GILD Earnings Call Transcript

Date: 2025-08-07

Quarter: 2

Operator: Good afternoon, everyone, and welcome to Gilead's Second Quarter 2025 Earnings Conference Call. My name is Rebecca, and I'll be today's host. [Operator Instructions] Now I'll hand the call over to Jacquie Ross, Senior Vice President of Treasury and Investor Relations.

Jacquie Ross: Thank you, Rebecca. Just after market closed today, we issued a press release with earnings results for the second quarter of 2025. The press release, slides and supplementary data are available on the Investors section of our website at gilead.com. The speakers on today's call will be our Chairman and Chief Executive Officer, Daniel P. O'Day; our Chief Commercial Officer, Johanna Mercier; our Chief Medical Officer, Dietmar Berger; and our Chief Financial Officer, Andrew Dickinson. After that, we'll open the call to Q&A;, where the team will be joined by Cindy Perettie, the Executive Vice President of Kite. Let me remind you that we will be making forward-looking statements. Please refer to Slide 2 regarding the risks and uncertainties relating to forward-looking statements that could cause actual results to differ materially. With that, I'll turn the call over to Dan.

Daniel P. O'Day: Thank you, Jacquie, and good afternoon, everyone. The team and I are pleased to be here with you today to share the results of a very successful second quarter. This quarter had special significance, of course, with the FDA approval of lenacapavir or Yeztugo for twice yearly HIV prevention. I want to take this opportunity to thank the many people who contributed to this remarkable achievement from the Gilead teams who discovered and developed lenacapavir to the participants in the PURPOSE studies as well as the KOLs, advocates, community partners and others who have been part of the lenacapavir journey. This is truly a milestone moment in the history of HIV with the launch of a groundbreaking innovation that could bend the arc of the epidemic. Moving to the quarterly results. We had another very strong quarter of clinical, commercial and operational execution. Excluding Veklury, base business sales of $6.9 billion grew 4% year-over-year, driven by robust growth across Biktarvy, Descovy, Livdelzi and Trodelvy. Product sales of $7.1 billion grew 2% year-over-year. The strong base business performance was partially offset by lower Veklury sales due to fewer COVID-19-related hospitalizations. HIV had a very strong second quarter with demand-driven growth of 7% year-over-year, more than offsetting the anticipated headwinds from the Medicare Part D redesign. Biktarvy grew 9% year-over-year to $3.5 billion, and Descovy grew 35% year-over- year to $653 million. This was Descovy's strongest quarter ever, highlighting the growth of the HIV prevention market into which we are now launching Yeztugo. It is now 7 weeks since FDA approval of Yeztugo, and we are very pleased with what we're seeing so far. Johanna and Andy will take you through our results in more detail. But overall, the strong commercial execution and operating expense discipline year-to-date support higher expectations for the second half of 2025. As a result, we are increasing our revenue and EPS guidance for the full year. From a clinical perspective, the second quarter was one of the strongest in Gilead's history. In addition to the FDA approval of Yeztugo, we received a positive CHMP opinion from the European Medicines Agency. With more than 1 million new HIV infections globally each year and over 600,000 HIV-related deaths, we believe lenacapavir is one of the most important scientific breakthroughs of our time, which brings a sense of urgency and responsibility to reach the communities most in need as quickly as possible. At the same time, we continue to fully evaluate lenacapavir's potential in the clinic. For example, we have just initiated PURPOSE-365, a Phase III trial evaluating once yearly lenacapavir for PrEP. Additionally, we continue to develop seven combination regimens

that utilize lenacapavir-based molecules for HIV treatment. In the second half of this year, we plan to share updates from ARTISTRY-1 and ARTISTRY-2. These Phase III trials are evaluating a potential new single-tablet regimen combining bictegravir plus lenacapavir that could further extend the reach of Gilead's current HIV treatment business. Moving to oncology. We announced back-to-back positive Phase III results for Trodelvy with the top line data from ASCENT-03 and the detailed data from ASCENT-04. We now have data that show highly statistically significant and clinically meaningful benefit for Trodelvy across first-line metastatic triple-negative breast cancer. Trodelvy is already the leading therapy for second-line metastatic TNBC. And with these data, we look forward to potentially advancing Trodelvy to the first-line setting where it could benefit twice as many patients. In cell therapy, we expect to provide a pivotal update from the Phase II iMMagine-1 trial evaluating anito-cel for multiple myeloma later this year. Given the compelling efficacy and safety data seen to date, combined with Kite's industry-leading manufacturing capabilities, we believe “anito-cel is well positioned as a potential best-in-class therapy for multiple myeloma. In summary, this is a very special time for Gilead that's underscored with our second quarter results. This highlights the strength of our R&D; engine and the level of excellence in our commercial and operational execution. Having built this positive momentum, we're excited by what's to come with continued innovation that will benefit patients and drive growth across our therapeutic areas. With that, I'll hand over to Johanna.

