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OVERVIEW:

Company Summary

REFINITIV

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PRESENTATION

Operator

Good day everyone and welcome to Pfizer's first-quarter 2025 earnings conference call. Today's call is being recorded.

At this time, I would like to turn the call over to Francesca DeMartino, Chief Investor Relations Officer and Senior Vice President. Please go ahead, ma'am.

Francesca DeMartino - *Pfizer Inc - Chief Investor Relations Officer*

Good morning and welcome to Pfizer's earnings call. I'm Francesca DeMartino, Chief Investor Relations Officer. On behalf of the Pfizer team, thank you for joining us. This call is being made available via audio webcast at pfizer.com.

Earlier this morning, we released our results for the first quarter of 2025 via a press release that is available on our website at Pfizer.com. I'm joined today by Dr. Albert Bourla, our Chairman and CEO; and Dave Denton, our CFO. Albert and Dave have some prepared remarks, and we will then open the call for questions. Members of our leadership team will be available for the Q&A session.

Before we get started, I want to remind you that we will be making forward-looking statements and discussing certain non-GAAP financial measures. I encourage you to read the disclaimers in our slide presentation, the press release we issued this morning and the disclosures in our SEC filings, which are all available on the IR website at Pfizer.com.

Forward-looking statements on the call are subject to substantial risks and uncertainties, speak only as of the call's original date, and we undertake no obligation to update or revise any of the statements. With that, I will turn the call over to Albert.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you, Francesca. Good morning, everyone. Thank you for joining our call. We are very pleased with our performance in the first quarter as we continue to execute with focus and discipline on our strategic priorities.

We are strengthening our R&D organization in our efforts to advance our pipeline and productivity, we are maximizing the value of key products in our commercial portfolio, and we are improving operating margins with our continued progress in making our company more efficient.

In the current volatile external environment, the underlying strength of our business and strong relationships with government leaders across the world help us navigate with agility. While we continue to engage and plan for contingencies, we are focusing day to day on what we can do to move our business forward. I want to emphasize our continued confidence that we are well positioned to enhance shareholder value.

Now, I will turn to our top strategic priority in 2025, improving R&D productivity as we advance our pipeline with sharpened focus. We are intensifying our rigorous commercial assessment and portfolio prioritization from early clinical development. This means we will be disciplined in managing our portfolio, directing investment and attention to potential blockbuster or mega-blockbuster, and scrutinizing the total number of assets under development.

Our danuglipron announcement earlier this month demonstrates our commitment to this approach. Discontinuing the development of danuglipron, one of the candidates in our obesity portfolio, although difficult, was the right decision for the company.

Going forward, we are committed to building our cardiometabolic pipeline, including obesity, by advancing internal programs such as our GIPR antagonist and pursuing external opportunities that could include partnerships or acquisitions. We will continue to be disciplined as we move through key decision points for our pipeline or our business development targets.

We believe we have the potential to address significant patient need with differentiated approaches that focus on supporting optimal weight management and related conditions. We will work on potential medicines and combination regimens that could be more accessible, better tolerated, easier to dose and more effective in supporting the right effects on body composition and muscle mass.

In addition to sharpening our focus in internal medicine, since expanding his role in January as our Chief Scientific Officer, Chris Boshoff has moved both thoughtfully and quickly in reshaping our R&D organization to also center on oncology, vaccines, and inflammation immunology in addition to internal medicines.

Chris has enhanced his leadership team with some terrific additions who are recognized as leaders in their field. Patrizia Cavazzoni is our new Chief Medical Officer, Jeff Legos is our new Chief Oncology Officer, and Jim List is our new Chief Internal Medicine Officer. These leaders each bring many years of experience, deep expertise and proven track records in guiding the discovery, development and approval of practice changing therapies and they are an excellent addition to our already strong cast of leaders in R&D.

We are on track for a strong year of anticipated pipeline catalysts in 2025. We are making progress toward anticipated multiple key milestones, including at least four regulatory decisions, up to nine Phase 3 readouts, and a significant series of pivotal program starts. With one of our key oncology programs, we aim to bring forward what could represent the first potential treatment advancement in more than 30 years for patients with BCG-naïve, high-risk non-muscle invasive bladder cancer.

We're encouraged by a positive readout for the pivotal Phase 3 CREST trial of sasanlimab in combination with BCG, a current standard of care. We presented the full data from this study this past weekend at the annual meeting of the American Urological Association.

Non-muscle invasive bladder cancer is a condition predominantly treated by urologists. In multiple market research and focus group studies, urologists stated a significant preference for a subcutaneous PD1 because it can be used in their practices and eliminates the need to refer patients to infusion centers.

We also anticipate meaningful readouts this year for Padcev and Elrexfio. Padcev already is a core therapy in our Oncology portfolio. Padcev plus pembrolizumab is the most prescribed first-line treatment for locally advanced/metastatic urothelial cancer in the US. We are working toward more than doubling the total addressable patient population in the US for Padcev with potentially registrational interim data we expect this year from ongoing pivotal studies in muscle invasive bladder cancer.

We are also working to reach a significantly expanded population of patients with multiple myeloma. We're anticipating a Phase 3 readout this year for Elrexfio in a study for double-class exposed relapsed/refractory multiple myeloma. If successful and approved, this would more than double the addressable population versus the currently approved indication. In addition to the increased addressable population, moving to earlier lines of therapy is expected to increase the duration of treatment and potentially create an inflection point in Elrexfio's growth.

We expect to begin pivotal studies for our investigational PDL1 vedotin ADC later this year for first-line metastatic head and neck squamous cell carcinoma and second-line non-small cell lung cancer. We also anticipate a first-line pivotal study start for SV, sigvotatug vedotin. This is a novel integrin beta 6- targeting vedotin ADC that, if successful and approved, has the opportunity to change the standard of care globally for IB6-expressing tumors.

Both these ADCs, PDL1V and SV are potential first-in-class ADCs using a vedotin payload that elicits immunogenic cell death and in combination with an immune checkpoint inhibitor demonstrates significant results.

Early data for PDL1V and SV in combination with pembrolizumab are highly encouraging. With both ADCs, we are targeting non-small cell lung cancer, the most frequently diagnosed cancer globally and the leading cause of cancer-related deaths. Lung cancer represents a substantial area of patient need and a growing market with the highest projected CAGR in Oncology through 2030.

In vaccines, another of our priority therapeutic areas, we see opportunities to enhance and augment our strong positions in the market. We're also planning a potential registrational study in adults later this year with our fourth-generation PCV candidate.

