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J.P. Morgan Day Two: Novo Talks Obesity Outlook, Lilly Looks To Alzheimer's, New Fields

by Scrip Team

Daily notebook from the J.P. Morgan Healthcare Conference: Novo makes its debut appearance and welcomes newcomers to the obesity market; Novartis weighs its options in obesity; Lilly expects donanemab to launch into a primed Alzheimer's market – and it continues to look for more large-market opportunities; and Apellis sees strong 2023 Syfovre sales.

Novo Nordisk Makes J.P. Morgan Debut

Novo Nordisk A/S CEO Lars Fruergaard Jorgensen presented in the Grand Ballroom for the first time as the company begins a new year of anticipated exceptional growth on the strength of the obesity drug Wegovy (semaglutide). The Danish company has generally stayed on the sidelines of the J.P. Morgan Healthcare Conference, as it is in a quiet period from the end of the fourth quarter until sales and earnings are released.

But with the company having grown in the last several years from a relatively niche diabetes specialist to one of the hottest names in the biopharma sector, Jorgensen took the stage to talk about the burgeoning obesity market and outlook for the therapeutic area.

More From J.P. Morgan

J.P. Morgan Day One: Novartis Reveals Two Deals, Pfizer's Bad Year, Bristol's Wobbly Growth

The chief executive didn't have any financial updates for investors but he said the company is poised for a sustained period of growth, and he welcomed the firm's big new rival into the market.

The launch of *Eli Lilly and Company*'s Zepbound (tirzepatide) for obesity late last year won't put a

dent in those growth projections, he predicted. Zepbound was approved by the US Food and Drug Administration in November, and Lilly has promised investors it will deliver a strong launch of the GIP/GLP-1 agonist for obesity, which has shown slightly higher weight loss versus Wegovy in clinical trials. (Also see "*Lilly Plans 'Big, Bold' Launch For Zepbound*" - Scrip, 8 Nov, 2023.)

"We know from the GLP-1 space that when you have efficacious products and you launch new efficacious products, it actually fuels the growth of the category," Jorgensen said. "We are only scratching the surface of the obesity market."

"The biggest challenge we have is not competition. It is actually awareness of obesity as a chronic disease, the need for medical intervention, the value it has on the health system."

And Jorgensen's competitive confidence extends to future oral drugs that could eventually reach the market.

"There's actually a very, very strong ... willingness to take that injection," he said. "If you ask many of these patients who have been on weekly injections with a GLP-1 they find it to be a really, really convenient treatment."

Plus, he predicted it may be difficult for oral drugs to establish a good safety and tolerability profile – as was Pfizer's experience with the development of two oral GLP-1 drugs it was studying for obesity – danuglipron and lotiglipron. (Also see "*Pfizer's Mixed Readout Places Doubt On Oral GLP-1 For Obesity*" - Scrip, 1 Dec, 2023.)

"Today we, I believe, are establishing a very safe profile of injectable treatments, and I think there'll be very low regulatory appetite for introducing oral treatments that come with some safety issues," Jorgensen said.

Novartis Not Ruling Out Obesity

Novartis AG may be interested in throwing its hat into the fast-growing area of obesity R&D. President-development and chief medical officer Shreeram Aradyhye said the company does have some undisclosed preclinical programs in development in the space and is closely watching developments in the field.

"From our perspective, we think that there is an opportunity," he said in an interview. "If you think of GLPs as the first generation, we think that there is the opportunity for next generation technologies, targets frankly, to be addressed."

The area of research does not fall far outside the company's core therapeutic areas, given the company's expertise in cardiovascular disease with drugs like Entresto (sacubitril/valsartan) and Leqvio (inclisiran).

“We have the long-standing expertise and knowledge in the company to be studying those, but those are very early-stage programs,” Aradhye said of the company’s internal assets.

Given the enormous long-term sales forecasts for obesity drugs and the remaining opportunity for new advances on safety, durability and convenience, all kinds of big pharmas are interested in joining Novo Nordisk and Lilly in the field, including *Pfizer Inc.*, *Amgen, Inc.*, *AstraZeneca PLC* and *Regeneron Pharmaceuticals, Inc.*

“We’re watching this thing evolve,” Aradhye said. “I feel like we’re in chapter one or two of this journey.”

Lilly’s Donanemab To Enter A Primed Alzheimer’s Market

Eli Lilly and Company expects a US Food and Drug Administration decision about its anti-amyloid antibody donanemab for early Alzheimer’s disease during the first quarter, entering the market behind its closest competitor but with more favorable perceptions of amyloid-targeting therapies, president of Lilly Research Laboratories Dan Skovronsky noted in an interview at J.P. Morgan.

Eisai Co., Ltd./*Biogen, Inc.*’s Leqembi (lecanemab) won accelerated approval in January 2023 and full approval that June with a concurrent favorable Medicare reimbursement decision, which applied to amyloid-targeting therapeutics broadly as long as they win full approval. (Also see "*Eisai/Biogen’s Leqembi Will See Broadened Access To Majority Of Patients*" - Scrip, 6 Jul, 2023.)