Johanna Mercier: Thanks, Dan, and good afternoon, everyone. We had another very strong quarter of commercial execution, culminating with the launch of Yeztugo following FDA approval in late June. Second quarter product sales, excluding Veklury of $6.9 billion, were up 4% year-over-year, primarily driven by 9% growth in Biktarvy and 35% growth in Descovy. We also delivered encouraging contributions from Livdelzi in its third full quarter of commercial launch and in Trodelvy, partially offset by lower HCV sales following a very strong second quarter in 2024. Sequentially, sales in our base business were up 10%, driven by growth in HIV, oncology and liver disease. Including Veklury, total product sales of $7.1 billion were up 2% year-over- year. While Veklury's share of U.S. hospitalized patients treated for COVID-19 remains well over 60%, the number of patients impacted by the pandemic continues to decline. This is reflected in second quarter sales of $121 million for Veklury and also in our updated full year guidance. Moving to Slide 8. HIV sales of $5.1 billion represented very strong 7% year-over-year growth, primarily driven by increased demand in addition to higher average realized price. Sequentially, sales were up 11%, reflecting inventory build and higher average realized price, both typical second quarter seasonal dynamics as well as higher demand. On Slide 9, Biktarvy sales of $3.5 billion were up 9% year-over-year, with commercial execution supporting a strong increase in demand. Sequentially, sales were up 12%, reflecting seasonal inventory build and higher average realized price as well as higher demand. Biktarvy once again expanded its U.S. market share and increased 2 percentage points year-over-year to over 51%. Biktarvy continues to lead in share in major markets around the world. Further strengthening Biktarvy's differentiation, FDA recently granted a label expansion to include the treatment of HIV in people with antiretroviral history who are not virologically suppressed with no known or suspected resistance. This new indication addresses an important unmet need for people with HIV, specifically those who come off therapy and then restart treatment. This label expansion reinforces confidence in Biktarvy to get such individuals to sustained viral suppression. Moving to Descovy. Second quarter sales of $653 million, increased 35% year-over-year with growing awareness of PrEP and unrestricted access driving both higher average realized price and higher demand. Sequentially, sales were up 11%, reflecting seasonal inventory dynamics and higher demand. Partly driven by strong execution from our commercial team and continued growth ahead of the Yeztugo launch, the U.S. PrEP market has now expanded to more than 0.5 million active users. This market continues to grow in the mid-teens year-over-year, highlighting progress on our goal of expanding the HIV prevention market. Additionally, Descovy for PrEP share grew once again this quarter, representing more than 40% of the U.S. market. Moving to Slide 10. We received FDA approval of Yeztugo as the first twice yearly injection for HIV prevention in mid-June, and the team has been executing what I consider to be the best planned commercial launch I have seen to date. Revenue in the first days of launch right at the end of the second quarter reflected planned inventory build as we expected. While it's still early days, we're extremely pleased with the feedback from both clinicians and consumers as well as the progress of our early discussions with payers and