With our fourth- and fifth-generation PCV candidates, we believe we can build on our leadership in the industry. Our fourth-generation candidate covers 25 serotypes, including potentially improved immunogenicity for serotype 3, which is one of the largest remaining contributors of disease. We are also working to accelerate progress with our fifth-generation candidate, which is in preclinical development and covers over 30 serotypes

As we continue to scrutinize the number of programs we are actively advancing, we'll have opportunities to accelerate or add others to help address significant patient need. One example is the recent accelerated start of a pivotal study of Nurtec for menstrually related migraine, which is estimated to impact more than half of women who experience migraine. We look forward to providing future updates about our pipeline progress as we continue to sharpen our focus on our most meaningful programs in prioritized therapeutic areas.

Commercial excellence in our key categories is another 2025 strategic priority. More than a year ago we decided to separate the US and International operations. Under the leadership of Aamir Malik, our chief US Commercial Officer; and Alexandre de Germay, our Chief International Commercial

Officer, we refined our commercial model to bring heightened focus helping us strategically prioritize our most impactful products and regions. It's working well.

In the US, our team demonstrated focus, the strength of our key products and continuous improvement in execution. In International, we were back to operational growth in the first quarter across all parts of the division. This was the result of prioritization and disciplined focus on key growth drivers to maximize return and accelerate new product penetration there.

Our performance was strong, both in the US and International markets across several key products, including the Vyndaqel family, Nurtec, Padcev and Lorbrena. Our Vyndaqel family of products had robust growth in the quarter, though we are seeing the impact of competition with a new market entrant and we anticipate this will continue through the year.

We will work toward maintaining our market-leading position that has come from six years of establishing credibility and expertise with the cardiology community. Our team remains committed to addressing high unmet patient need by helping to improve diagnosis and ensuring appropriate patients with ATTR-CM receive treatment.

Demand continued to strengthen for Nurtec, with revenue growing 40% operationally in the quarter. Our commercial teams effectively engaged with health care professionals and we were pleased with strong outperformance of our newly launched consumer campaigns. We are pleased with the continued strength also of our Oncology portfolio.

Padcev, for example, grew 25% operationally, driven by increased market share in first-line metastatic urothelial cancer. Lorbrena grew 39% operationally as we continued to see strong adoption with it emerging as a potential first-line standard of care for patients with ALK plus metastatic non-small cell lung cancer.

I&I is another key commercial category for Pfizer and we're drawing on our extensive experience in launching medicines in this therapeutic area. Familiarity among health care professionals continued to improve for Cibinqo, which grew 42% operationally in the quarter.

Our commercial team is continuing to work toward increased patient access for this JAK inhibitor for patients ages 12 and up with moderate-to-severe atopic dermatitis. With Litfulo we're encouraged by the growth we've seen to date.

We'll seek to further unlock access to this advanced systemic treatment for patients with severe alopecia areata. These highlights show how we are positioned to further expand and sustain our performance trajectory among our core brands. And with that, now I'll turn it over to Dave to speak about the other two strategic priorities.

David Denton - *Pfizer Inc - Executive Vice President, Chief Financial Officer*

Thank you, Albert, and good morning. I'll begin this morning by reinforcing the fact that our solid financial results demonstrate our strong executional focus. We continue to concentrate on driving positive patient outcomes and delivering on our financial commitments, while navigating an ever-complex external environment.

Our productivity improvement programs continue to drive a more efficient organization enhanced by our strong operating margin in the quarter. Going forward, we expect to improve our cash flows, reduce our debt leverage and have more flexibility for our three capital allocation pillars. Our focus remains on creating long-term shareholder value. We will continue to invest in our business for the long term while prudently returning capital to our shareholders.

Now, let me start with our first-quarter results, touch on our capital allocation priorities, and then our cost improvement initiatives. I'll finish with a few comments on the macro environment, and our 2025 guidance, which we are reaffirming today.

For the first quarter of 2025, we recorded revenues of $13.7 billion, a decline of 6% operationally. The decline was largely due to lower Paxlovid revenues, in part due to last year's one-time Paxlovid revenue credit recorded in Q1 2024.

In addition, US revenue was tempered by changes in the IRA Medicare Part D design, which took effect in the first quarter. Partially offsetting the decline was growth in several in-line products in the US and overall growth internationally.

On the bottom line, we reported first quarter 2025 diluted EPS of $0.52 a share and Adjusted diluted earnings per share of $0.92, ahead of our expectations due to overall strong gross margin and cost management performance.

Our performance continues to show that our refined commercial approach is working. We continue to focus on key products and geographies, the deployment of our commercial field resources globally, and the continued optimization of our marketing resources into key priority areas.

We saw strong contributions across our product portfolio, primarily driven by the Vyndaqel family, Comirnaty, Padcev, Nurtec and Lorbrena more than offset by declines in Paxlovid, Eliquis, Xeljanz and Ibrance. Adjusted gross margin for the first quarter expanded to approximately 81%, primarily the result of favorability in accrued royalties, partially offset by unfavorable product mix. Focus on cost management across our manufacturing network will remain a priority.

Total Adjusted operating expenses were $5.2 billion for the first quarter of 2025, a 12% decline operationally versus last year.

Looking at the components, Adjusted SI&A expenses decreased 12% operationally, primarily reflecting our ongoing productivity improvements driving a decrease in marketing and promotional spend for various products and lower spending in corporate enabling functions. Adjusted R&D expenses decreased 12% operationally, driven primarily by a decline in spending due to pipeline optimization efforts expected to be reinvested later this year and into next year.

We continue to be disciplined with our operational expense management. Q1 Reported diluted earnings per share were $0.52 and our Adjusted diluted EPS was $0.92 which benefited from our efficient operating structure, in addition to favorable global income tax resolutions in multiple tax jurisdictions spanning multiple tax years as well as a favorable change in the jurisdictional mix of earnings.

With that, now let me quickly touch upon our capital allocation strategy, which is designed to enhance long term shareholder value. Our strategy consists of maintaining and growing our dividend over time; reinvesting in our business at an appropriate level of financial return; and making value enhancing share repurchases.

In Q1, we returned $2.4 billion to shareholders via our quarterly dividend; invested $2.2 billion in internal R&D; and completed business development activity as expected was minimal. We achieved our 3.25 gross leverage target at the end of 2024, a key priority towards improving our capacity for business development.

In addition, the monetization of our Haleon investment has contributed to our improved cash position. As a reminder, in January, we monetized approximately $3.0 billion of our Haleon shares and, in March, we monetized the last tranche of our Haleon shares, receiving approximately $3.3 billion in net cash proceeds. With this sale we have now fully exited our ownership in Haleon. Overall, our objective remains to de-lever our balance sheet over time, which will further support our return to a more balanced allocation of capital between reinvestment and direct return to shareholders.

We continue to be disciplined with our operational expense management, progressing multiple cost improvement programs as we remain focused on driving long-term margin improvement over the coming years. We continue to expect initial savings from Phase 1 of our manufacturing optimization program in the latter part of this year with approximately $1.5 billion in savings from Phase 1 that's expected by the end of 2027. In addition, we are progressing the evaluation of other strategies to improve our network structure and product portfolio, respectively.

