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Eli Lilly & Co. (LLY)

Q1 2025 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Ladies and gentlemen, thank you for standing by, and welcome to the Lilly Q1 2025 Earnings Conference Call. At this time, all participants are on a listen-only mode. Later, we will be conducting a question-and-answer session and instructions will be given at that time. [Operator Instructions]

I would now like to turn the conference over to your host, Mike Czapar, Senior Vice President of Investor Relations. Please go ahead.

Michael Czapar

Senior Vice President-Investor Relations, Eli Lilly & Co.

Good morning. Thank you for joining us for Eli Lilly and Company's Q1 2025 earnings call. I'm Mike Czapar, Senior Vice President of Investor Relations. Joining me on today's call are Dave Ricks, Lilly's Chair and CEO; Lucas Montarce, Chief Financial Officer; Dr. Dan Skovronsky, Chief Scientific Officer and President of Lilly Immunology; Anne White, President of Lilly Neuroscience; Ilya Yuffa, President of Lilly International; Jake Van Naarden, President of Lilly Oncology; and Patrik Jonsson, President of Cardiometabolic Health and Lilly USA. We're also joined by Marc Kemen, Wes Taul, and Wai Wong of the Investor Relations team.

During this conference call, we anticipate making projections and forward-looking statements based on our current expectations. Our actual results could differ materially due to several factors, including those listed on slide 4.

Additional information concerning factors that could cause actual results to differ materially is contained in our latest Form 10-K and subsequent filings with the SEC. The information we provide about our products and pipeline is for the benefit of the investment community. It is not intended to be promotional and is not sufficient for prescribing decisions. As we transition to our prepared remarks, please note that our commentary will focus on our non-GAAP financial measures.

Now, I'll turn the call over to Dave.

David A. Ricks

Chairman & Chief Executive Officer, Eli Lilly & Co.

Thank you, Mike. Q1 was another exciting quarter. We increased our revenue, advanced our pipeline, invested to drive future growth, and shared the first Phase 3 clinical data from our oral GLP-1, orforglipron. Dan will share more details during the R&D update, but we're pleased with the results from the ACHIEVE-1 trial for orforglipron in patients with Type 2 diabetes. These data met our expectations and are the first steps to delivering our overall goal for the program, which is to create a medicine that offers injectable GLP-1 like efficacy, safety, and tolerability, with the convenience of a once daily pill that can be manufactured at scale to meet global demand. This scientific breakthrough has the potential to eventually impact hundreds of millions of people around the world with chronic diseases. And we expect Phase 3 data from seven global clinical trials to read out over the next 12 months across Type 2 diabetes and obesity. We also expect potential regulatory submissions for obesity to begin worldwide by the end of 2025.

On slide 6, we list Q1 financial metrics and highlight progress related to our strategic deliverables. Revenue grew 45% compared to Q1 of 2024. Our key products defined as Ebglyss, Jaypirca, Kisunla, Mounjaro, Omvoh,

Verzenio, and Zepbound, grew by more than $4 billion and now account for $7.5 billion of revenue for the company. In addition to the orforglipron readout, we achieved several other key pipeline milestones this quarter. They include the approval of Jaypirca in the EU for CLL. The approval of Omvoh in the US, EU and Japan for Crohn's disease, and the initiation of a Phase 3 program for olomorasib in resected adjuvant non-small cell lung cancer. We also shared plans to more than double our manufacturing investment in the US. In total, we've announced over $50 billion of new US manufacturing investments since 2020, including our most recent announcement to build four new facilities, of which three will be API or active pharmaceutical ingredient facilities.

Lastly, we distributed $1.3 billion in dividends in the first quarter and executed a $1.2 billion share repurchase. We realized there is a lot of investor focus right now on tariffs and trade. So, I'll make a few comments that reflect our current views on these complex and quite dynamic matters. We support the US government's goals to increase domestic investment. However, we don't believe tariffs are the right mechanism. Enhanced tax incentives and/or the extension of the Tax Cuts and Jobs Act are better tools to achieve their goals. The announced tariffs currently in effect do not materially change Lilly's 2025 financial outlook. However, the expansion of tariffs in other geographies, or increases in retaliatory tariffs would have a negative effect on Lilly and for our industry.

As a company, Lilly has a large US manufacturing footprint, with 10 active projects ongoing to build and expand new sites. Upon completion of our manufacturing agenda, we will be able to supply medicines for the US market entirely from US facilities, as well as increase the volume of medicines we export. We will continue to execute our US manufacturing agenda. However, we urge the administration to negotiate deals with key trading partners, as soon as possible to level the playing field for American exporters like Lilly, and remove harmful tariffs and non-tariff market access barriers in the developed economies.

Now, I'll turn the call over to Lucas to review our Q1 financial results.

Lucas E. Montarce

Chief Financial Officer & Executive Vice President, Eli Lilly & Co.

Thanks, Dave. As shown on slide 7. Q1 was another strong quarter of financial performance with revenue growing 45% compared to Q1 2024, driven by our key products. Gross margin as a percentage of revenue was 83.5% in Q1, an increase of 1 percentage points versus the same quarter last year. Gross margin was positively impacted by improved production costs and favorable product mix, which were partially offset by lower realized prices.

Marketing, selling and administrative expenses increased 26% as we invested in promotional activities to support new launches across our therapeutic areas. R&D expenses increased 8%, driven by higher development expenses for late-stage assets and additional investments in early stage research. In Q1, we recognized acquired IPR&D charges of $1.57 billion, primarily related to the previously announced acquisition of Scorpion Therapeutics PI3K-alpha inhibitor program. In total, IPR&D charges negatively impacted earnings per share by $1.72.

Our non-GAAP performance margin, which we define as gross margin, less R&D, marketing, selling and administrative expenses as a percentage of revenue was 42.6%, an increase of over 11 percentage points from Q1 2024. Our Q1 effective tax rate was 20.2%. The Q1 tax rate was negatively impacted by the previously described non-deductible acquired IPR&D charges. At the bottom line, we deliver earnings per share of $3.34 in Q1, inclusive of the negative impact of $1.72 from acquired IPR&D charges. This compares to earnings per share of $2.58 in Q1 2024, inclusive of $0.10 of acquired IPR&D charges.

On slide 8, we quantify the effect of price, rate and volume on revenue growth. US revenue increased 49% in Q1, driven by strong volume growth of our key products, including Zepbound and Mounjaro, partially offset by a 7% decline in price.

Moving to Europe, revenue increased 71% in constant currency. Q1 2025 was positively impacted by a one-time benefit of $370 million related to further restructuring our alliance with Boehringer Ingelheim. Excluding this benefit, constant currency revenue grew 46%, driven primarily by Mounjaro, partially offset by a 7% decline in price. Japan revenue grew 15% in constant currency, with volume growing 16%, driven by Mounjaro and Jardiance.

