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J.P. Morgan Day Three: Biogen Still Shopping For Deals, Sanofi Explains Its View On Oncology

by Scrip Team

Daily notebook from the J.P. Morgan Healthcare Conference: Biogen is still looking for deals, just smaller; Sanofi's push in immunology has pulled it away from oncology; Sage provides updates on Zurzuvae launch; and Takeda plans a big program for its TYK-2 inhibitor.

Biogen Is Doing Deals, But Not Another Reata

Biogen, Inc. CEO Christopher Viehbacher said during his fireside chat at the J.P. Morgan Healthcare Conference that the company remains in deal-making mode but noted that it is not likely to pursue another transaction like last year's $7.3bn acquisition of *Reata Pharmaceuticals, Inc.*, which brought in the on-market Friedreich's ataxia drug Skyclarys (omaveloxolone). (Also see "*Biogen Buys Time For Leqembi Ramp-Up With Reata Acquisition*" - Scrip, 28 Jul, 2023.)

"We couldn't afford to do another Reata, at least this year," Viehbacher said. "But we're generating quite a bit of cash flow every year and we certainly have the capability of doing licensing deals, and I'm not sure we need to do another Reata."

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He said Biogen will be focused on earlier-stage licensing deals, like long-term agreements the company has made with *Ionis Pharmaceuticals, Inc.* around the development of antisense oligonucleotides for a range of diseases. And as the CEO has indicated before, Viehbacher said Biogen is looking to broaden its scope from neuroscience to adjacencies

in rare diseases and immunology, where drug development has a more traditional path.

“And part of the reason for that is, in most of what we do at Biogen, we can't do a proof-of-concept study, so we're doing these regulatory studies, these approval studies – lengthy, expensive and have no idea whether they're going to work or not,” he said. “And I think what we'd like to do is have parts of our R&D come through a classical drug development chain, where we can do a Phase II and assess safety and efficacy before we spend money on the pivotal studies.”

Sanofi Down, But Not Out, In Oncology

Sanofi has a big strategy to become one of the leading immunology companies in the world, riding on the coattails of Dupixent (dupilumab), but as part of the emphasis on immunology and inflammation, oncology has certainly been moved to the back burner.

Management didn’t mention oncology once during the corporate presentation at J.P. Morgan, and when asked at a press briefing on 10 January about the company’s commitment to oncology, CEO Paul Hudson admitted that Sanofi hasn’t been able to build the critical mass it needs to establish a franchise.

“You have to really be able to stand up an entire franchise to be able to do great science and make the economics work, and we felt we’d be getting further from that, not closer,” Hudson said.

The company has had a series of disappointments in cancer, including most recently the Phase III failure of the antibody-drug conjugate (ADC) tusamitamab ravtansine in a Phase III trial in non-small cell lung cancer, following the Phase III failure of the oral selective estrogen receptor degrader (SERD) amcenestrant. (Also see "*Sanofi Falls Further Behind In Cancer*" - Scrip, 21 Dec, 2023.)

“We are not out of oncology, but our bets are much earlier,” he added. “That’s just changed the tonality because it’s a huge consumer of investment in R&D.”

Sanofi’s new head of R&D Houman Ashrafian, who left a career in venture capital for the position, insisted the company is keeping a toehold in cancer drug development, but is taking a step back to scan the horizon for intriguing new breakthroughs. Ashrafian also underscored the company’s commitment to rare disease and vaccines. (Also see "*Sanofi Picks Venture Capitalist Ashrafian To Succeed Reed As R&D Head*" - Scrip, 31 Aug, 2023.)

But immunology & inflammation is where Sanofi is placing most of its bets. Its pipeline includes the BTK inhibitor tolebrutinib for multiple sclerosis, which could be filed in 2024, but many of the assets are targeted for filing further out, in 2027 or later, including an IRAK4 degrader for

atopic dermatitis, an anti-TL1A for irritable bowel disease, and an oral anti-TNF.

Sage Optimistic About Zurzuvae Based On Early Days Of Launch

Sage Therapeutics, Inc. is prepared to turn its newly approved Biogen-partnered Zurzuvae (zuranolone) into a blockbuster product based on its postpartum depression (PPD) indication alone and is optimistic about the drug's commercial prospects based on the early days of its launch, CEO Barry Greene told *Scrip* in an interview during J.P. Morgan.