the effectiveness of our launch preparations and execution to date. Notably, the first Yeztugo prescription was written within hours of approval with the first product shipped within 24 hours and the first dose administered within days, well ahead of our expectations. Prior to launch or any commercial engagement, Yeztugo's unaided awareness among healthcare providers was at 72%, more than twice the typical prelaunch awareness with aided awareness at 95%. I look forward to sharing more about Yeztugo's early performance in the coming quarters. We are well on our way to achieving our target of 75% access for Yeztugo within 6 months of launch and 90% within 12 months. Outside the U.S., we have just received a positive CHMP opinion and expect a European Commission decision on lenacapavir in the next 2 months. Our launch preparations in our initial target European territories are underway. Gilead is committed to facilitating access to lenacapavir for those who could benefit from HIV prevention regardless of where they live. With that in mind, we recently announced a partnership with the global fund to bring lenacapavir to approximately 2 million people in primarily low and lower middle-income countries over the next 3 years. We were also pleased that the World Health Organization and the International AIDS Society both recently announced new HIV prevention guidelines recommending the use of lenacapavir. As we look at the rest of 2025 on Slide 11, it's clear that we are seeing very strong performance in both HIV treatment and prevention. With that in mind, we're increasing our full year sales guidance and now expect HIV sales to grow approximately 3% in 2025, up from our prior assumption of flat revenue year-over-year. This updated HIV guidance is driven by strong Biktarvy and Descovy performance so far this year and our expectations for the second half. Some additional considerations. First, we've made no change to our assumption regarding the impact of Medicare Part D redesign, which at the start of the year, we expected to impact our HIV business by approximately $900 million in 2025. Excluding this headwind, HIV growth this year would be more than 7%. Second, given the recency of launch, we have made no changes to launch assumptions surrounding Yeztugo. And finally, given a broad range of possible policy outcomes, our updated HIV guidance assumes no changes to the current landscape. Moving to liver disease on Slide 12. Sales of $795 million, were down 4% year-over-year, following a particularly strong second quarter of 2024. This reflects lower average realized price and lower patient starts in HCV, partially offset by the very strong launch of Livdelzi as well as demand for HDV and HBV products. For HCV, U.S. pricing has been impacted year-over-year by Medicare Part D redesign, while volume was driven by the timing of purchases in both the U.S. and internationally. In primary biliary cholangitis, we continue to be pleased with Livdelzi's performance in the U.S. as well as the early launches in Europe following approval last quarter. Overall, revenue almost doubled from $40 million in the first quarter to $78 million in the second, driven by growing second-line PBC market share with our focus on both market expansion and persistence of therapy. Looking ahead, we are particularly encouraged by the demand we're seeing for Livdelzi in new patient [starts.] That said, and after a tremendously strong second quarter, we do expect sequential growth to be more moderate in the third quarter, reflecting continued growth in new patients, but a slower uptake among switch patients where cadence of physician visits remains a gating factor. Moving to Slide 13. Trodelvy sales of $364 million were up 14% year-over-year and 24% sequentially, reflecting Trodelvy's continued strength in metastatic breast cancer and more than offsetting on a year-over-year basis, the expected decline associated with the withdrawal of the bladder cancer indication in the U.S. Internationally, we have seen strong demand growth, both year-over-year and sequentially, where launch momentum and share gains continue across major markets. Building on our market leadership in second-line metastatic triple-negative breast cancer, we're working towards filing for approval in the first-line setting based on the potentially practice-changing results from the ASCENT-03 and ASCENT-04 trials. As a reminder, there are almost twice as many patients in the first-line metastatic setting compared to second line as well as longer duration of therapy, and we look forward to expanding the options available for patients in this earlier line setting. For cell therapy on Slide 14 and on behalf of Cindy and the Kite team, second quarter sales of $485 million were down 7% year-over-year, primarily driven by lower demand, partially offset by higher average realized price. As expected, our Kite cell therapies continue to face competitive headwinds, although sales were up 5% sequentially, helped by favorable FX impact in addition to higher demand for Yescarta in the U.S. and Tecartus globally. It's taking time to reduce the barriers to broaden adoption of cell therapy, but we're making progress. For example, FDA recently removed the CAR T class requirement for a REMS

program, which we believe will reduce the burden of CAR T administration for healthcare providers, patients and caregivers, and we're pleased to see these changes starting to be rolled out across authorized treatment centers. FDA also made additional changes to the CAR T product labels that will have meaningful impact on patient and caregiver quality of life. This included a 50% reduction in the time patients need to remain near their treating center and a 75% reduction in driving restrictions. We continue to believe that outpatient delivery remains key to broader cell therapy adoption. With that in mind, new real-world data shared at ASCO highlighted the viability of outpatient administration for Yescarta. This is also reflected in increasing outpatient adoption over time, suggesting growing physician comfort with the use of Yescarta in this setting. Our efforts to educate physicians and patients on the potential benefits of a onetime CAR T treatment are also ongoing. Most recently, we highlighted new 5-year overall survival analysis from Tecartus in B-cell acute lymphoblastic leukemia at EHA, the longest follow- up of any CAR T therapy in this indication. Together, these new data support our goals of bringing cell therapy closer to patients and increasing adoption. Wrapping up our second quarter, I want to thank the commercial team for delivering yet another strong quarter of impact for patients and financial results for Gilead. Any commercial organization is energized by new product launches, and we are so fortunate to have several new, exciting and impactful products in our portfolio. The Yeztugo launch marks a unique moment for Gilead, and I know the commercial teams share a sense of both excitement and responsibility given the potential to truly transform the HIV landscape in the coming years. And so with that, I'll hand the call over to Dietmar.