As part of our goal to return to pre-pandemic operating margins, we remain on track to deliver on our goal of at least $4.5 billion in cumulative net cost savings from our ongoing cost realignment program by the end of this year. And today, we announced our expectation that this program will deliver an additional $1.2 billion in net savings, primarily in SI&A, in part by leveraging digital tools, including automation and AI, as well as simplification of business processes. The savings are expected to be fully realized by the end of 2027.

Furthermore, we have identified additional opportunities to drive improvements in productivity and operational efficiency in our R&D organization, again, through enhanced digital enablement and automation. We expect approximately $500 million in savings associated with these efforts to be realized by the end of 2026 with the savings re-invested within R&D programs.

Now, in total, we expect approximately $7.7 billion in savings by the end of 2027 to drive operating efficiency, strengthening our business with the potential of contributing significantly to our bottom line over the period.

Now, let me turn to our full year 2025 guidance. As you are aware, the pharmaceutical industry is currently navigating a complex global landscape shaped by rapidly evolving trade and tariff policies. To help navigate this fluid environment, we've established a cross functional team to analyze a range of potential outcomes while developing strategies to help mitigate the potential impact to our business in both the short and long term.

These actions include the management of current inventory levels in certain jurisdictions, leveraging our domestic manufacturing footprint, and the potential production of certain API and products in the US. Should we be impacted by further tariffs in the future, we will assess the impact of the policies enacted and provide information at the appropriate time.

Let me now spend a few minutes on our 2025 guidance which remains unchanged, and to be clear, does not include the potential impact of future changes in trade and tariff policies. We expect total company full-year 2025 revenues to be in the range of $61.0 to $64.0 billion, and full-year 2025 Adjusted diluted earnings per share to be in the range of $2.80 to $3.00, which reflects our expectation of strong contributions across our product portfolio and focus on disciplined cost management.

As we finish Q1 with earnings strength, and excluding the potential impact related to future tariffs and trade policy changes, we are currently trending toward the upper end of our Adjusted diluted earnings per share guidance

In closing, let me emphasize several key aspects of our business. We will continue our focus and execution to maximize the commercial value of our product portfolio, and we remain committed to driving value-creating innovation while strengthening our pipeline.

Additionally, our cost improvement programs are set to deliver operating margin expansion. Expected productivity gains will be driven by leveraging our digital capabilities and simplifying our business processes.

Our improved balance sheets set the stage for more balanced and enhanced capital deployment, focused on creating value for our shareholders. And with that, I will now turn it back over to Albert for Q&A.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you, Dave. Operator, please assemble the Q&A. Let's start the Q&A.

QUESTIONS AND ANSWERS

Operator

Vamil Divan, Guggenheim.

Vamil Divan - *Guggenheim Securities LLC - Analyst*

Great. Thanks so much for taking the questions. Maybe two if I could. So one, just, appreciate your prepared remarks. Mentioned the dividend. Your commitment to maintaining and growing the dividend over time. But I think we've just gotten sort of increasing questions about this from

investors over the last few months, especially with some of the tariff uncertainty and how that might impact cash flows. And obviously, you're now talking about maybe getting more active on the business development side.

So maybe just to reinforce that if even one more time and nothing else just like the level of commitment you have there. And even if there's an impact from the tariff side, you still feel comfortable in being able to maintain and growth. And then my second question is --

Okay, yes, I just had one other, if I could. Just on the COVID business and just your views obviously understand the nuances around the Paxlovid sales this quarter. And obviously vaccine sales will come late in the year. But do you still see that business being relatively stable this year relative to last year, or has that changed from what your expectation for at the beginning of the year? Thank you.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Dave will tell you about dividend and then Amir and Alexandre about the comp.

David Denton - *Pfizer Inc - Executive Vice President, Chief Financial Officer*

Yeah, Vamil, clearly consistent with my prepared remarks, the dividend remains a critical component and a key component of our capital allocation strategy. As you can tell, we've been very focused on improving the operating margin and performance of our business, thus improving our cash flow yield over time. This is all in support of all of our capital allocation priorities with dividend being a key component of that.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you, Dave. And let's start with Amir.

Aamir Malik - *Pfizer Inc - Executive Vice President, Chief US Commercial Officer*

Thanks, Vamil. So you asked about Paxlovid. Paxlovid utilization trends very closely to infection rates, and we see a 50% treatment rate and close to an 80% fulfillment rate when there's infection. And we've set up a very good commercial model to do that.

I think what you saw in Q1 was largely the function of the fact that we have a lower winter wave, but we still treated over 750,000 patients starting the year with about 100,000 a week and tapering off at around 35,000 to 40,000.

And while these numbers are lower than the consensus numbers, they're very much in line with our expectations and what we track for the business. And what we've seen in multiple years now is that over the course of the year, you have two COVID waves, one in the summer and one in the winter. The peaks and valleys and the timing of those vary, but we have had consistently multiple waves.

And our baseline assumption is that we will have those waves this year as well, and that we will be able to execute our business, including Pax utilization in the way that I described, consistent with those waves.

We've also set up a model where we can successfully transition the Medicare patients out of USG and into our traditional Medicare model beginning March 1 of this year. And so we can't predict exactly what the timing and shape of those waves will be, but we're ready to execute again.

Alexandre De Germay - *Pfizer Inc - Executive Vice President, Chief International Commercial Officer*

Yeah, international, I will start with Comirnaty. As you know international Comirnaty is bigger than Paxlovid. Now on Comirnaty, we beat consensus quite nicely by $130 million, essentially driven by execution. As you know, in international, December is in the Q1 of 2025. So in December, we

continue to execute our contracts in the UK and in Europe. And in competitive setup like in Japan, we maintain very strong leadership there until the end of the vaccination.

Now, as we move into Q2 and Q3, we will start actually shipping our vaccine into Southern Hemisphere countries where vaccination campaign is going to start, and in particular, in Brazil, where we won the two-year contract adult, which is a very important vaccination country.

Now, when we talk about look Paxlovid, you know Paxlovid is smaller internationally. And we performed as we were expected. We have now Paxlovid commercially sold in 49 markets. So there is no more advanced purchasing phenomenon. So it's really associated with utilization.

The point is, in international, we have actually low utilization compared to the US. We still need to do some work in terms of utilization and treatment.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you, Alexandre. Operator, please, the next question.

Operator

Evan Seigerman, BMO Capital Markets.

Evan Seigerman - *BMO Capital Markets - Analyst*

Hi guys, thank you so much for taking my question. And I don't want to touch on the reasons for the danu discontinuation. But I more want to look forward, as you think about a potential obesity asset, what are some key aspects of the profile that you're looking for, either from an internal perspective or potentially externally? Thank you so much.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Let's start with Chris and then go to Andrew.