Moving to China, Q1 revenue increased 21% in constant currency. Volume growth was primarily driven by Mounjaro. As a reminder, we recently initiated a limited Mounjaro launch in China with the expectation to gradually increase commercial launch in the second half of 2025 as supply becomes available. Revenue in the rest of the world increased 17% in constant currency, primarily driven by volume growth from Mounjaro, and, to a lesser extent, Verzenio.

Slide 9 provides an update on the performance of our key products. Beginning with immunology, we have seen encouraging US uptake of EBGLYSS in atopic dermatitis. New patient starts are increasing and we are making good progress securing access and reimbursement. EBGLYSS is currently covered by two of the largest pharmacy benefit managers, and we expect further access improvement later this year. As of May 1, EBGLYSS will be reimbursed on plans that account for 60% of people who are commercially insured. For Omvoh, we have received approval of Crohn's disease across the globe as a second indication. Commercial activities is going to drive new patient starts in this larger patient population.

Moving to oncology, Jaypirca was recently approved in Europe for relapsed or refractory CLL in patients who previously treated with a BTK inhibitor. We anticipate launches beginning in Q2. We also expect readouts from additional global Phase 3 trials later this year, which we believe will be important to evaluate Jaypirca in earlier settings of CLL, including a head-to-head comparison with ibrutinib. Verzenio global sales grew 10% in Q1, as Verzenio continues to be the standard of care in high risk early breast cancer. As expected, we have seen some impact from competition in early breast cancer. However, Verzenio share of marketing high risk early breast cancer is a stable and total prescription to continue to grow. US prescription grew by 7% in Q1, partially offset by the wholesaler inventory destocking in the quarter.

International volumes for Verzenio business grew 30% in Q1. Within neuroscience, Kisunla is now approved in 12 countries. We have seen steady increase in the use of blood-based biomarkers. The conversion rates from diagnosis to treatment and the number of new patients starting treatment in both the US and Japan. While it is encouraging to see progress, we do still expect that it will take some time to build this market. We expect US regulatory action for the modified dosing regimen for Kisunla in the next few months.

Finally, moving to Cardiometabolic Health, both Mounjaro and Zepbound posted a strong revenue growth. Mounjaro sales were $3.8 billion, more than double the same quarter last year. In the US, Mounjaro exited Q1 as the market leader in new prescription within diabetes incretin analogs. Outside the US, Mounjaro has launched in over 40 countries and Q1 was another quarter of steady sequential growth. We recently launched in India and Mexico and plan to continue with additional country throughout 2025.

Our focus internationally is on seeking reimbursement for Type 2 diabetes and developing the ecosystem to treat obesity as a chronic disease. Zepbound performance was also robust, as sales increased by $1.8 billion to $2.3 billion in the quarter. Zepbound is the US branded anti-obesity market leader in both total prescription and new

prescription, reaching 60% and 74% respectively at the end of Q1. We also launched higher dose Zepbound vials adding two additional doses for patients to access Zepbound through the self-pay channel. The uptake of Zepbound vials has been strong and vials accounted for approximately 10% of total prescription and 25% of new prescriptions in Q1.

On slide 10, is an update on trends in the US incretin analog market, which includes incretin prescriptions in both Type 2 diabetes and obesity. Q1 was another quarter of steady market growth as total prescriptions grew by 46% compared to Q1 2024. Lilly performance was strong as a four-week rolling average share of market increased by 5 percentage points compared to Q4 2024 and by 10 percentage points compared to the same quarter last year.

On slide 11, we provide an update on capital allocation.

Moving to slide 12 is our updated 2025 financial guidance. Our performance in Q1 was strong, and we are encouraged by the underlying trends we saw across our portfolio of medicines. As a result, we are reaffirming our revenue and performance margin guidance. Our non-GAAP earnings per share guidance is unchanged except for Q1 charges related to acquired IPR&D. As Dave mentioned, the situation regarding trade and tariffs remains dynamic. We continue to monitor the external environment. However, we estimate that the announced tariff currently in effect will have a limited impact financially, which we have absorbed within our 2025 guide.

Now, I will turn the call over to Dan to highlight our progress on R&D.

Daniel M. Skovronsky

Executive Vice President, Chief Scientific Officer, President-Lilly Research Laboratories & President-Immunology, Eli Lilly & Co.

Thanks, Lucas. I'll start with key data from our recently completed orforglipron Phase 3 trial, and provide some context on our development plans and timelines for this important molecule. I've previously said that our hypothesis was that orforglipron could deliver efficacy, safety and tolerability similar to the best seen for available GLP-1 monotherapy injectables. I believe the results from ACHIEVE-1 trial support that hypothesis.

Let me start with efficacy. Beginning on slide 13, you can see the reduction of 1.3% to 1.6% for hemoglobin A1c. Given the relatively low baseline of 8.0 in this 40-week monotherapy study, patients on the two highest doses ended the study with a mean A1c of about 6.5%, similar to the lowest levels achieved in trials of other monotherapy GLP-1 agonists.

In fact, with orforglipron more than 65% of patients achieved an A1c less than or equal to 6.5%, which is below the American Diabetes Association's defined threshold for diabetes. In a key secondary endpoint, orforglipron also helped people with diabetes lose approximately 16 pounds or 7.9% of their body weight at the highest dose. These data are in line with weight loss demonstrated with existing injectable GLP-1s in patients with diabetes, especially when considering the baseline weight and other demographic factors in this trial.

Given that the study was only 40 weeks in duration, participants had not yet reached a weight plateau at the conclusion of this study. This result is encouraging as we look ahead to our first Phase 3 readout in people with obesity that we expect in Q3. Most importantly, we were pleased to see the safety profile of orforglipron in this trial. The most common adverse events were gastrointestinal, which is consistent with the GLP-1 class. We did not see any hepatic safety issues in ACHIEVE-1.

As you can see on slide 14, discontinuations due to adverse events were low, with only 4% to 8% of patients discontinuing orforglipron due to adverse events. The slow and stepwise dose escalation we utilized in Phase 3,

combined with the relatively long, about 24-hour half-life of this molecule, resulted in a tolerability profile that matched our expectations and was consistent with weekly injectable GLP-1s.

The ACHIEVE-1 full results will be presented at the ADA's 85th Scientific Sessions and will be published in a peer-reviewed journal. This was the first of several Phase 3 trials that we'll read out for orforglipron.

On slide 15, you can see how ACHIEVE-1 fits into the broader orforglipron development program. Over the next 12 months, we expect to get results from four additional diabetes trials, where we're studying orforglipron compared to insulin and head-to-head versus other oral diabetes medicines. We also expect to get results in our two obesity Phase 3 trials, one trial in people with obesity without diabetes and a second trial in people with obesity and diabetes.