Dietmar P. Berger: Thank you, Johanna, and good afternoon, everyone. I'd like to start on Slide 16 by recognizing the years of tireless effort across many research and development teams at Gilead, Kite and our partners that contributed to a spectacular quarter of clinical results. In April and May, we announced positive top line results from ASCENT-04 and ASCENT-03 that showed Trodelvy regimens demonstrated highly statistically significant and clinically meaningful efficacy with the potential to be practice-changing in first-line metastatic triple-negative breast cancer. In May and June, we shared promising early results from our next-generation bicistronic CAR-Ts in lymphoma and glioblastoma. In June, we shared updated data from our pivotal iMMagine-1 trial in fourth-line and later relapsed and/or refractory multiple myeloma that further reinforce our belief in anito-cel's" best-in-class potential. And also in June, we achieved FDA approval of Yeztugo, our breakthrough twice yearly injectable for HIV prevention, which we truly believe has transformative potential. We believe lenacapavir will help bring us closer to our goal of ending the HIV epidemic in the years ahead. You have heard Johanna's excitement about the commercial launch in the U.S. And in July, we were pleased CHMP adopted positive opinions for our EU marketing authorization application and for EU medicines for all, which enables a streamlined assessment for WHO prequalification and additional global regulatory reviews. These are critical advances in our plans to help make lenacapavir available to people who need to be protected from HIV globally. This is a moment of pride for this Gilead team and has given me personal pause as I recognize and appreciate the brilliance of the team of scientists that we have here and the determination to keep out innovating ourselves to achieve the best possible experience and outcomes for those we serve. With that in mind, our work in HIV continues. As you can see on Slide 17, with the approval of Yeztugo, we continue to target up to eight additional HIV product launches before the end of 2033, including five that would come to market by the end of 2030. In HIV prevention, we have initiated our Phase III trial evaluating once yearly intramuscular injections of lenacapavir for HIV prevention, now called PURPOSE-365. If successful, this could launch as early as 2028. In HIV treatment, we continue to expect an update on our new daily oral combination of bictegravir and lenacapavir in the second half of the year from ARTISTRY-1 in people with HIV on complex regimens. In addition to ARTISTRY-1, we now expect to provide an update for ARTISTRY-2, the second Phase III trial for BIC/LEN for virally suppressed people with HIV or people looking to switch regimens. Looking at our weekly HIV treatment programs, we expect the Phase III update on the lenacapavir plus islatravir combination in 2026 with a view to potential launch in 2027. As we announced, our wholly owned weekly WONDERS program evaluating the combination of GS-4182, one of our lenacapavir prodrugs and GS-1720, one of our long-acting integrase inhibitors is on clinical hold pending further analysis. We are making progress on our other oral long-acting candidates and continue to expect our wholly owned once-weekly program to be moving forward with a delay of 3 to 6 quarters. Among the rest of our

leading HIV programs, three are in Phase I, namely our monthly oral and our quarterly and twice yearly injectables. We look forward to sharing updates on these in due course. Finally, we continue to plan for our Phase III study evaluating lenacapavir plus broadly neutralizing antibodies or bNAbs as a potential twice yearly injectable treatment. We continue to target commercial launch in 2030. Moving to oncology on Slide 18. Trodelvy's impact in metastatic triple-negative breast cancer was reinforced with highly statistically significant and clinically meaningful results in the Phase III ASCENT-03 and ASCENT-04 studies in the first-line setting. At ASCO, we presented potentially practice-changing detailed data from ASCENT-04, showing treatment with Trodelvy plus pembrolizumab resulted in an 11.2 months median progression-free survival, a 35% improvement versus chemo plus pembro for first- line PD-L1 positive metastatic triple-negative breast cancer. We saw an early trend for improvement in overall survival with Trodelvy plus pembro, though we would note these data are immature. Still, these results are remarkable given the high share of patients who crossed over to Trodelvy following disease progression in the control arm, which would be expected to mask a potential overall survival benefit. We will be filing for full approval based on the primary median PFS endpoint for both ASCENT-03 and ASCENT-04 with a potential FDA regulatory decision expected in 2026. We plan to share detailed Phase III ASCENT-03 data at an upcoming medical meeting, which will allow it to be considered for future guideline updates. These results are encouraging as we continue to evaluate Trodelvy in earlier lines of breast cancer. In addition to ASCENT-03 and ASCENT-04, our other Phase III breast cancer programs include ASCENT-07 in chemo-naive hormone receptor positive HER2-negative metastatic breast cancer, evaluating Trodelvy following endocrine and CDK4/6 inhibitor therapies. This is an event-driven trial, and we will update you in due course. And ASCENT-05 in high-risk early triple-negative breast cancer, evaluating adjuvant Trodelvy plus pembro. As would be expected with an earlier line trials in a potentially curative setting, it will be several years before we are able to provide an update. We also remain focused on clinical execution of our five other ongoing Phase III programs for Trodelvy and domvanalimab across lung, endometrial and upper GI cancers. Moving to Slide 19. And on behalf of Cindy and the Kite team, we were pleased to present new data from across our cell therapy pipeline at the ASCO and EHA Congresses. In partnership with Arcellx, data from the iMMagine-1 trial at EHA demonstrated the consistent and compelling efficacy and safety profile of anito-cel. We continue to believe anito-cel has the potential to offer a best-in- class profile, and we look forward to presenting pivotal data from this trial towards the end of the year. As a reminder, we continue to target 2026 for a commercial launch. From our next-generation construct at ASCO, we presented initial data from the bicistronic CD19, CD20, Kite-363 CAR T, which we believe has shown a promising profile in B-cell malignancies, and we have selected Kite-363 to be evaluated in Phase I trials of autoimmune and neuroinflammatory conditions. In the second half of this year, we will decide which program to advance in hematology, choosing between our 3 next-generation CAR T constructs. Additionally, in collaboration with the University of Pennsylvania, Perelman School of Medicine, ASCO data on the bicistronic EGFR-IL13Ra2 CAR T strengthens proof-of-concept for expanding CAR Ts to treat solid tumors. Overall, we remain excited in the potential of our next-generation therapies to offer improved efficacy and safety profiles and to reach patients faster as we work towards our goal of bringing potentially curative therapies to patients. Finally, moving to our pipeline milestones on Slide 20. We have had an extremely productive and successful quarter overall. Looking to the rest of the year, we expect the pivotal update from our iMMagine-1 trial evaluating anito-cel in fourth line or later relapsed or refractory multiple myeloma, the European Commission decision on lenacapavir for PrEP following the recent positive CHMP opinion and the Phase III update for ARTISTRY-1, evaluating BIC/LEN in people with HIV on complex regimens. We have also added a new milestone, a Phase III update for ARTISTRY-2, evaluating BIC/LEN in virologically suppressed people with HIV. Together, ARTISTRY-1 and ARTISTRY-2 have the potential to support global regulatory filings that could expand the reach of Gilead's HIV treatment business. With that, I'll turn the call over to Andy.