Chris Boshoff - *Pfizer Inc - Chief Scientific Officer and President, Research & Development*

Thanks very much. Thanks for the question. Yeah, as Albert has stated, danuglipron was the right decision for Pfizer based on totality of data. And as we said previously, a single asymptomatic participant in a dose optimization study with rapid dose titration experience a potential drug-induced liver injury, which recovered rapidly after treatment discontinuation.

Although we're not 100% sure this is due to danuglipron, the risk was high enough for us to discontinue the program while still being committed to obesity and employing our global resources for other opportunities. Cardiovascular metabolic is one of our core strategies within internal medicine, an area with significant remaining unmet need. And just a reminder, for obesity alone up to 60% of patients discontinued current approved medicines after 24 months.

We will continue to apply our global capabilities to advance our pipeline of differentiated oral medicines, including our oral GIPR antagonist currently in Phase 2 and advancing our preclinical portfolio to the clinic. We believe the future will be more fragmented based on differentiated or unique combinations with an emphasis on tolerability, accessibility, and convenience. The future will also become more personalized based on combinations addressing specific diseases associated with obesity and with metabolic dysfunction, including neurology, cardiovascular, and respiratory.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

And Andrew.

Andrew Baum - *Pfizer Inc - Chief Strategy and Innovation Officer, Executive Vice President*

Yeah. I mean, I think Chris gave you a very full answer. I would just underline that although you referenced obesity, the role of incretins and potentially other modalities or targets more broadly needs not to be underestimated. And obviously, this extends beyond cardiovascular medicine. And we are interested in all the potential opportunities that exist with these molecules.

In terms of which assets or which portfolio of assets we're seeking to build I think there's two axes. Number one, obviously, is clinical differentiation. And Albert referenced some of the ways you can do that in terms of scheduling, tolerability, muscle preservation, but there are others too.

But then separately, there's commercial differentiation, which really references the indications that we pursue. So I hope that gives you some idea of our direction of travel. And when we have something to say, you'll be the first to know.

Evan Seigerman - *BMO Capital Markets - Analyst*

Good to know.

Operator

Tim Anderson, Bank of America.

Tim Anderson - *BofA Global Research - Analyst*

Thank you. I have a question on tariffs. I figured, if anyone is close to this, it's probably Pfizer, Albert, seeing as you're Chairman of PhRMA. If sector-specific tariffs come through, do you think that's likely to be through the 232 investigation route? Or do you think it could still happen somehow through the IEPA route. To me, it seems like it would be 232, but not everyone agrees. And your best sense of timing for when everyone might have more information from the Administration.

And then last question, is it an absolute pipe dream to think that sector-specific tariffs might really only be applied to countries that could, in fact, pose a threat to national security like China. It's hard to see Ireland being an enemy of the country.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you, Tim, and I would agree with the last comment that you made also. But let me tell you where we stand with tariffs. First of all, we had on April 2, an executive order, but basically placed tariffs across the board to everything we can see or feel or dream, except two things, pharmaceuticals and semiconductor.

Clearly, there is risk going forward, but it's a very, very different ballgame. If you are part of the tariffs and you hope to be excluded, then if you are not part and you try not to be included. Then on April 14, the Administration made even more clear what is their concern with the pharmaceutical sectoral investigation.

And they made it clear by launching it through a 232, which, as you pointed out, it is an investigation that is connected with national security threats. This is not something new. The first Trump administration had expressed serious concerns about several essential medicines that they are made outside the US. The Biden continued with these concerns. Actually, the Trump administration had also a list created with those medicines

in the first one. And now with the second Trump administration, not only through the 232, but through my discussions with the highest level of the government, they are confirming that this is their primary concern. And I think it's legitimate. I think no country wants to have critical medicines produced outside of the country, particularly, they don't want to have critical medicines produced in countries that tensions are high or can be escalated.

So there is, I think, a very clear distinction in the way that they look at it in terms of what products they are talking about. And there is a very clear distinction as to what comes from friendly countries or what comes from adversary countries.

So with all of that in mind and knowing that we are engaging and we have very productive discussions with all the Secretaries that are involved and the White House staff that are involved into that, I'm cautiously optimistic, as I said, given the data that we have not been there. And I hope that we will weather it successfully.

We will work with the Administration to make sure that their concern on national security will be addressed with the best possible way. I think that was the only question, right? So, let's go to the next question, please.

Operator

Steve Scala, TD Cowen.

Steve Scala - *TD Cowen - Analyst*

And two questions. The first one is very similar to the one that Tim just asked. And that is, Albert, given your unique insights into the thinking in Washington do you think MFN legislation is only the most remote of possibilities or even simply not going to happen?

And then secondly, what is the percent utilization of the US plants? It's great to have this vast network in the US, but if there's little or no excess capacity or flexibility, then it's a more limited advantage?

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you very much for both questions. Look, on the MFN, first of all, I can't speak about what would be the intentions of the government, but I can comment on what I have seen so far. And the president issued an executive order that was focusing on pharmaceuticals. That was very, very extensive. So cover a lot of topics over that.

MFN was not mentioned over there. On the contrary, what was mentioned over there was the pill penalty, but he instructed so that we will find ways to resolve. What was mentioned over there was PBM reform and transferring of rebates to the patient. What was mentioning over there was 340B reform.

So I would say that -- clearly, one can say that when the President issued an executive order, then you can read into what are the priorities of the Administration. And I think that so far, the way I have seen it, it is the pill penalty, it is the 340B, it is the PBM reform, and it is to lower the cost for the patients because right now in the US, the patients they are paying disproportionately out of pocket for their medicines compared to other medical interventions. So that's my two cents on that.

And again, I'm cautiously optimistic, but nothing is certain. And we are working continuously to influence the thinking and the decision making, in particular understanding what is it that they want to achieve so that we can provide productive solutions.

On the percentage of utilization of our manufacturing sites, first of all, it is quite good. I don't want to go to the details, but there is ample room if there is a need to transfer production to accommodate. We have huge manufacturing capacity right now in the US, particularly for everything that

is injectable. And the -- our ability, if there is any, is clearly there. And without the need to build new facilities, just utilize the current ones and transfer production there.

Operator

Umer Raffat, Evercore ISI.

Umer Raffat - *Evercore ISI - Analyst*

I have two here, if I may. First is on dividend and second is a follow-up to something Albert mentioned. Perhaps first on dividend. I know there's obviously LOEs coming up over the next three to four years with net income and free cash flow pressures. How much of that pressure could be offset by potential OpEx cuts that you're taking underway? I guess said differently, can you hold net income at or near the current levels? That's part one of the question.

And then also, if a tariff impact approaching, I don't know, 15% to 20% of bottom-line kicks in, can you still confirm your commitment to dividend? And finally, Albert, you mentioned the distinction between friendly versus unfriendly countries, but in the initial tariff announcement, that didn't necessarily seem to hold true, so why should that apply in the case of pharma?