Biogen/Eisai’s Aduhelm (aducanumab) won accelerated approval based on amyloid plaque removal and the product was not a commercial success because of its mixed Phase III results related to cognitive decline and because it could not achieve broad Medicare coverage. (Also see "*How Biogen’s Aduhelm Bet Became A Commercial Bust*" - Scrip, 6 Jun, 2022.) Lilly initially pursued accelerated approval for donanemab, but the FDA rejected the application and the company sought full approval instead. (Also see "*Lilly’s Donanemab, Now At FDA, Poised To Join Alzheimer’s Armamentarium*" - Scrip, 17 Jul, 2023.)

"I think over the course of the last year, I'd say [there’s been] a huge change,” Skovronsky said. “A year ago, still probably in the backlash of some of the aducanumab discussions, a lot of doctors were saying, 'I don't know if this class of medicines has any benefit,' and I never hear that anymore. What I hear from the majority of doctors now is, 'Oh, yes, I understand the efficacy of these medicines. This is an important benefit. Disease slowing is important to many patients.'”

What doctors want to know from Lilly about donanemab is who are the right patients for treatment – the patients most likely to benefit and experience the fewest side effects, particularly amyloid-related imaging abnormalities (ARIA).

“And so, you've seen us, and Eisai as well, present data on which subsets of patients seem to get the most benefit, which subsets of patients have higher risk of ARIA,” Skovronsky said. “I think that's normal for a new class of medicines, particularly in a fragile population like the Alzheimer's population. Doctors want to move carefully. We're not in-market yet, but when we come to market, I think [we're] fully aligned with that idea. We want physicians and patients to move carefully and start in a comfortable place for picking the right patients.”

Lilly Content With Small Deal Strategy, Large Indications

Lilly CEO Dave Ricks told the firm’s J.P. Morgan session that the firm remains committed to its business development strategy focused largely on smaller transactions with earlier-stage companies. But asked if Lilly would consider a larger, later-stage transaction Ricks noted that he would “never say never.”

“If someone had like a platform or like a really strong pipeline that we could add value to, I don't think number next to the price is such a big deal anymore,” he said. The reality is, the CEO pointed out, that most biopharma buying opportunities are at the smaller, earlier end of the spectrum. Lilly also prefers to invest in assets and companies where it can add value and often that means buying or licensing something at the research or preclinical stage.

“Getting things before they're being developed is a good idea,” Ricks said. “But also, in our domains of expertise, we better be able to call balls and strikes than our competitors and maybe better than even venture capital. And if we can do that, we can pick winners.”

In terms of indications where Lilly is looking to do deals, the company’s preferences lean more toward large, broad indications than narrow, rare indications.

“As we think about how to spend our resources going forward, it seems unlikely we're going to be able to grow rapidly by pursuing a lot of small ideas,” Ricks said. “We need a few big ideas, and I think that's what Lilly is for, is to pursue big unmet needs in very large populations, so we'll be looking in that space.”

Apellis’ Syfovre Delivers In First Year

Apellis Pharmaceuticals appears on track to establish its geographic atrophy drug Syfovre (pegcetacoptan) as a blockbuster commercial brand. During a presentation on 8 January, the company reported that fourth quarter sales of Syfovre were $114m and sales for the year were $275m.

Sales of $200m or more for new drugs in the first year of launch are generally considered a marker for a blockbuster-sized trajectory. Syfovre launched in February as the first drug to reach the market for geographic atrophy, the advanced stage of age-related macular degeneration and a leading cause of blindness. (Also see "*Apellis Set For Blockbuster Success With Syfovre, The First*

Approved Geographic Atrophy Drug" - Scrip, 20 Feb, 2023.)

The drug was expected to be a blockbuster eventually – given there were no approved treatments for geographic atrophy previously – but Apellis also ran into an unexpected safety issue in the real-world setting. Shortly after launch, reports of retinal vasculitis raised questions about the near-term trajectory. (Also see "*Apellis' Syfovre Sales Overshadowed By Safety Concerns*" - Scrip, 31 Jul, 2023.) But cases of serious adverse events have remained rare and the company appears to have returned to solid growth.

CEO Frederic Francois said the launch of Syfovre is among the strongest in the industry. In the 10 months since launch, 160,000 vials of Syfovre have been distributed, of which 150,000 were administered to patients, he said.

"Here we are with Syfovre being the market-leading treatment for GA in the US, with approximately 95% of patients in this country being treated with Syfovre within that market segment," Francois said. "That is because this is a drug that shows more efficacy over time, where we have more experience and where we can create more vision for patients."

Apellis does have new competition in the market. Astellas Pharma launched Izervay (avacincaptad pegol) for geographic atrophy shortly after Syfovre reached the market following US Food and Drug Administration approval in August. (Also see "*Astellas' Izervay Joins Geographic Atrophy Market, Intensifying Competition*" - Scrip, 7 Aug, 2023.) Astellas acquired the drug through the $5.9bn acquisition of Iveric Bio. (Also see "*Astellas Paying $5.9bn For Iveric To Boost Ophthalmology Presence*" - Scrip, 1 May, 2023.)

Apellis reported preliminary US net product revenues of approximately $138m in the fourth quarter and $366m for the full year, including Empaveli, another formulation of pegcetacoplan approved for adults with paroxysmal nocturnal hemoglobinuria (PNH).