Andrew D. Dickinson: Thank you, Dietmar, and good afternoon, everyone. Starting on Slide 22, our second quarter results show continued strength in execution across the company. Our base business was up 4% year-over-year to $6.9 billion, driven by growth in Biktarvy, Descovy, Livdelzi and Trodelvy. Reflecting fewer COVID-related hospitalizations, Veklury sales were down 44% year-over-year, resulting in total product sales of $7.1 billion, up 2% year-over-year. Moving to our non-GAAP results

on Slide 23. Second quarter product gross margin was up 1% from the same quarter last year to 87%, driven by a more favorable product mix. R&D; expenses were up 9% compared to a relatively low second quarter of 2024, reflecting investments in clinical manufacturing and study activities. I'll highlight that we continue to expect full year R&D; expenses to be roughly flat on a dollar basis from 2024 and year-to-date R&D; expenses are tracking in line with our internal expectations. Acquired IPR&D; expenses were $61 million in the second quarter, primarily driven by the “Kymera” collaboration we announced in June. SG&A; expenses were flat year-over-year with higher sales and marketing expenses, primarily related to our HIV franchise, offset by lower G&A; expenses. Second quarter operating margin was 46% or 47%, excluding acquired IPR&D.; The non-GAAP effective tax rate was 19% this quarter, in line with our expectations. And finally, non-GAAP diluted EPS was $2.01 for the quarter. Moving to our full year guidance on Slide 24. We had an extremely strong first half of 2025 driven by our HIV portfolio and bolstered by the encouraging momentum in both Livdelzi and Trodelvy. With that in mind, we are updating our full year 2025 guidance as follows: we now expect product sales, excluding Veklury, of approximately $27.3 billion to $27.7 billion, representing an increase of $0.5 billion in our base business expectations for 2025. This update reflects HIV growth of approximately 3% year-over-year driven by the outperformance of Biktarvy and Descovy year-to-date, FX tailwinds and softer cell therapy expectations where we now expect a modest decline for full year 2025 versus full year 2024. I'll note that our assumptions have not changed in the following areas: firstly, our assumptions for the impact of Medicare Part D redesign remain unchanged from the beginning of the year, and we expect approximately $1.1 billion of impact to our business. Secondly, while we're very encouraged by the launch dynamics of Yeztugo to date, we are not updating our assumptions for Yeztugo revenue in the second half of 2025 at this time. And finally, we have not updated our expectations for the impact of potential tariffs or other changes to the broader policy environment. We continue to expect the impact of known tariffs to be manageable in 2025. Moving to Slide 25. We are reducing our full year 2025 expectations for Veklury by $400 million to approximately $1 billion, reflecting the current path of the COVID-19 pandemic, including lower hospitalization rates in the first half and the trends we've seen in the first month of the third quarter. As a result, total product sales is expected to be in the range of $28.3 billion to $28.7 billion with $0.5 billion increase in base business expectations, partially offset by lower COVID-19 related sales. For other items in the P&L;, on a non-GAAP basis, we now expect product gross margin to be approximately 86%, reflecting strong performance year-to-date and a more favorable product mix. We expect R&D; expenses to be roughly flat on a dollar basis from 2024 which is consistent with our expectations at the start of the year. And we expect acquired IPR&D; to be approximately $400 million, reflecting $315 million of expenses so far this year, in addition to known commitments and expected milestone payments. SG&A; expenses are now expected to decline by a mid- to high single-digit percentage compared to 2024, updated to reflect higher HIV sales and marketing expenses and other corporate expenses associated with higher 2025 base business expectations. Rounding out the P&L;, we expect operating income to be between $13 billion and $13.4 billion. Our effective tax rate to be approximately 19%, consistent with our prior guidance. And we expect our full year diluted EPS to be between $7.95 and $8.25, an increase of $0.20 at the midpoint compared to our prior guidance. Looking ahead, we will continue to monitor the macro landscape carefully, and we expect that our disciplined approach to operating expense management positions us well to adapt as needed in the months ahead. On Slide 26, our capital priorities remain unchanged, and we returned $1.5 billion to shareholders in the second quarter. This included $527 million of share repurchases, currently being executed under our 2020 plan. We expect to complete the 2020 program over the next several quarters, and our Board recently approved a new $6 billion program to support continued share repurchases. These repurchases are intended to offset equity dilution at a minimum but can also be used opportunistically as you've seen in the first half of 2025. Overall, Gilead delivered another very strong quarter of clinical and commercial execution, supported by our disciplined operating model. As we look to the second half of the year, we believe that Gilead is well positioned for near-term and long-term growth and we remain focused on delivering on our strategic commitments. With that, I'll invite Rebecca to begin the Q&A.;