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Dave, why don't you take the dividend question?

David Denton - *Pfizer Inc - Executive Vice President, Chief Financial Officer*

Yes. So Umer, clearly, in my prepared remarks and what we said very consistently is our objective is to improve our operating margin performance over time. And we've said that knowing quite well that we have LOEs approaching. Some of the improvements in productivity that we are making are in design to improve operating margin in the face of those LOEs.

At the same time, our business is actually evolving such that particularly in the oncology space, where we're leaning into that business, and those products actually yield a very high gross margin and operating margin performance. So the short answer is yes, we can withstand that. And secondly, we're very focused on improving our operating margin over time in the face of those LOEs.

Clearly, you've also heard us reiterate very specifically our focus on maintaining and growing our dividend over time, and we would continue to do that. And we work hard to understand the environment looking forward. And I don't want to hypothesize on what could happen, but clearly, we're watching the situation closely and our commitment to dividend is steadfast.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

And I think, David, you made also very clear quantitative calculations of what we expect. And when we put a number out there, we know that we can hit it. And David spoke about $7 billion by year 2027, while maintaining the R&D at the current levels of investment, which I think it is a key strategy to offset, first of all, to navigate an uncertain environment, that's the best way to do it is to be productive.

Another comment I want to make on that is that the cuts are not across the Board or they are not by just reducing resources that are valuable. They are very strategic. And they are happening, first of all, with the deployment of technology.

AI right now has a dramatic impact in the ways that we have able to secure cost reductions and digital technology in general, but also through significant business simplification that we are implementing. And we looked at every single thing of how we do things. And when you find simpler

things of doing it, there is a significant cost element associated. So all in all, I think, as Dave said, we have our targets, and we are very confident. You can calculate it. We made them public, and we are very confident that we will achieve them by the year 2027.

Now as regards the tariffs if that would be on friendly or non-friendly countries, look, it's up to the government to decide what they're going to do. But it's very, very clear in my discussions. But national security concerns -- is very clear for my discussion at least, national security concerns are pretty much associated not with friendly countries.

Operator

Chris Schott, JPMorgan.

Chris Schott - *JPMorgan - Analyst*

Just my first question on guidance. Pfizer's gross margins for this year, are we -- should we still think about full year gross margins in the mid-70s range? Or has that changed following some of the upside with 1Q?

And maybe just a second part of that, I'm just interested in the level of conservatism that's baked into the guidance here. It seems like the year is off to a very strong start, particularly on the cost side. And just as we think about the progression in the rest of the year, should we think about any offsets from the upside we saw this quarter?

David Denton - *Pfizer Inc - Executive Vice President, Chief Financial Officer*

Yeah. Thanks, Chris. Dave here. Clearly, we are very confident in our outlook for 2025. As you noted, we entered -- we finished Q1 in a position of strength, both from a top line and a bottom-line perspective. As I look at our operating plan, we've exceeded both top line and bottom line in Q1 based on our expectations internally. So we're off to a very solid start.

Secondly, as I look forward, we're -- in Q1, we have three quarters left to go. I look at us maintaining our guidance range. But giving you some color that our top of it, we're essentially derisking the balance of the year from a financial delivery perspective.

We're still faced with some uncertainty from a macro environment perspective, so we're watching that cautiously. At the same time, we're prepared to go into the vaccination season in a position of strength, but really with still some uncertainty around how the macro environment might play out in that space as well. So I hope that helps.

I think from a gross margin perspective, off to a nice start. We haven't changed our guidance and our color on that. But we're continuing to focus on improving our gross margin over time and improving our operating margin over time, which I think is even a more critical component for us. And if you look -- in Q1, we posted a little over 40% from an operating margin perspective with really solid performance. So again, off to a really solid start.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you. So you don't have any conservatives in your guidance. He is the best.

Operator

Geoff Meacham, Citi.

Geoff Meacham - *Citi - Analyst*

I had two quick ones. Albert and Andrew, just from a strategy perspective, what would you say ranks as a higher priority just with respect to how you tier what would be multiple BD actions? Is it the TAM? Is it sales through LOE? Is it peak sales after? I wasn't sure how much that's evolved in the current macro backdrop?

And then I guess a question for Albert, what incentives would you want to see in tariff negotiations that would maybe tip the balance for Pfizer to increase manufacturing investments here in the US?

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Yes. On the strategy, maybe I make some comments and then I ask also, Andrew. It is very clear that we are facing -- everybody knows LOEs. Those LOEs are starting in '26, '27, '28, '26 is a smaller number, '27 is a bigger number, '28 is the biggest number, then goes down.

LOEs are one-time events, right? So to prepare for that, we had a significant number of new launches that they are growing. And we did significant business development, but it is growing because they were all early assets, what we bought. So they were, let's say, having in front of them the growth period.

So what we project, it is that those growing assets will offset the LOEs in '26, '27, '28, more or less. And then following that because, of course, LOEs are a one-time event, they continue growing. And then we have a significant step up in the growth when the last LOE is going out.

Now what is our strategy in addition to having business development and new product launches. As we know that with the LOEs we are not going to be a strong top line growth story for the next three years, given the LOEs, we expect to become a EPS growth story. And this is why you see here right now the very acute focus on our improvement of margins. Also, we expect even more importantly, that will be a pipeline story during the next three years.

We are very focused in the R&D productivity. We are -- we have learned from past mistakes in the R&D productivity. We are moving with very decisive steps to bring new Phase 3 studies. And I think once the studies start, also people will start modeling in their models or upgrading the probabilities of success as we are moving to Phase 3 studies to reflect what I just told you that as the pipeline matures, the growth post should look among the top tier of the industry. So that's more or less a strategy.

Now, within that, we have $10 billion to $15 billion of capital to allocate that we are very prudent in how to do it, and Andrew will speak about it. But in the bottom line, it is that we would like to see in the first three years, a multiple expansion given the maturation of our pipeline. And of course, an EPS growth given our strong focus on the costs. And Andrew -- and the BD will be a bonus to all of that. What do you think?

Andrew Baum - *Pfizer Inc - Chief Strategy and Innovation Officer, Executive Vice President*

So just on -- I think Albert gave you a very clear answer. In answer, just picking up on the a specific question that you asked, I think it's all of the above, TAM, LOE as well as obviously as value.

I think the other thing I would also add that perhaps you didn't mention is I'm very keen that we build sustainable franchises. And I'm thinking more of the longer term and the shorter term, but we need to have breadth and durability just as we've done internally with expanding and building on Ibrance franchise with our novel CDK4, CDK2s, and we have other assets as well within breast cancer and some with ADCETRIS. BD is another tool within our arsenal to build on the internal discovery and development that we have with our existing pipeline.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

On the tariff negotiations that you said, what would you expect to see so that you will invest in the US? I think it's certain. If I know that there will not be tariffs and the heavy certainty, then there are tremendous investments that can happen in this country, both in R&D and manufacturing.