Assuming success in these Phase 3 programs, we plan to submit orforglipron for obesity in Q4 later this year, followed by Type 2 diabetes in the first half of 2026. We also have an ongoing Phase 3 trial in obesity in the maintenance setting, the Phase 3 trial on obstructive sleep apnea, and obesity, and we will initiate a Phase 3 trial in hypertension later this quarter. We look forward to seeing more data from this robust clinical development program as we continue to find the impact orforglipron can have for patients.

Moving on to other R&D updates since our last call. On the regulatory front, following discussions with the FDA, we've withdrawn our US application for the heart failure with preserved ejection fraction indication for Tirzepatide. We believe the positive Phase 3 data from the SUMMIT trial do support an indication. However, FDA indicated an additional confirmatory clinical trial is required. Regulatory reviews are ongoing in other countries.

Continuing with updates in Cardiometabolic Health, we're sharing today plans to initiate a new Phase 3 trial studying our triple agonist, Retatrutide, in patients with obesity, and chronic low back pain. We're also announcing today next steps for our Oral Once-Daily program targeting lipoprotein(a), Muvalaplin. In Phase 2 data we presented last year, Muvalaplin lowered lipoprotein(a) levels by up to 85% at the highest tested dose. Based on these data, we plan to initiate a Phase 3 program later this year in atherosclerotic cardiovascular disease and we're excited about the potential to bring what could be the first ever oral small molecule approach for lowering lipoprotein(a) to patients.

Moving to oncology. We've now started a new Phase 3 program with olomorasib in KRAS G12C mutant resected adjuvant lung cancer. This is the third potential indication that we're simultaneously pursuing for olomorasib.

Across our therapeutic areas, we made good progress in our early phase portfolio and we advanced five new medicines into Phase 1 clinical trials, as shown on slide 16.

I'll now turn the call back to Dave for closing remarks.

David A. Ricks

Chairman & Chief Executive Officer, Eli Lilly & Co.

Thanks, Dan. We know uncertainties exist right now in trade tax and international relations. While Lilly is actively engaged in shaping the external environment, we're mostly focused on executing our winning strategy, discovering, developing, and making new medicines that can help people live healthier lives. We made good progress this quarter, and we are well positioned to deliver strong and sustained growth going forward.

Now, I'll turn the call over to Mike to moderate our Q&A session.

Michael Czapar

Senior Vice President-Investor Relations, Eli Lilly & Co.

Thanks, Dave. We'd like to take questions from as many callers as possible. Consistent with prior reporters, we will respond to one question per caller, and we'll end the call promptly at 11 am.

Paul, please provide the instructions for the Q&A session and then we're ready for the first caller.

QUESTION AND ANSWER SECTION

Operator: Certainly, at this time we'll be conducting a question-and-answer session. [Operator Instructions] And the first question today is coming from Asad Haider from Goldman Sachs. Asad, your line is live.

Asad Haider

Analyst, Goldman Sachs & Co. LLC

Q

Thanks. Thanks for taking the question. Dave, just in light of the CVS formulary announcement this morning, favoring the Wegovy over Zepbound, there are clearly some investor concerns about the PBM dynamic in obesity given what we've seen in other big healthcare markets in the past, where two PBMs – where PBMs [ph] pit (00:22:07) two companies against each other. So two-part question. Number one, what is your expectation on market share dynamics in the next weeks and months from the CVS formulary loss?

And then second, can you talk to your strategy on how you're going to be navigating an environment where we could see PBMs continue to try and restrict formulary access between Zepbound and Wegovy? Thank you.

David A. Ricks

Chairman & Chief Executive Officer, Eli Lilly & Co.

A

Yeah. Thanks for the question. We're not surprised that this kind of thing was announced. If we look at what's happening in the market, we're pretty deep into a replacement cycle, particularly on obesity and Tirzepatide, as we've highlighted on this call, is gaining a lot of market share. Basically, most of the growth in the category is happening with our medicine.

Of course, the private pay market is an important segment. We'd like to grow that segment and we'd like to grow choice and access in that segment. So we're not interested at all in one-of-one deals of reducing access and choice for doctors and patients. We want to expand it. So this type of thing isn't too interesting to us, but it's understandable that it can happen, and obviously, in this one case did. Our focus is on making better medicines and more accessible medicines. So orforglipron is a topic today, excited by the possibility of an oral that could be more widely distributed around the world, and here in the US with GLP-1 – injectable GLP-1 like profile, like Dan highlighted, and of course, on driving more advanced therapies as well, a combination or triple acting agents like Retatrutide. So that's our focus.

It doesn't surprise me that this happened and we'll work through it recognizing in this case as well we're talking about the templated lives at CVS, and probably opt in rates for employers in the templated part of their book are pretty low compared to the national average, just to maybe inform your analysis, and we'll work through it. Our job will be to continue to drive share and preference for our brand. I think the team has done a great job of that year-to-date, and we'll continue to focus on that while we wait for the orfor launch and read the data later this year.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Great. Thanks, Dave. Thanks Asad. Next question please.

Operator: The next question will be from Geoff Meacham from Citibank. Geoff, your line is live.

Geoff Meacham
Analyst, Citigroup Global Markets, Inc.

Q

Good morning, guys. Thanks for the question. For Dan or for Dave, when you look at the positioning of orforglipron, is the ultimate goal to have meaningfully more indications than Tirzepatide just given the oral convenience? I think when you look beyond just weight loss would seem that a broader cardio investment makes sense, but maybe also perhaps combos in INI or autoimmune and or even neuropsych? Thank you.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Great. Thanks, Geoff. We'll go to Dan talk about the workflow development strategy.

Daniel M. Skovronsky
Executive Vice President, Chief Scientific Officer, President-Lilly Research Laboratories & President-Immunology, Eli Lilly & Co.

A

Yeah. Thanks, Geoff. And I think you're correctly pointing out that oral medicine like orforglipron could be acceptable for use in a number of broad indications, particularly primary care type indications. That's guided our thinking on indications that we're pursuing. I think coming out of this readout, we have even more confidence in this molecule and we'll aggressively pursue whatever directions we think work. Combinations surely are on the table where that makes sense for patients, particularly in disease areas where there could be synergy with other mechanisms. Probably there are a number of good ideas in immunology and neuroscience as you point out.

Also, just a reminder, Geoff, we – it's not our only oral incretin. We have another molecule behind that and we're continuing to innovate with even multifunctional orals. So I'm pretty excited about what's yet to come here and surely we start with Type 2 diabetes and obesity, but more to come.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Great. Thanks, Dan. On to the next caller, please.