Operator: [Operator Instructions] Our first question comes from Tyler Van Buren at TD Cowen.

Tyler Martin Van Buren: Great. Congratulations on the progress. I know you'll be shocked to hear this

question, but can you please elaborate on the early uptake with Yeztugo and whether you expect the early prescriptions to trend linearly from here or if it's still very early in what is expected to be a more of an exponential launch curve?

Daniel P. O'Day: Yes. Go ahead, Johanna, please. We are very surprised to get that question.

Johanna Mercier: Tyler, thanks for the question. It's Johanna. Yes, we're really pleased with the launch so far. And you're right, it's still early days, we're about 6 weeks in, but super thrilled to see what's been going on. I think number one, a lot of that has to do with the readiness of the cross-functional teams as the day that we got -- or I should say the hour we got the approval, everything was basically ready to turnkey and get going. So the teams have hit the ground running and just really proud to see how they're working together in pods across the U.S. to make sure that this happens. We've already had over about 25,000 customer calls executed in the field and just understanding that our target base is about 15,000. So many of those customers have seen either a representative or a medical sales representative more than once. And that's how we see kind of the uptake and the excitement. When we think about the awareness at launch, it was already kind of double what we usually see in industry at launch, right? We were looking at about a 72% unaided awareness. Usually, those numbers in the 30s or so. And then, of course, our aided awareness was 95-plus. So we really knew that as we were going into this, we were ready and now it's up to us to pull it through. You heard me say a couple of early data points around first script within hours, injection within a couple of days and tracking that super closely, the piece that maybe is important to understand as well is how access is playing out here. We've always said about -- you should expect 75% or so access at 6 months' time point and then about 90% at 12 months and the medical exceptions are basically the way people are working through this, and we have a great field reimbursement team that is there to provide that end-to-end reimbursement support to make sure we can pull through those scripts as quickly as possible. But different plans will take different times, and that's what we're obviously very conscious of. At the same time, I will say we have a couple of early wins that we're really proud of. One, I would say, is the J-code which sometimes is having a miscellaneous J-code is great. But having the J-code come through is actually really important and just simplifies the whole billing and reimbursement process. And we got confirmation that our J-code is coming through for October 1. You probably know from other launches, usually, that takes at least 2 to 3 quarters. And so that's a little bit ahead of our expectations. And then we've had some early commercial wins, where some plans have come in as of August 1. And then we had also some state Medicaid wins. And namely, I just want to highlight, we have a couple more than this, but 2 out of the 4 biggest PrEP states -- prevention states are California and Florida, and both of those are on formulary as of August 1. So we're really pleased to see that more and more lives are getting access and working through kind of those medical exceptions as we go and really high interest from a lot of our payers to make sure we can have those discussions. So we've engaged with multiple accounts, over 200 accounts we've engaged with to make sure they have all the information they need to make those formulary decisions. And so that's what we're working through. And that's obviously going to take a little bit of time, as you know. But I think we're very well on our way to achieve our goals. So super excited. Hopefully, you can hear it and see all the data to -- the proof points to support it. I think we have the right team, the right attitude and the responsibility to make sure we really make a difference here with Yeztugo and bend the curve of this epidemic. So stay tuned as a little bit more data comes through in the next quarter and more to come.