And the reason is that the tax environment that has forced a lot of manufacturing outside the US has significantly changed now. We have a global minimum tax around 15% that has been established right now. So it's not as good in the US. Although when President Trump did the first tax, we had a huge inflection of capital coming back from Pfizer and others.

And now I'm sure and I know because I talked to him, but he would like to see even a reduction in the current tax regime particularly for locally produced goods. So that would be a huge incentive to also bring manufacturing here, right?

And it's not that bad, but that requires a lot of capital. And in periods of uncertainty, everybody is controlling their cost as we are doing. And then it's very frugal with their investments as we are doing so that we are prepared for any day. So that's what I want to see.

Operator

Trung Huynh, UBS.

Trung Huynh - *UBS Equities - Analyst*

Just another one on costs and guidance and one on BD. So on your cost realignment program, you announced an additional $1.2 billion saving by $27 million. How much of that can come out in '25? And how should we think about the step-up of costs for the rest of the year following what seems to be you guys exceeding savings targets, but also reiterating a guide?

And then on BD, you've mentioned external opportunities. How much is the macro environment impacting your decision in the timing of BD given the volatility and unknowns? And then on the other side of the table, do you think sellers are hesitating given valuations are meaningfully lower than the start of the year?

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Dave, why don't you take the guidance and then Andrew, you can speak to BD a little bit. And I will also comment

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David Denton - *Pfizer Inc - Executive Vice President, Chief Financial Officer*

On the cost side, keep in mind that we're focused on taking $4.5 billion out by the end of this year, well on track with that. The additional $1.2 billion that we've identified, probably modest delivery of that in 2025, most of that in '26 and '27, but maybe a little bit.

I think from an R&D perspective, the $500 million that we're saving in improving productivity and R&D, largely that will happen this year to be reinvested in R&D late this year or maybe even bleed into next year to some degree.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you. And on BD, Andrew, valuations are low, uncertain though is high, so how you see things?

Andrew Baum - *Pfizer Inc - Chief Strategy and Innovation Officer, Executive Vice President*

Yeah. I mean I think as you might imagine, we're very awake to the external environment, but we're comfortable with the $10 billion to $15 billion budget that Dave effectively forecast or gave at the beginning of this year.

In terms of the question of have sellers Adjusted to the new valuation the market is applying, I think it depends. I think generally, it takes some time in some categories where there is increasing therapeutic density because there's an ever-expanding array of assets mainly coming from China. I think there's an additional force, which is causing companies to become more amenable to lower valuations. But I think it really depends.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

And Trung, what I tell my team constantly is never let a good crisis go to waste. And with crisis, there are risks, but also there are tremendous opportunities because things are changing, the status quo change. So you need to be strategic. You need to be smart. You need to be disciplined. But you need as Warren Buffet said, sell when prices are high and buy when prices are low. And prices are low.

Operator

Kerry Holford, Berenberg.

Kerry Holford - *Berenberg - Analyst*

Firstly, in the context of US tariffs and the debate there, I wonder if you might tell us what proportion of your US drug sales are currently made end to end in the US. Can you give some examples of brands that delivered end-to-end in the US today?

And then a question for David on COGS. Can you just quantify the US dollar impact of that revision of estimated accrued lots in Q1? Can you tell us what that specifically relates to and just to confirm that's intended to be a one-off adjustment?

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you, Kerry. Look, around which percentage of production we have here, et cetera, we are not disclosing this information. So we won't go into those details. When it comes to the impact of the US dollar, I will ask Dave to comment.

Dave also you speak about the impact of IRA so that people can get a good picture of the puts and takes of the first quarter sales.

David Denton - *Pfizer Inc - Executive Vice President, Chief Financial Officer*

Yeah, sure. So maybe let's take this in points here. First, I know there's been a lot of volatility in FX, in currency fluctuations. We're probably an outlier in the sense that we gave guidance in December. So if you look point-to-point from December to now, FX is largely immaterial to us given the fact there's been a lot -- there's been a roller coaster ride to get from point A to point B. But right now, FX is largely not an impact to Q1 and for the balance of the year.

Secondly, if you look at Medicare Part D redesigned, in Q1, it dampened our US revenues by approximately $650 million as we expected. That dampening will lessen in the back half of the year as we continue to offset that a bit with incremental prescriptions.

Third, included in our guidance that we didn't really speak about is there are some tariffs in place today, we anticipate those tariffs to be approximately $150 million for 2025. We are contemplating that within our guidance range, and we continue to again, trend to the top end of our guidance range even with those costs to be incurred this year.

Operator

Akash Tewari, Jefferies.

Akash Tewari - *Jefferies - Analyst*

I realize there's a lot of uncertainty on tariffs, but hearing Merck give color on Q1, it seems like some of your peers are hinting the bottom line impact of tariffs could be manageable. So let's say the tariffs are broadly 25% on your transfer price, which I'm sure is a scenario your teams planned for. Would it be fair to say that the bottom-line earnings impact would be a single-digit percent basis with reasonable mitigation steps.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you, Akash. I will never go to that statement, and we have made statements in the past we have been burned. So I'm very cautious and careful about that. If there are tariffs, we have detailed contingency plans that they are minimizing the impact, but I'm right now focusing more on the fact that we should not have tariffs. And only if we have, we should try to implement measures. I'm sure all companies are doing the same. Sorry, I can be more specific. I know you're interested on that.

Operator

Terence Flynn, Morgan Stanley.

Terence Flynn - *Morgan Stanley - Analyst*

Great. Maybe two for me. Another one on tariffs. I know Scott Gottlieb is on your Board referenced a Grand Bargain on the news a couple of weeks ago. And you've given a lot of color here, Albert, in terms of your discussions with the Administration. So can you confirm if something along those lines is in the works?

And the second question is on the pipeline that you guys and your partner Arvinas recently reported some Phase 3 data for Vepdeg from the VERITAC-2 study. Just wondering how that data change or impact your strategy for this drug in the frontline setting.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you very much. Unfortunately, I'm not aware of Scott's comments on the Grand Bargain. Of course, I follow him on TV, but also more importantly, I speak with him very regular, very often. And he advised me in several topics. But I don't know his comments on Grand bargain.

And clearly, right now, there are two things in the horizon. One, it is an executive -- one, it is 232 process on tariffs or pharmaceuticals that have been excluded from overall tariffs, geographical profile tariffs. And that's on national security.

There is also an executive order of the president that is focusing on 340B, reducing the cost of patients, PBM reform, removing the pill penalty. Those are the things that we are engaged right now, not in any other type of markets. And then on Arvinas, I will ask Chris, to comment on that.

