023. The investment is meant to capitalize on scientific advancements and to back Bayer's increasing commercial focus on the US, where the company will generate a greater percentage of its revenue going forward.

"Historically, our revenue contribution out of the United States is simply smaller than it would be for a typical pharmaceutical company of our size," Guth said. "We reported revenues in 2022 of $4.7bn in North America ... and that's essentially less than 25% of our overall revenue in pharmaceuticals ... and we see an opportunity to significantly increase our commercial presence and the revenue contribution out of the US over this decade." Bayer reported €12bn in total revenue for the first quarter of 2023, including €4.4bn in pharmaceutical revenue. (Also see "*Xarelto Declines Are New Normal At Bayer*" - Scrip, 11 May, 2023.)

Current Bayer blockbusters – the anticoagulant Xarelto (rivaroxaban) and ophthalmology drug Eylea (aflibercept) – are commercialized in the US by *Johnson & Johnson* and *Regeneron Pharmaceuticals, Inc.*, respectively, but the company has launched the prostate cancer drug Nubeqa (darolutamide) and Kerendia (finerenone) for chronic kidney disease (CKD) in patients with type 2 diabetes in the US on its own. Nubeqa, Kerendia and two Phase III drug candidates are forecast to generate €12bn in combined peak global sales, more than half of which is expected to come from the US.

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“We've communicated that we're intending to double the size of our US business by the end of the decade,” Guth said.

Bayer expects Nubeqa and Kerendia to generate peak annual sales of €3bn each, while the company has forecast €1bn in sales for elinzanetant in the treatment of vasomotor symptoms associated with menopause and €5bn in sales from the next-generation oral anticoagulant asundexian, a Factor XIa inhibitor with the potential for reduced bleeding relative to Factor Xa inhibitors, such as Xarelto. (Also see "*Bayer Outlines Asundexian Phase III Plan, Hoping To Prove Safety Benefit Over Eliquis*" - Scrip, 29 Aug, 2022.)

Bullish Bayer Highlights Four Future Blockbusters

By Kevin Grogan

11 Jan 2023

The German group has shone a light at the J.P. Morgan Healthcare Conference on its new launched drugs Nubeqa and Kerendia, plus its late-stage candidates asundexian and elinzanetant, as it prepares for life after patent expiries on Xarelto and Eylea.

Read the full article here

“We decided a few years ago to embark on what I would describe as a transformative growth journey here in the US, really doubling down on expanding our commercial presence,” Guth said. “With the launches of Nubeqa and Kerendia, we're in the midst of that and it's a great success, but we’re also expanding our R&D presence in the United States.”

R&D Growth Means Research, People Gains

Bayer’s $1bn investment in R&D in the US includes spending on additional research and development activities as well as increased R&D hiring. The company has about 1,500 R&D employees in the US, a number that has tripled over the last few years, and it plans to keep growing at its own and its partners’ sites, particularly at four key life sciences hubs in the US – San Diego and San Francisco on the West Coast, and Boston and Raleigh, NC, on the East Coast.

R&D in San Diego includes drug discovery work ongoing at *Vividion Therapeutics, Inc.*, which Bayer acquired for $1.5bn up front in 2021 and now operates as an independent subsidiary, as well as work with other local partners. (Also see "*The Inside Story On How Bayer Swooped On NASDAQ-Bound Vividion*" - Scrip, 5 Aug, 2021.) In Boston, the company opened a new $140m precision oncology R&D site in late 2022. Its R&D in Raleigh is anchored by the gene therapy work ongoing at *Asklepios BioPharmaceutical, Inc.* (AskBio), acquired for $2bn up front in 2020. (Also see "*The Inside Story On How Bayer Swooped On NASDAQ-Bound Vividion*" - Scrip, 5 Aug, 2021.) And in the San Francisco Bay Area, Bayer historically has focused on biologics manufacturing in Berkeley, where its work is expanding to cell therapies.

Guth noted that 10 or 15 years ago, Bayer didn't necessarily have the financial capacity to commercialize big products like Xarelto and Eylea in the US by itself or to have a big R&D presence in the US.

"Today, we're in a significantly different position and feel confident, and are in fact also encouraged by the evidence of success to build out that greater, larger, independent presence in the United States," he said. "If I look at R&D, there's simply great science happening in the US and that's something we have to continue to tap into and be a part of."

Bayer has long been a proponent of partnering as a means of investing in new drug classes and drug modalities, particularly in areas such as precision oncology and cell and gene therapies, and will continue to invest in R&D by pursuing business development and investing in new start-ups, Guth noted. The company's impact investment arm, Leaps by Bayer, has invested $1.7bn in more than 55 life science and agriculture companies since 2015, including companies that it has acquired or partnered with, such as *BlueRock Therapeutics LP*. Leaps by Bayer will invest another $1.4bn through the end of 2024, he noted. (Also see "*No Slowdown From Bayer On Business Development Front*" - Scrip, 28 Feb, 2023.)