Operator: The next question is coming from Chris Schott from JPMorgan. Chris, your line is live.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Great. Thanks so much. Just another orforglipron data. Just post the data we've seen here, can you just elaborate a bit more on the role you see orforglipron playing in the core obesity and diabetes market relative to injectables? And maybe as part of that, any thoughts on what type of share you would envision orals taking in the market over time? Thank you.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Great. Thanks, Chris. We'll go to Patrik to talk about that role of oral in the broader [indiscernible] (00:26:42) market.

Patrik Jonsson
Executive Vice President, President-Lilly Cardiometabolic Health & President-Lilly USA, Eli Lilly & Co.
A

Hey, thanks a lot, Chris. I think significant opportunities here for orforglipron. Just looking at the Type 2 market today, we know that approximately 50% of patients have a preference for an oral, given everything else equal on the efficacy and the safety side. And similarly, on the obesity side, we know that we have approximately 25% of the patients in the US suffering from needle fear. So I think that position us very nicely to be a first line incretin for both Type 2 and chronic weight management. The other benefits as well, I think with an oral here, we can scale and reach patients that is more or less impossible with only injectables. So I think it provides a huge global opportunity for us with orforglipron and also from a manufacturing side, probably a significant benefit as well. So overall, I think tremendous opportunities here with orfor, both Type 2 and obesity in the US and other markets where we've launched, but also to scale globally to an extent we can't do with injectables.

David A. Ricks
Chairman & Chief Executive Officer, Eli Lilly & Co.
A

Maybe two quick adds there in segments that we're thinking about actively. One, of course, we're doing the maintain studies, which switch people from injectable to oral to maintain weight loss. That's a big unmet need in the market. People like the idea of stepping down and using less medicine. They're trying things on their own now and we'll have science-based solution using oral, which we think will be an attractive choice. That data is not in hand yet. We need to wait for that to prove that out. But I think that's an interesting segment that will probably grow quite large over time, Chris.

The other one is reaching segments of the population that maybe have comorbid risk, maybe not comorbid disease, have overweight, but not obesity, and don't need dramatic weight loss, but sustained lower body weight is an important factor in their long-term health, and we'll look at studies there. I think the prior question was alluding to that in terms of indications that might be suitable for that space. So we have big ambitions here and, of course, need to see the full data package come in on obesity, but a pretty exciting opportunity.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.
A

Great. Thanks, Patrik. Thanks, Dave. We're ready for the next question, please?

Operator: The next question will be from Terence Flynn from Morgan Stanley. Terence, your line is live.

Terence C. Flynn
Analyst, Morgan Stanley & Co. LLC
Q

Great. Thanks for taking the question. Two part on orforglipron as well. I know you're obviously not going to comment directly on pricing at this point, but maybe just conceptually, if you're delivering the same profile as an injectable medicine, why would you decide to price lower, I guess, given you price to value? And then as you think about having a portfolio of weight loss medications potentially in 2026, does that give you additional leverage with some of these PBM discussions? Thank you.

David A. Ricks
Chairman & Chief Executive Officer, Eli Lilly & Co.
A

[ph] Okay. So (00:29:40) on the risk curve again, Terence, with a two-part question. But we'll go to Patrik to weigh in the thoughts on the orfor pricing and then the portfolio implications as well.

Patrik Jonsson
Executive Vice President, President-Lilly Cardiometabolic Health & President-Lilly USA, Eli Lilly & Co.

A

Well, thanks a lot, Terence. I think in terms of pricing, we normally don't comment on that until the time of launch. But I think truly having a portfolio in this space, and as Dave shared earlier on oral, that we actually could approach patients with a BMI above 27, lower BMIs, Tirzepatide probably will play as foundation for treatment of chronic weight management for quite some time to come, and potentially a triple agonist, right, where you could target people with a BMI above 35, and so I think that gives us a position of strength in this marketplace.

David A. Ricks
Chairman & Chief Executive Officer, Eli Lilly & Co.

A

Maybe just one, like policy related add, like how do we think about pricing forward, especially in a category like this. The past was really about very high list prices and relatively deep discounts to leverage PBM access. And we've been very vocal about trying to move away from that path, basically to have a more transparent, closer pricing between list and net. Maybe important to say that based on this morning's news as well. So we priced Zepbound at a discount to the competitor, a meaningful discount on list price, with the idea of trying to squeeze those two numbers together. We'd like to continue that progress so that patients and payers have a more similar basis for cost sharing and net cost. I think that's a better way forward.

So just as Patrik and the team work on pricing strategies, et cetera, know that in the background, we're trying to push these two numbers together over time, reduce gross to net spreads, have less rebate flow into the channel and more transparent overall pricing.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Great. Thank you Dave. Thank you Patrik. Next question please?

Operator: The next question will be from Mohit Bansal from Wells Fargo. Mohit, your line is live.

Mohit Bansal
Analyst, Wells Fargo Securities LLC

Q

Great. Thank you very much for taking my question. I think going back to the CVS announcement this morning, there are two ways to look at it. I mean, one could be which, obviously, the stock reaction is like that. It seems like, I mean, Zepbound versus Wegovy kind of price war? Or the other way could be, I mean, looking at CVS comments, it seems like a lot of employers did not opt in and CVS is finding a way to actually provide affordable access to this medicine. How do you view this development? And in longer term, I think, is it a better versus GLP-1s you see or is it a GLP-1 versus the access situation you see this is going to evolve over a couple of years?

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Thanks for the question, Mohit. I think, Dave, do you want to elaborate on some of the earlier comments about the CVS?

David A. Ricks
Chairman & Chief Executive Officer, Eli Lilly & Co.
A

[indiscernible] (00:32:26). I mean, I think those are good questions to ask Novo and CVS, really. Just pointing out that the book of business we're talking about is smaller employers who tend to tell it, take the templated formulary, the opt-in rates already are low. So it is possible that depending on what net price that CVS is going to offer these clients, so you get more opt-in. I think that's a net good thing overall, because what we see despite the press is when employers opt in, they tend to not opt out. Employees like to be on these medicines. And there's a big study yesterday you may have seen from Aon, which looked at real world data, which is very compelling. Within two years, there's ROI, a 40% reduction in MACE events in the real world, et cetera. So that could be good as you're saying.

On the other hand, I guess, we're focused on innovation and differentiation. We see kind of a mega category here that will have many different choices and solutions. And it seems like the wrong idea to reduce choice. Maybe there's patients who are taking Zepbound in one of these formularies, and as of July 1, they won't have that choice. I think they'll be quite upset about that. And we'll see how the market reacts and how much share gets moved ultimately. But as I said, our preference is to expand access, not reduce it.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.
A

Thanks, Dave. Next caller please?

Operator: Next question will be from Alex Hammond from Wolfe. Alex, your line is live.