Chris Boshoff - *Pfizer Inc - Chief Scientific Officer and President, Research & Development*

Thank you for the question. As you know, in the Phase 3 topline results, VERITAC-2 was reported in March and the last two months. We met the primary endpoint in the estrogen receptor 1 mutant population which was statistically significant and clinically meaningful for progression-free

survival. Overall survival still too early, very immature, but we did not reach statistical significance and improvement in PFS and they intend to treat overall population.

We plan to present detailed results at ASCO. It's a late-breaking oral presentation. And we'll also start sharing the data with global regulatory authorities to potentially support regulatory filings. We are continuing the combinations with CDK4 atirmociclib, which we're excited about as well as with CAT6 on this project with vepdegestrant -- the combinations with vepdegestrant and shall then work with Arvinas to not just only file but work with Arvinas to discuss future plans for the Phase 3 program.

Operator

Dave Risinger, Leerink.

Dave Risinger - *Leerink Partners - Analyst*

Thanks very much, and thank you for all the updates. So I have two questions, Albert. First, current Washington leadership is very supportive of the traditional technology sector, but it's taking the opposite approach towards biotechnology. So not withstanding a few of the things that you mentioned that might be marginally positive, such as the pill penalty.

Washington is actively degrading proven medical science, collapsing the NIH, and driving reduced investments in the biotechnology sector in the United States. Could you please comment on that? And how you and other biopharma companies are responding when you engage with Washington?

And then separately, with respect to the 232 investigation, since we can't see what's going on outside, could you just explain exactly how that investigation is progressing? How Pfizer is engaging on the 232 investigation front? And what we should watch? And when should we see news on 232?

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Look, we are clearly concerned about several of the statements that we have seen and approaches regarding FDA and some statements that they are not in correlation with what science has proven over the decades and what the vast majority of the scientific community. When I say vast, I'm talking 99.9% are behind. And sometimes they use this 0.1% as a point to challenge the remaining.

So I think there is scientific truth. And that scientific truth, it is well presented. And this is not only a US thing, it's not only the CDC and the FDA and the NIH, but it is the UK health authorities, and it is the French health authorities, and the Spanish health authorities, and Korean health authorities, and the Japanese, and Israel. And I can go on and on. So this thing of a conspiracy theory, but someone -- it's not that the whole world and the whole authorities of the world want to implement wrong side.

So I am very convinced that we are in the right side of history, and those people are in the wrong. But I want to tell you that the -- those views are not expressed by the entire Administration. And there are many people that they don't share those views. And I would say that we had also a president that -- he spearheaded the Warp Speed Operation. And he created this miracle that saved --

I mean, there was no other country that had done something like that in the world. And the entire world was able to save their economies and survive based on what Operation Warp Speed did, the President and members of his Cabinet at the time on (inaudible) and Jared and all of them, they work with us to do.

Actually, I told him that he should have received the Nobel Prize for that, and that was unfair that he didn't. It was serious contribution. But the thing that I discussed with everyone in the Administration and I think that resonates a lot with Democrats and with Republicans, with everybody in the Administration, including HHS and everywhere. It is that Chinese right now are progressing with the speed of light in their science.

Biotech, it is dominant. The US has the dominant scientific position in biotech because we have created this ecosystem of biotech and pharma and academia and all of that. This is exactly what the Chinese have replicated in the last four years. And in the last four years, IRA was a significant setback for us that took down a lot of funding of the private sector towards biotech.

So the biotech is now currently, also because of tariffs but also because of the four previous years, they are at historical low. And as a result, there is very little money going to the biotech. That China is doing the opposite. And right now, they are having very, very good science.

And I think that's something that they should -- everybody be concerned. And they should be concerned not only from commercial but also from national security point of view. Imagine if in the next pandemic, the medicines that will help, will not be invented in this country, but in another country. That will be a problem.

Now the 232 investigation, it is an investigation, but it basically is launching. And then the Secretary of Commerce is running it and is gathering information to see if there is any national security risk with the way that medicines are available in the US, the supply chain of the medicines.

The process has been launched. They have requested information publicly. And companies will submit information, the PhRMA association will submit information. Everybody who has an interest on that will submit information and probably proposals. And those things will be assembled.

Although the time -- this process is time limited, which I think it is 270 days, I don't recall well, but it is -- I think they need to complete it with 270 days, knowing how fast this Administration works. I think they will do the work faster.

Operator

Mohit Bansal, Wells Fargo.

Mohit Bansal - *Wells Fargo Securities, LLC - Analyst*

And I'll have one more for you. So pharmaceutical manufacturing is a little bit more complex. There are layers of API, manufacturing of drug substances as well as fill finish. And to my understanding, a fill finish majority of part is already in the US, but I would love to understand from your conversations, is there a specific focus of the Administration to bring the API part of it or the drug substance manufacturing part of it to the US? And how feasible it is to bring API or move into some friendly countries if not Americas? Would love to get your perspective on that.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Yes. I think for things that they are considering national security, they are looking the entire value chain. So they want to see the precursors, the APIs, and where the products are made. And they are making very clear distinction, I think, on where those products are made so that they can assess the risk.

Transferring manufacturing, even under the most lucrative investments available and even under the most favorable regulatory framework to provide approvals, et cetera, it's a multi multiyear process. So it's not something that can be resolved within a year.

So I believe they will focus on a manageable number of products, which are the most important so that they can have that built and secure the national security. But I think the question right now is on everything, on API, on precursors on where the products are made, et cetera.

Operator

Courtney Breen, Bernstein.

Courtney Breen - *Bernstein - Analyst*

A couple that we had, one clarification on tariffs. And apologies if we missed it. But this was just kind of if you can provide any comments on inventory and kind of work that you're doing already to bring inventory into the US.

And then the second question is just on the pipeline. I know kind of you can ask some details about the things that you're looking to prioritize. But can we expect an R&D Day through -- at some point this year that will help us better understand the overall pipeline strategy and help us understand that reallocation and perhaps even better assess and evaluate that pipeline in our sell-side models?

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you, Courtney. I will ask Chris to comment on the pipeline. But on the tariffs, as David also said, I think, in the beginning, you can imagine, we have done everything that we have to do to make sure that we mitigate. So that includes inventories, of course, and many other things that we have built into the country so that we can weather any scenario that is needed. And every month, also, we're increasing those position, so to make sure that as I said in rainy days, we are well positioned. Chris, on pipeline.

Chris Boshoff - *Pfizer Inc - Chief Scientific Officer and President, Research & Development*

So thank you for the question. Just to -- a reminder, we've got a number of products that we're currently excited about that will read out later this year, for instance, Padcev's muscle invasive if that's positive, it will triple the population. Elrexfio, Albert mentioned double-class exposed will double the population. Sansanlimab, obviously read out just now. Potentially up to 38,000 patients eligible in the US.