Daniel P. O'Day: Thanks, Johanna. Thanks, Tyler, for the question. I just want to add, I'm really impressed with the team's early launch support here, and we look forward to updating you in quarters to come.

Operator: Our next question comes from Terence Flynn at Morgan Stanley.

Terence C. Flynn: Great. Congrats on all the progress as well. Johanna, you mentioned Descovy had one of its best quarters ever. I think if you look at the growth trajectory there, it's obviously been very robust and looks to be tracking well above the 8% rate that I think is implied in your longer-term guidance for the PrEP market when you guys look out to 2030. So just wondering how durable this kind of a growth rate is given what you're seeing out there in the market and a lot of the work you're doing -- you've done ahead of the Yeztugo launch? And then just one clarification. Can you just comment on the accuracy of Yeztugo IQVIA data for us if you have any visibility there?

Johanna Mercier: Sure. Thanks, Terence. So a couple of things. One is the PrEP market is growing nicely at about double digit, right, about 15% or so year-on-year. And that obviously has to do with a lot of the work that we've been pulling through, a lot of initiatives in the field to increase awareness about prevention and the importance of prevention. And that's why we were excited to share that those numbers are growing quite actively, and we're at about 500,000 or so active users in PrEP which is well on our way to kind of those goals that you were referring to of over 1 million by mid-30s. We do think that there's an opportunity for us to basically continue that growth in the marketplace, especially with the excitement with Yeztugo, I think the PURPOSE-1 and PURPOSE-2 data are just so powerful that they're really having impact in the field. So we will continue to drive that. To your comments around Descovy and the incredible performance that we've been seeing with Descovy, right, that 35% share, a lot of that has to do with basically continued favorable access that we've seen over the last 6 to 9 months or so where we're seeing the co- pays come down to $0 in many cases. Our access basically jumped up a little bit. And we're now at about -- if you think about unrestricted access, we're at about 88% of the total lives covered. And we are about 98% total covered lives. So about 10% still have a little bit of restriction either step edit or prior auth. But that's actually a big jump. And then the teams have done an incredible job with those plans that had those changes is really to increase those shares of Descovy in those plans. So that's what you're seeing in the uptake. What I would suggest, though, is that Yeztugo gets traction and ramps up over the next coming quarters, you will probably see a little bit of a decline because the intent with Yeztugo is obviously to look at the total PrEP market and make sure that we're differentiating there across all the orals as well as other long-acting. So you will see a little bit of a shift in the mix, right, as we go forward. Hopefully, that addressed that question. And your quick comment on IQVIA data. Listen, it's still really early, but we do believe IQVIA data is directionally aligned. It's just some accounts, some channels are not represented in IQVIA, as you well know, so they're not reflected in the data. I think we're going to need a couple of more quarters to stabilize, as you've seen in the past with other launches. Having said that, we are so pleased kind of with what we're seeing in the initial uptake, the customer response. I think I will tell you the excitement is palpable internally, externally. And I would also say that we're also tracking really closely kind of the customer uptake as well, right? So as it goes through into the reimbursement because our teams are making sure that we can pull those scripts through and what really matters through IQVIA is users that are getting the injection. So we're tracking both of those really closely. So stay tuned, but I think a couple more quarters will help us kind of normalize that data.

Operator: [Operator Instructions] Our next question comes from Umer Raffat at Evercore.

Umer Raffat: Congrats on all the progress with Yeztugo. I figured I'll go in a different direction on potentially a risk factor for the business. In a scenario where the industry does converge around an MFN proposal, which is focused on Medicaid, how do you see the impact to Gilead business from a revenue perspective? And obviously inclusive of the mandatory and CPI rebates you do pay to Medicaid already.