In its late-stage R&D pipeline, Bayer initiated its Phase III clinical trials in stroke prevention for patients with atrial fibrillation in December of last year and in secondary stroke prevention in January of this year, with results still a few years away. However, the company is near completion of the Phase III program for its NK1/3 antagonist elinzanetant in the treatment of vasomotor symptoms, with results expected in the second half of 2023, although the company recently announced plans to initiate a study of the drug in menopausal women with breast cancer or a history of breast cancer. (Also see "*Women's Health Still Key to Bayer Despite Early Research Shift*" - Scrip, 28 Mar, 2023.)

Bayer's US Focus Growing As Pharma Pressure Builds

Bayer's focus on the US is intensifying, however, at a time when pressure on biopharmaceutical industry profits in the US is also rising, as interest in lowering drug costs increases. The Inflation Reduction Act (IRA) was signed into law in the US in 2022 with provisions to lower patients' out-of-pocket costs in various ways, many of which are supported by drug makers. A provision granting drug price negotiation for products covered by Medicare, however, has put the industry on the defensive. (Also see "*Merck & Co. Files First IRA Suit, Signaling Industry Is Ready To Fight*" - Scrip, 6 Jun, 2023.)

Under the IRA, the Centers for Medicare and Medicaid Services (CMS) will begin negotiating pricing for an escalating number of drugs covered by Medicare, starting in 2026, nine years after US Food

Industry Looks At IRA Drawbacks And

and Drug Administration approval for small molecules and 13 years after FDA approval for biologics. Pharma companies already have altered some of their R&D and investment decisions to account for the shorter period in which they will be able to generate a return on their investments in small molecules. (Also see "*IRA Drug Pricing Implications Impact Pharma Views On Deal Terms, Valuations*" - Scrip, 3 Mar, 2023.)

Guth, who is a member of the health section of the BIO board of directors and a member of the PhRMA board of directors, is well aware of the implications of the IRA.

Silver Linings

By Jessica Merrill

20 Jan 2023
Industry leaders are concerned about the outlook for small molecule drugs in particular, but execs at the J.P. Morgan Healthcare Conference were also optimistic there could be chances to shape the implementation of certain policies.

Read the full article here

"First, for [Bayer] specifically, the situation is a little different, because as mentioned, we're under-indexed historically in the United States, so our exposure to the IRA is more limited than it is for other pharmaceutical companies in the United States," he said. "We do not expect any of our products to be called for negotiation until the end of the decade, and we have issued our peak sales guidance for Nubeqa, Kerendia, asundexian and elinzanetant also with knowledge of the IRA."

That said, Guth continued, "I clearly believe that there's some good in the IRA and that's in particular the focus on reducing out-of-pocket cost. I think that that is something we as a company have long advocated for as have many of my colleagues in other pharmaceutical companies, because we today see far too many Americans that either don't initiate a treatment or discontinue a treatment prematurely in view of very significant out-of-pocket costs."

His concern with the IRA is its unintended consequences, he said, listing three key worries. "One is that we turn the choice of a technology from the science to politics, and at the end, to favor biologics over small molecules," Guth said. "And to make that a political choice to me is a big problem because small molecules remain a very important part of the work we as an industry do."

The second area of concern is related to the disincentives of continued innovation over the lifecycle of a product, where companies working on oncology medicines, for example, may not pursue additional indications because of the shorter period for a return on investment for a small molecule versus a biologic, he noted. The third concern relates to the potential for limited access to new medicines if drug makers decline to make them available in the US, as has happened in

Europe.

“Today, if you look at new medicines that were developed, 85% are available to patients in the United States, to Americans, compared to only 61% in Germany, and 52% in France,” Guth said. “As an example, my dad passed away from lung cancer some five years ago. He lived in Germany and had no access to a treatment that was available to patients in the United States and we ultimately, through a lot of work, got him access on a compassionate use basis, and that prolonged his life by, in his case, another two years, and it was a gift for him and others of us as a family.”

Bayer leadership has been critical of moves by European governments aimed at cutting health care and pharmaceutical costs that drug makers fear will hurt innovation in Europe, further limiting access to novel medicines in the UK and other countries. (Also see "*Bayer May Not Launch In Innovation-Unfriendly European Markets*" - Scrip, 1 Mar, 2023.)

“I would say that folks are starting to understand what the unintended consequences of the IRA may be,” Guth said. He noted that the biopharma industry was able to partner with academia and the government to rapidly develop medicines and vaccines during the COVID-19 pandemic, so there is a chance that they can work together to solve some of the challenges raised by the IRA.