Alexandria Hammond
Analyst, Wolfe Research LLC
Q

Thanks for taking the question. Just one quick one on TRAILBLAZER-ALZ 3. So during the 4Q call, Dan mentioned that the team is closely watching the preclinical trial, and the study will read out when the target number of progression events were accrued. Can you update us as to where we are from that event's point of view and remind us of what a successful trial looks like? Thank you.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.
A

Great. Thanks Alex. We'll go to Anne for the question on the welcome question on the Alzheimer's portfolio.

Anne E. White
Executive Vice President & President-Lilly Neuroscience, Eli Lilly & Co.
A

Yes. Thanks so much for the question on Alzheimer's. And as we mentioned in the past, we have completed enrollment in the TB3 study. And as you said, it's an event based study, so the timeline for the readout is driven by this. And although our clinicaltrials.gov lists the date in 2027, we believe it could be earlier than that. So we're looking forward to that.

Now, these are patients who have elevated levels of amyloid but no detectable symptoms. And our goal is to significantly reduce the risk that people ever experience the symptoms of Alzheimer's disease. So that's the goal to study. The actual endpoint is time to event of clinical progression, and we measure that by the CDR global score. So really preventing people from moving to the symptomatic stage, which is the stage at which the greatest impact is happening. So what we saw on TB2 obviously got us very excited about the potential outcome here with

the fact that patients earliest in disease and early symptomatic did so well and had such a significant slowing of progression, 60%. So we'll look forward to sharing more as the events occur. And again, we'll share more timing when we have those events reached.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Great. Thanks Anne. Next question please.

Operator: The next question will be from Seamus Fernandez from Guggenheim. Seamus, your line is live.

Seamus Fernandez
Analyst, Guggenheim Securities LLC

Q

Thanks for the question. So I'll go with another non-obesity question. How is EBGLYSS tracking against your ambition of it being a best-in-class launch? Is your vision for peak sales in line with consensus sales of $2 billion or do you see an opportunity materially higher than that? And if not, is the barrier related to Sanofi's claimed rebate wall or something else like the breadth of the label or perceived efficacy differentiation? Thanks so much.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Great. Thanks Seamus. We'll go to Dan to talk about the Ebglyss launch dynamics and some goals for the brand.

Daniel M. Skovronsky
Executive Vice President, Chief Scientific Officer, President-Lilly Research Laboratories & President-Immunology, Eli Lilly & Co.

A

Yeah. Thanks, Seamus. We certainly do have high aspirations for EBGLYSS. It's a great medicine. We saw amazing data in our clinical trials. I think this prepared us well to take on the market leader in atopic derm, which is a large and growing market. And in the early months of launch, we've seen good uptake as you can see reflected in the numbers. And I think probably most telling is what we're seeing and hearing from physicians. Initially, I think in any launch, people try it in their most severe patients, people who might have failed other therapies. And when they see good responses there, they move it into the first-line setting. That's exactly the motion we're seeing from physicians. They're happy with the results they're getting, and they're using it more and more. A lot of work to do and you point out the heavy competitive dynamics, but I like the asset I have. In terms of the rebates and coverage, I think as Lucas said, we're seeing a growing coverage here in the United States. And I think we'll overcome any issues there without trouble. So we look forward to broad access and continued accelerating uptake.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Great. Thank you, Dan. Next caller please.

Operator: The next question will be from Tim Anderson from Bank of America. Tim, your line is live.

Tim Anderson
Analyst, BofA Securities, Inc.

Q

Thank you. A question on kind of going back to formulary positioning in obesity. So I know you don't want to play the one of one formulary game, but it's still something that might occur anyway because Novo is losing share to you, and price is really the only lever they can pull at the moment. And some payers will look at one of one as a

way to manage spend. I know that some states have already taken that approach. Now we're seeing CVS do it. So really the question is, I guess, of covered lives today, what percent of payers already are having this one of one approach? And just, again, your view for how this is going to evolve going forward, whether you like it or not? Thank you.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Thanks, Tim. For the next question on CVS, we'll go to Patrik.

Patrik Jonsson
Executive Vice President, President-Lilly Cardiometabolic Health & President-Lilly USA, Eli Lilly & Co.

A

Yeah. Thanks very much, Tim. One-on-one is quite rare in the marketplace today when it comes to obesity. And as Dave said earlier, we deal with the contract negotiations all the time and we're not entirely surprised with the announcement this morning, taking into account Zepbound's strong performance. For us, we will just continue to execute as strong as we can, and I think we have a tremendous momentum in the marketplace with a net switch that is quite significant to Zepbound in the marketplace. We will continue those efforts across the PBMs, Medicaid and also Medicare, and of course, our self-pay effort with vials as well.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Great. Thank you, Patrik. Next question please.

Operator: The next question will be from Evan Seigerman from BMO Capital Markets. Evan, your line is live.

Evan David Seigerman
Analyst, BMO Capital Markets Corp.

Q

Hi, guys. Thank you so much for taking my question. I wanted to touch on Tirzepatide and HFpEF. The update was a bit surprising today. Can you provide some additional detail on what FDA wants to see in regard to additional data? And what you didn't have from the SUMMIT trial that was to demonstrate the clear enough benefit? Thank you.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Yeah. Thanks, Evan. We'll go to Dan for the question on the heart failure dynamics.

Daniel M. Skovronsky
Executive Vice President, Chief Scientific Officer, President-Lilly Research Laboratories & President-Immunology, Eli Lilly & Co.

A

Yeah. Thanks, Evan. It's probably obvious to you as it is to us that that was a study with a really strong and profound benefit for patients. So we're excited about the opportunity to help patients with that. I think from the FDA perspective, they want multiple trials to support this indication. And I think that that's probably where we ended it. It's possible we could get additional data from other trials to support resubmission here.

On the other hand, just remember that all of the patients in this trial and the proposed indication are already covered under the obesity indication. So it's not a new population to treat. It's rather a new benefit for people that might already be widely understood to doctors today. So it's a bit unfortunate we're in this position and it could have a bit of a curtailing effect on investment in HFpEF, which is a pretty serious unmet medical need. So I'm

sorry to see that, but it's kind of hard to think of the incentive for doing large outcome trials in this population that's already covered under an existing indication and the benefits are well understood.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Great. Thanks, Dan. Next question.

Operator: Next question is from James Shin from Deutsche Bank. James, your line is live.

James Shin
Analyst, Deutsche Bank Securities, Inc.

Q

Hey, good morning, guys. Thank you for the question. Maybe one for Lucas. I know revenue guidance was maintained, but is the mid to high single digit price headwind still intact following the CVS formulary decision on Zepbound and also given the movement in FX? Thank you.

Lucas E. Montarce
Chief Financial Officer & Executive Vice President, Eli Lilly & Co.