And in a number of Phase 3 programs, we're accelerating or that already started or will start later this year. on the next six to nine months, including for oncology, the two ADCs Albert mentioned sigvotatug vedotin, PDL1V.

Atirmociclib, continuing Phase 1 -- Phase 3 in first-line ER-positive breast cancer and vaccines, PCV fourth generation, but also potentially starting first and only-to-market opportunity with the C. difficile vaccine and for internal medicine ponsegromab, which again, discovered in-house, potential brand-new opportunity. This is opening a new field in cancer cachexia.

In terms of an R&D Day, we're not planning it, but as you know, we currently have the Pflashes which is organized by our IR team. The next one coming up will be on breast cancer, and we will continue throughout the year these Pflash events.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

And in general, our intention is to provide as much visibility on our data as possible without undermining publications, of course. So I think the Pflashes are making very good job right now. And we can intensify also how we do that so that we have smaller bites of information that are referring to a specific product and after a month, another product, and after a month, another product rather than shower everyone with a lot of data and information in one day. But we will find the best way and we are listening right now.

We are listening to all the analysts that they are giving us ideas on that. We are listening to all our investors. They are giving us ideas on how best to communicate our pipeline.

Operator

Asad Haider, Goldman Sachs.

Asad Haider - *Goldman Sachs - Analyst*

Thanks for all the color on the macro and tariff side. I'll ask a couple of product-specific questions. First, on Vyndaqel, can you just double-click on how competitive dynamics are playing out in that market relative to your own expectations?

Second, on the internal oral GIPR agonist, can you remind us of the timelines on when we'll start to see more data? And then third, on these nine Phase 3 readouts that you're highlighting other than Elrexfio, which you've highlighted in the past, where do you see the biggest disconnect in analyst models relative to your own internal expectations?

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Aamir, you talk about Vyndaqel. Chris, maybe you explain on GIPR. And Andrew, you can speak about where the biggest differences are.

Aamir Malik - *Pfizer Inc - Executive Vice President, Chief US Commercial Officer*

Thanks for the question. On Vynda in the US, I think we are off to a very good start in the new year. We've grown revenue and that is a combination of multiple things, including the fact that diagnosis rates are improving. We've improved access, and therefore, have had strong new patient starts, certainly versus last year, more than 70% and versus Q4, almost 20% new patient start growth and continued compliance with our existing base of patients.

And all of that has driven very, very strong volume growth year over year and sequentially. And we are managing that revenue growth despite the offset of the impact of IRA Part D redesign that Dave spoke to.

Now we're obviously seeing impact of competition, principally ATTRUBY and -- principally on newly diagnosed patients. We'll continue to stay close and monitor that. how that evolves and how AMVUTTRA settles into the market as well. But the year is off to a good start. Our team is executing well, and we have confidence we will grow for the balance of the year.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Alexandre, can you comment also on Vyndaqel in the international market that is growing very healthy over there?

Alexandre De Germay - *Pfizer Inc - Executive Vice President, Chief International Commercial Officer*

Yeah, absolutely. So we had also a good growth of 36% this quarter above expectations from the analysts. What's driving that is essentially a significant increase in our treated population. We have actually reached a 52% growth in patient treated on Vynda in Q1 versus Q1 last year. So a very healthy trends.

And we see that this trend will continue for essentially three reasons. One, because our diagnosis rate has potential to expand in pretty much all our key markets outside of the US. Two, because of profile, our clinical profile is differentiated and will support our standard of care status we be living in key market, And three, which is open underestimated, we, after three years of hard work have finally reached access, reimbursement in 46 markets.

And we just received actually reimbursement in Korea in March of 2025. So that will kind of flow into our business and we'll continue to sustain a significant growth, we believe.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you, Alexander. Chris, GIPR?

Chris Boshoff - *Pfizer Inc - Chief Scientific Officer and President, Research & Development*

Oral small molecule GIPR antagonist was discovered in-house. It's potentially person class oral small molecule GIPR antagonist. And the Phase 2 study is now ongoing. This is a study in obesity in combination with liraglutide with the GLP-1. The PCD is listed on clinicaltrials.gov at the end of 2025.

So expect beginning 2026 potential data if the data positive in the Phase 2 study, then it could be a potential to be a using combinations to drive weight loss, both with internal or external opportunities.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you very much, Chris, and then Andrew, disconnect between our projections that you came to interrogate very carefully and your colleagues in your previous life.

Andrew Baum - *Pfizer Inc - Chief Strategy and Innovation Officer, Executive Vice President*

So I'd start with the two ADCs, which are now in Phase 3 first-line trials for non-small cell and head and neck. So SV and PD-L1V. Now part of the reason I think that the Street may have -- these may have flown under the radar is they move very, very quickly on the back of very strong Phase 1 data straight into Phase 3. And so I think some focus on that will be useful.

We obviously have the benefit of having seen access to more data than you have, but we look forward to sharing that with you in the near future. And hopefully, that would align your expectations closer to ours internally.

Chris already mentioned C. diff, which will begin our Phase 3 end of this year, beginning of next year. very significant unmet medical need. And then -- and this is not by any means a comprehensive list. But the two other ones I would mention is the CDK4, which I name check previously, which builds on our legacy with Ibrance. It's the first-in-class. It promises much better tolerability and efficacy.

Again, it's in our frontline head-to-head trial versus the current standard of care. And that is a $15 billion-plus market. So very sizable an area that we have a lot of expertise in.

And then the final one is ponsegromab, which I've addressed before. Look, we need to see how the data pans out. If it translates into a meaningful progression-free survival benefit or even a survival benefit, then obviously, it's a home run in terms of the value to both patients. But in addition, the revenue potential, alternative is supportive care therapy, and that's still a significant product, albeit at a different price point and a different order of magnitude.

But nevertheless, there is a very substantial delta look further out between what I can see or we can see and how the Street is modeling some of those forecasts. So we look forward to hopefully narrowing the gap in the months ahead.

Albert Bourla - *Pfizer Inc - Chairman of the Board, Chief Executive Officer*

Thank you, Andrew. That was the last question. And just a couple of comments. We had a very solid performance in the first quarter. Keep in mind that already $650 million negative in the US have been already absorbed in the results of the first quarter because of IRA. And that's from a total of $1 billion net, $1.5 billion gross for the year.

So it's a very strong start. I think in the strategic priorities, we continue to guide us in acting on our greatest opportunity. The discipline will continue. I think the team that we have running right now the company, probably the best I have ever seen in Pfizer. And Pfizer had traditionally very, very strong teams.

So I'm cautiously optimistic that we will turn this around. And we will translate the very good operational performance over the last five quarters at least, into also meaningful shareholder value. Thank you very much, and till the next earnings call.

Operator

This does conclude today's program. Thank you for your participation. You may disconnect at any time.