The US Food and Drug Administration approved Zurzuvae for PPD in August but issued a complete response letter (CRL) for major depressive disorder (MDD), saying that another pivotal trial was needed to clear the positive allosteric modulator of the GABA-A receptor for MDD, a much larger indication. The drug required Drug Enforcement Administration scheduling, so it did not launch for PPD until mid-December.

"I believe that Zurzuvae is the key to unlock the blockbuster potential in PPD and help many, many women suffering from PPD," Greene said.

Sage Readies Zurzuvae For December Launch With Slow Ramp As Payer Talks Progress

By Mandy Jackson

07 Nov 2023
Sage and Biogen set a $15,900 list price for Zurzuvae, the 14-day postpartum depression drug approved in the US in August, and expect broad access but formulary discussions will continue into 2024.

Read the full article here

He noted that one out eight women who deliver babies in the US suffers from PPD, or about half a million women annually. Sage is optimistic about Zurzuvae's prospects to treat many of these mothers because of the response the drug has seen pre- and post-launch in terms of media coverage of Zurzuvae and PPD that have helped to destigmatize the disease, inclusion of Zurzuvae in treatment guidelines adopted by the American College of Obstetricians and Gynecologists (ACOG) and pre-Christmas prescribing activity for Zurzuvae.

"We made the drug available December 14 and so that gave us about 10 days where [doctor] offices were open and moms could access their health care provider," Greene said. "In those 10 days, we saw a robust response from the medical community. We saw moms getting diagnosed and Zurzuvae being written – and not only by psychiatry, but Zurzuvae being written by OB/GYN and primary care – so, we're really enthusiastic in the early days of launch. Our goal going forward is to establish Zurzuvae as the frontline treatment of women suffering from PPD."

Both Sage and Biogen have sales teams in the field talking to doctors about PPD and an omnichannel effort is under way to provide digital education about Zurzuvae. Payers also have

been receptive to Zurzuvae, Green said, finding the product attractive because it treats a serious medical condition with a two-week regimen rather than a chronic medication. So far, the only utilization management tool that some payers are implementing is a requirement for a physician attestation that the patient has PPD and not some other form of depression, he added.

As for whether or not Sage and Biogen will pursue further development of Zurzuvae for MDD, running another Phase III clinical trial in the larger indication is not on the near-term horizon.

"We're solely focused with Zurzuvae on PPD," Greene said. "If there are any changes to MDD or we make decisions about MDD, we will update, but people should be focused on Zurzuvae for PPD only."

Takeda To Take TYK2 Inhibitor Into IBD At High Dose

Takeda Pharmaceutical Co. Ltd. is planning a big development program for its oral TYK-2 inhibitor TAK-279, acquired from *Nimbus Therapeutics, Inc.* for $4bn upfront in December 2022. The company has already outlined some plans for Phase III studies in plaque psoriasis and psoriatic arthritis, including plans to run a head-to-head trial against *Bristol Myers Squibb Company*'s Sotyktu (ducravactinib) in psoriasis, not for registration but for the commercial market.

In an interview at J.P. Morgan, president R&D Andrew Plump said the company also plans to move quickly into Phase IIb studies in ulcerative colitis and Crohn's disease.

Sotyktu, which was approved for psoriasis in 2022, failed mid-stage clinical trials in ulcerative colitis and Crohn's disease, raising the risk for Takeda to run the studies.

"That raises the question of is it Sotyktu or is it the mechanism," Plump said. "Of course, we can't answer that until we run the study, but we have a strong level of confidence that this will be effective in IBD.

Takeda's bullish outlook stems from the efficacy that has been seen in preclinical and clinical studies so far with TAK-279, as well the underlying genetic hypothesis and the mechanism of action. (Also see "*Takeda Will Take TYK2 Inhibitor Into Phase III, Looks For Dosing Edge Over BMS Rival*" - Scrip, 8 Nov, 2023.)

"What's clear when you look at the totality of the data, you need more TYK2 inhibition to see activity in IBD than you do for psoriasis or psoriatic arthritis," Plump said. "We strongly believe that TYK2 inhibition will provide benefit in these patients and that Sotyktu just didn't dose high enough."

Takeda is in discussions with the US Food and Drug Administration about the Phase IIb study

design, and while the company hasn't disclosed the dose it will take forward, Plump said it will be higher than the 30mg dose that is being studied in psoriasis. "It will be substantively above that so we can really push the full range of activity, and we'll probably be looking at something that's about three-fold more inhibition over a 24-hour period," Plump said.