A

Yeah. Thank you for the question, James. Maybe just jumping into it right away. As you've heard, we are reaffirming our guide for the full year that the midpoint continue to be in that 32% range for the year. We are off to a good start with the strong growth that we see in the first quarter. To your question about the price, yes, again, I mentioned last time and I reaffirm it now again, that mid to high-single digit price erosion, we've seen that in the first quarter, by the way, minus 6% in price. So it's very consistent with what I share in the last earnings call. So overall, I think, that, that perspective has not changed both in terms of the guide and our expectations on price for the year. Maybe just again, to provide a little bit more perspective on how things evolve, on how we think about the guide. There are always dynamics taking place during the year, as you can imagine, and we factor those ones as part of our forecasting process.

So, as Patrik alluded, we are not surprised with this. And again, we will continue to navigate. We feel strongly about the update that we are seeing nowadays, and we will continue to navigate through this throughout the year.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Great. Thank you, Lucas. Thanks for the question. Next question please.

Operator: The next question will be from Umer Raffat from Evercore. Umer, your line is live.

Umer Raffat
Analyst, Evercore ISI

Q

Good morning guys, thanks for taking my question and congrats on recent orforglipron updates. I had a question – a two part question on orfor's safety. First, I recall you mentioned no hepatic safety signal was observed and no Hy's law. Could you confirm there was no numerical imbalance on ALT above five times? And on diarrhea, I recall it was in the low to mid 20s across the second highest and highest dose. How should we think about that heading into the obesity trial, especially with longer duration? Thank you very much.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Thanks so much for the question on the safety profile for orfor.

Daniel M. Skovronsky
Executive Vice President, Chief Scientific Officer, President-Lilly Research Laboratories & President-Immunology, Eli Lilly & Co.
A

Okay. Thanks. Those are very specific questions, which I may not precisely know the answer to honestly. But as far as the overall liver safety profile, including kind of mean changes and excursions from the mean, we didn't see anything of concern here and it looked very similar to placebo. So I think we feel confident that additional data readouts coming, of course, but so far, so good. I think with respect to rates of diarrhea, you're pointing out that they were a bit higher in this study than we've seen in previous studies. They were also higher in the placebo rate.

I think we might need to move to an understanding of diarrhea rates as a sort of a ratio of drug to placebo, because they can be pretty variable depending on the country that you enroll the trial. And we saw that effect in this study with some countries having very high diarrhea rates and placebo and drug, and also the way that's ascertained by the investigator. So I didn't see anything of concern there. But I do need our trials probably across Lilly seem to have slightly higher diarrhea rates than others. But let's see what we see in the obesity rate. That's not the main focus here. Probably the more telling indicator of tolerability is going to be discontinuation due to adverse events. That's what probably matters the most in the real world.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.
A

Great. Thank you, Dan. Thanks for the question. Next question please.

Operator: The next question will be from Steve Scala from TD Cowen. Steve, your line is live.

Steve Scala
Analyst, TD Cowen
Q

Thank you very much. My recollection is that Lilly used aggressive formulary positioning as a lever with Taltz against other IL-17 competitors, and therefore reduced choice. Would you refresh our memories on what that did for Taltz in terms of share and incremental sales? And if you're willing to at what discount? And how can that experience inform us on the outlook for Zepbound and Wegovy on the CVS formulary? Thank you.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.
A

Great. Thanks, Steve. Dave, we'll go to you for the history on BioMeds?

David A. Ricks
Chairman & Chief Executive Officer, Eli Lilly & Co.
A

Yeah.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.
A

So four score and seven years ago.

David A. Ricks
Chairman & Chief Executive Officer, Eli Lilly & Co.
A

No, we launched Taltz almost a decade ago. I have a different recollection. I was in charge of it at the time. Actually, we had a situation where we were the follower, and what we tried to do is go from one on one in a new category to two of two. And that's what I think we more or less achieved over the course of the first three or four years of the brand. Of course, things have changed since then with IL-23s and now a third IL-17 entering, and you do see one of ones. But I guess maybe a point to raise here is that kind of payer behavior is more common in the pharma industry when you have more than two players and when you have product profiles that are clinically kind of close to each other. Just pointing out in the obesity space, it's neither of those things are true, and it'll be interesting to see how this experiment works. We have more differentiation coming.

So I think there will be more choice needed in the marketplace, not less. It's really never been our strategy in a category to use the payer channel to drive share exclusively. Even when we had big advantages on clinical profile, I mean, Jardiance, is an example of that, where we always sought to have multiple choices in that class. So different memory than yours, Steve, although you've been doing this a long time as well. And that doesn't mean we didn't have some situations that were one on one for Taltz, but it wasn't our preferred position. And frequently we didn't offer different rates to get there. So, that's also – all that's true now, we as a company position want more choice, and particularly where innovation is flourishing and we have a lot of it coming, it wouldn't be in our interest.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.
A

Great. Thank you, Dave. Next question please.

Operator: Next question is coming from Courtney Breen from Bernstein. Courtney, your line is live.

Courtney Breen
Analyst, Bernstein Institutional Services LLC
Q

Hi, everyone, thanks for the question. Perhaps just following on from Steve's question as well. Can you clarify for us, because I think a number of investors are concerned, and obviously we see that in the share price today. How many current patients on Zepbound are being covered by CVS Caremark today?

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.
A

Okay. Thanks for the question, Courtney. Maybe give some color on the rough magnitude Patrik, on the CVS Zepbound [ph] dynamics (00:47:51)?

Patrik Jonsson
Executive Vice President, President-Lilly Cardiometabolic Health & President-Lilly USA, Eli Lilly & Co.
A

Yeah. I don't have a specific number of lives to share today. But I think when you look at [indiscernible] (00:47:59) it's not the entire CVS account. We're talking about the subset of plans that Dave shared earlier. And we also need to understand what is the level of employer opt-in in those plans. And we believe it's not on the high end. So I think that's probably the guidance we can provide today and I think we will just continue our efforts to drive increased employer opt in across other plans and segments. But that's the number I – that's the only thing I can share today.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.
A

Great. Thank you, Patrik. Next question please.

Operator: The next question will be from David Risinger from Leerink Partners. David, your line is live.

David Risinger
Analyst, Leerink Partners LLC

Q

Yes. Thanks very much. So I'm hoping that you can comment, Dave, on discussions with the Trump administration on tariffs outside of the 232 investigation. So the driver of my question is that the countries of origin for Lilly's drugs, IP and API are obviously not in countries that represent national security threats. And I'm curious about the discussions to satisfy the Trump administration's interests in having drug companies record more profits in the United States and generate more tax revenue in the United States? Thank you.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Great. Thank you, Dave. Dave, go ahead.

David A. Ricks
Chairman & Chief Executive Officer, Eli Lilly & Co.

A

[indiscernible] (00:49:24) burning question. I mean, you're correct in pointing out that the Section 232 mechanism is a national security mechanism, and that's where the pharma review sits today separately. There's an agenda item in the administration to repatriate supply chain, and one we support. And then, thirdly, there's a question of raising revenue while they're going through a reconciliation process and so forth.

So just on those three things. The 232 review, I think, has merit in the sense that if we look at what are really a lot of commonly used generic medications, some of which invented by Lilly long ago, or other innovative companies have moved toward offshore sources, single source sources, and potentially in competing countries where you can imagine a future conflict and a potential problem. We see that, too. I think the branded industry would like to help with that problem, if we could. Fundamentally, it's kind of a market mechanism problem where there's no real good pricing available, so there's not going to be an onshore presence until there is. But in the case of emergency, maybe we could work with them. I think there's a big question of whether tariffing that would do anything to move the supply chain. And maybe that's the subject of that review. And we would hope the 232 review would be kind of cabin to that question.

Secondly, is the trade imbalance broader thing? And as you're pointing out, we – so we have a mixed source, US and non-US, but most our non-US is Irish origin. And we're in the process, we made a decision four years ago with the board to move away from just a pure efficiency, whether it be tax efficiency or cost to goods efficiency and move to a more of resilient position. We've been at this a little while and we'll continue to do that. And so that will rebalance naturally our sourcing. We'll have more choices.

So I think tariffing that could have a transient effect for Lilly, but probably not a long term one. We think the real answer there, as I said earlier, is to reduce the gap that led to that problem at the beginning of which is really an income tax situation. And when the US is at 35 and Ireland was whatever 15. So, I think tax reform is key to that and we'll fix that problem for the long term. Within Lilly, we've made investments to sort of contain that anyway.

The raising revenue in general is a separate point, and one that we point out that our industry pays a disproportionate amount of income tax, and that actually because of the – in the 2017 Tax Cuts and Jobs Act, there are provisions for a minimum global tax, basically, so that we already pay tax on foreign sourced income. So

that really doesn't change, whether we move it back to the US or not. What that does is it has an effect of raising income tax in these third countries, which it actually has done over the last seven years. So, I think we're well positioned within the mix of companies. I think these issues are complicated and hard to reduce the soundbites. 232 has substance. I think the trend on for the industry, and certainly for [ph] the ability (00:52:52) of re-domesticating is well underway. And, we hope we don't have to get into a tariff discussion, hopefully we pass a tax bill and this can normalize.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Great. Thank you, Dave. Next question please.

Operator: The next question is from Kerry Holford from Berenberg. Kerry, your line is live. Kerry, please check your mute button. Your line is live.

Kerry Holford
Analyst, Joh. Berenberg, Gossler & Co. KG (United Kingdom)

Q

Apologies. Thank you. A question on the cash pay approach here in the US in Zepbound. CVS also announced that its pharmacies would stock the Wegovy cash pay pens. So my question is whether Zepbound cash pay vials are available in the US in any pharmacy chain today. And given your enthusiasm for that opportunity, cash pay in general, I'm interested in whether you're considering additional channels outside your online LillyDirect portal. Would that be an opportunity for you as well within the pharmacy chains in the US? And then a related question. Do you ultimately intend to ever offer the Zepbound pens via the cash pay route, or do you intend to keep that separation? Thank you.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Thanks, Kerry. Related question again, getting close to the line there. But, Patrik, do you want to take the question on the vials, the cash pay distribution, and if we would ever think of other formulations?

Patrik Jonsson
Executive Vice President, President-Lilly Cardiometabolic Health & President-Lilly USA, Eli Lilly & Co.

A

Yeah. I think we're very pleased with the performance in our self-pay segment. And if we look just on Q1, we had revenues above $200 million and 25% of the NBRx for Zepbound are initiated in Q1 through self-pay and 17% of the entire market NBRx in self-pay. And I think we stated from the beginning when we launched LillyDirect that we did this to remove friction for patients and that we would continue to add products, add services and other components. I think you should expect more to come through LillyDirect. I don't have anything to announce today, but I would just emphasize that the price change that we announced earlier this year and the launch of high dose vials has significantly contributed to an even further acceleration of the market growth. So I think we are doing something here to really enable more patients to access both medications at a relatively competitive price.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Okay. Thank you, Patrik. Next question.

Operator: The next question is from Akash Tewari from Jefferies. Akash, your line is live.

Akash Tewari
Analyst, Jefferies LLC

Q

Hey, thanks so much. It seems like your team is really going after this 75% of Americans who are both overweight and obese. Would long term net pricing have to approach insulin levels for that to become reality? Additionally, the street models long term margins going above 50%, while your team has been insistent that that 40% to 45% range is really sustainable. How much of that delta is really us misunderstanding your volume over price approach to GLP-1s long term?

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Thanks, Akash. We'll go to Patrik and then potentially Lucas to talk about both pricing long term and margins.

Patrik Jonsson
Executive Vice President, President-Lilly Cardiometabolic Health & President-Lilly USA, Eli Lilly & Co.

A

Well, I would say, when we look at the overall portfolio, I think we have stated from the beginning that we will continue to take a very disciplined approach here. But also what Dave shared, we probably see an evolution here where you see a delta in between this price and net price for patients. And I think that's pretty much what's guiding us from a portfolio perspective moving forward.

Lucas E. Montarce
Chief Financial Officer & Executive Vice President, Eli Lilly & Co.

A

Yeah. And I already commented from the pricing perspective. I think the price impressions are consistent with the trends that we have seen in the last 12 months, and that's what we are forecasting moving forward. It's a very dynamic situation as well, but we remain disciplined on our approach to provide optionality and have an open access for patients. So...

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Great. Thank you, Lucas. Thank you, Patrik. Next question.

Operator: The next question is from Trung Huynh from UBS. Trung, your line is live.

Trung Huynh
Analyst, UBS Securities LLC

Q

Hi, guys. Thanks for the question. Just on orfor obesity expectations. So in a similar way to outlining your thoughts on the orfor diabetes ACHIEVE data, how are you thinking about the weight loss for orfor in the ATTAIN obesity studies? And, on the tolerability side of things, can you just give us any color on when you had those GI side effects and discontinuations in ACHIEVE. Was it early or later? Just thinking about how tolerability could be from the ATTAIN versus ACHIEVE studies? Thanks.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Thanks, Trung. We'll go to Dan for the orfor questions?

Daniel M. Skovronsky
Executive Vice President, Chief Scientific Officer, President-Lilly Research Laboratories & President-Immunology, Eli Lilly & Co.
A

Yeah. Thanks. These are important questions, particularly the expectations for the obesity study and it probably takes some pain again to remind people that this is a monotherapy GLP-1 agonist, not a dual agonist like Tirzepatide. So we need to expect a weight loss that could be seen with GLP-1 monotherapy which, as we showed in SURMOUNT-5 is quite different than what we get with two actions that Tirzepatide has. So SURMOUNT-5 was a 72-week trial in obesity patients that Lilly ran that included monotherapy GLP-1 injectable in the form of semaglutide up to 2.4 milligrams.

And I think in that study, we achieved about 13.7% weight loss with the GLP-1 monotherapy. This is a similar trial. It's not exactly the same orforglipron, but probably we should expect to be somewhere near that. I think on tolerability, the study also had about a 20 some percent of the patients, maybe 21% of the patients with vomiting, which is probably the most reliable indicator of GI tolerability and the most consistent across trials. So that's our expectations. Again, it's still to match the best available data from an injectable. In this case, I'm focused on the trial that we conducted since we're conducting this trial with orforglipron.

With respect to when did the discontinuations and tolerability events occur in the previous study, I think it was pretty similar to what we've seen in the past with injectables that usually these things happen early in the study when people increase their dose. Actually, some of the difference between the top two doses was probably just a chance because it happened pretty early in the study when actually patients would have been on the same dose level during the escalation scheme. So nothing of concern there. I think if we'd seen a different pattern with events happening late in the study, I think that would be more concerning, but that is not what we saw.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.
A

Great. Thanks, Dan. We're going to try to do a couple more quick ones. So next question please.

Operator: The next question is from Carter Gould from Cantor. Carter, your line is live.

Carter Gould
Analyst, Cantor Fitzgerald & Co.
Q

Hi. Good morning. Thanks for taking the question. I appreciate all the upfront commentary on tariffs. I guess, Dave, given sort of your unique perspective in Lilly's active role in shaping policy, it's somewhat surprising we didn't hear you talk about some of the drug pricing risk. I guess anything you can share there around if you think potential MFN legislation is a priority or possibility in the coming balance of the year? Thank you.

David A. Ricks
Chairman & Chief Executive Officer, Eli Lilly & Co.
A

Yeah. Well, I think it's always a risk for the industry. I think we point out that it's not coherent to have a discussion about that without talking about real net pricing versus real pricing in Europe. And that pulls you into a PBM reform discussion and a 340B discussion. So it's a complicated matter. I think you have to ask what would be the vehicle for such a thing. And there's certainly appetite in both parties to pursue this. Our goal, by the way, long term is, to make sure that we can have a discussion, as I mentioned earlier, a trade with Europe, that would really change how drugs are priced in that continent and developed economies pay more for the R&D costs. That's the real answer here.

But I think right now we're hyper focused as an industry on fixing the IRA problem that was created as to small molecules. I think our enthusiasm for that policy change is high. And that'll be the focus on the bill that's being contemplated now in May to get out of the house. So that's the focus today, and we'll try to manage the risk you're talking about in the background, all the while pointing out that it can't be independently looked at as list price in the US versus Europe. It's a nonsensical idea.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.
A

Thanks, Dave. We'll try to squeeze in one or two more.

Operator: Thank you. The next question is coming from Rajesh Kumar from HSBC. Rajesh, your line is live.

Rajesh Kumar
Analyst, HSBC Bank Plc
Q

Hi there. Thanks for taking my question. Just on access and coverage of Zepbound. Could you update us on how that looks now compared to, say, a year back same time? How many more patients have coverage in the US? And what are the next steps, especially in light of compounders being blocked from selling competing products, which are no longer allowed for Lilly's product at the moment?

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.
A

So we'll go to Patrik for an update on Zepbound access progress?

Patrik Jonsson
Executive Vice President, President-Lilly Cardiometabolic Health & President-Lilly USA, Eli Lilly & Co.
A

Thank you very much. You know, what I think we shared earlier about the formulary access is probably the easiest step. And the more challenging step is going to get employers to opt in. And we have made some significant progress there in 2024. We started the year with approximately 50% of the employers opting in, and by the end of 2024, we were at mid to the high 50s. So, progress there on employer opt in. But also in other segments, in Medicaid, we have actually moved from 11 states being covered by the end of 2024 to 14 states covering now an incremental state Medicaid that have opted in in April, specifically for OSA. And on OSA, we know that the CMS has issued guidance that plans can reimburse for OSA, but they have 180 days since the approval, which took place late December last year. So we expect some progress in Medicaid as well during the second half of this year.

In terms of compounding, I think it's really hard to assess the magnitude of that market. But I think a couple of important cuts here, not all of those patients are necessarily on label. And B, that is also a matter of pricing that we believe that our price point of $349 is actually quite competitive.

And thirdly, in terms of the overall presence in the marketplace where we currently have a strong momentum, we have more than 75% of patients starting anti-obesity treatment starting on Zepbound. So I think we'll continue to execute along those lines across both segments and we see progress being made every week.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.
A

Great. Thanks, Patrik. And then last question please.

Operator: The last question today will be from Kripa Devarakonda from Truist Securities. Kripa, your line is live.

Srikripa Devarakonda
Analyst, Truist Securities, Inc.

Q

Hey, guys, thank you so much for taking my question. I have a question about the Bimagrumab Phase 2 trial, which is expected to be completed by June. Any update on when we might see data? We've heard the potential to see data in June at a conference. Also, can you help set expectations for the data? Thank you so much.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

A

Okay, thanks, Kripa. We'll go to Dan to talk about the Bimagrumab.

Daniel M. Skovronsky
Executive Vice President, Chief Scientific Officer, President-Lilly Research Laboratories & President-Immunology, Eli Lilly & Co.

A

Yeah. Thank you for the question on Bimagrumab. There are actually two Phase 2 trials. The first one that was conducted actually before we acquired the asset was in combination with semaglutide. That'll be the data that will be disclosed first. The ongoing trial is in combination with Tirzepatide. And of course, that's the trial of greater interest to us. And I don't think we've commented on when we might disclose that data. Remember that this is an agent that was designed to see if we could have an effect on – a positive effect on lean mass as well as a decrease in fat mass. And so that's what we're trying to see how that works in combination with these drugs.

Michael Czapar
Senior Vice President-Investor Relations, Eli Lilly & Co.

Thanks, Dave, for closing comments. Okay, great. Thank you all for participating today on earnings call and your interest in the company. Please follow up with the IR team as you have questions, which I'm sure you will after today. Everyone have a great day. Take care.

Operator: Thank you. And ladies and gentlemen, this does conclude our conference for today. This conference will be made available for replay beginning at 1 PM today, running through June 5 at midnight. You may access the replay system at any time by dialing 800-332-6854 and entering the access code 538637. International callers can call 973-528-0005. Again, those numbers are 800-332-6854 and 973-528-0005, with the access code 538637. Thank you for your participation. You may now disconnect your lines.