Daniel P. O'Day: Yes. Thanks, Umer. Maybe I'll start, and then I'll hand it over to Johanna to talk specifically about the Medicaid portion of it. I just want to be clear that, obviously, we are having discussions and working with the administration on the whole topic of MFN, I would say just as a backdrop to all this but given the general business uncertainty in the country and also some of the sector- specific uncertainty, it's even more important that we're at this stage in Gilead's history of driving forward with all these new launches controlling operating expenses. And I remind you, as you know, we have very limited patent exposure until the end of 2033 with a very strong clinical development plan to be able to support the patients with that medicine prior to 2033. So I just put that in the backdrop. Obviously, we very much support the concept of finding ways to have patients better afford their medicine in this country while also preserving the right ecosystem here. Now specifically related to your Medicaid question, I'll hand it over to Johanna to talk about how that could or could not impact us.

Johanna Mercier: Right, I mean, so you know Medicaid business for us in HIV. I'm going to focus on HIV, the biggest piece of our business is around mid- to lower 20s. And so that is something that is important to us. Remember, the co-pays, so the patient out-of-pocket cost for Medicaid is incredibly low. It's either $0 or a couple of dollars per script, and there's a lot of support for that. I mean obviously,

what we're tracking is also not just potential demo projects and things like that with MFN, but we're also tracking the current legislation with Medicaid as to the Big Beautiful Bill. And we are tracking that realizing that most of those have implications late '26 into '27. So no immediate impact at this point in time. Having said that -- all of that said, HIV is very different. And it is a disease that, obviously, if you don't treat it, I think the repercussions and the consequences are not just that individual patient. They could be much broader such as a local epidemic of HIV in the United States. And so that's why many individuals or most individuals that are diagnosed with HIV, there's really always a safety net program to support them in their treatment and whether that state's programs, ADAP programs, foundations, or even Gilead's patient access programs, these are all pieces of the puzzle that we're thinking through to make sure we wrap around, to make sure that those patients get coverage and access to the medicines they need.

Operator: Our next question comes from Evan Seigerman at BMO Capital Markets. Evan?

Evan David Seigerman: Really congrats on the progress. Given the importance of the Yeztugo launch and the recent changes to the HHS preventative task force. If PrEP is removed as a preventative medicine broadly, how does this change your approach to commercialization? [indiscernible].

Johanna Mercier: I heard most of that. It's Johanna, Evan, I'll take that one. Yes. So listen, let me start by saying the USPSTF guidance is something we truly support. We believe in preventative services. We think it's very important across all diseases, but namely in HIV when you think about prevention. The current guidelines are well enforced. They support the $0 co-pay and without access restrictions or step edits or whatnot for HIV prevention. And we believe that also includes Yeztugo as we're going forward with those conversations with the plan. As I mentioned earlier, Descovy is well covered, 88% of access with no restrictions. Having said all of that, if there was to be a change in the future, not that we foresee that. If there was to be a change, I just want to remind you that these guidelines didn't really have legs until probably less than a year ago, probably about 2, 3 quarters ago. And before that, the prevention market was still growing very strong, same rates basically that we're seeing today. And we were very successful with Descovy at about a 40% share or so. We're now closer to about -- a little bit towards the 44%, 45% share now and the market is still growing at around the same rate. So we do believe that whether we have USPSTF that's ideal. If it was to change in any way, we still believe we could work through it and just work closer with our payers to make sure that people have access to HIV prevention moving forward just as they do today.

Operator: Our next question comes from Chris Schott at JPMorgan.

Christopher Thomas Schott: Congrats on the progress. I just wanted to ask about the treatment pipeline and specifically just elaborate on your confidence on the 4182, 1720, the weekly treatment combo, the WONDERS program following the clinical hold announced earlier this year. I guess just kind of next updates we should be watching for on that combo? And just how does that stack up relative to some of the other treatment combos that you're working on?

Daniel P. O'Day: Chris, we'll get Dietmar's voice here.

Dietmar P. Berger: Yes. The -- Thanks, Chris, for the question. Our confidence in the treatment pipeline is high, right? And remember, we not only work on a weekly approach. We also work on daily, monthly, every 3 months and every 6 months approach. So the pipeline is deep. We have a variety of different molecules. And if you look at 4182 and 1720, one of them is a lenacapavir pro-drug. The other one is an INSTI. And we have several other molecules of those classes in our portfolio. So what we're currently doing is we're trying to understand the data further. We're doing preclinical and clinical analysis to really isolate the observation that we had to make sure we understand which of the molecules led to that observation. And then to move forward expeditiously with one of our other molecules that we have in the portfolio in a new combination to really get that weekly treatment opportunity to patients. I also want to mention that we obviously have our Phase III ISLEND program, islatravir and lenacapavir ongoing which is currently in Phase III, the next update on that program is coming 2026 and the estimated launch for that one is in '27. With regards to our wholly owned program, kind of the WONDERS program and the succession of that, we will update you in due course.

Operator: Our next question comes from Geoff Meacham at Citibank.

Geoffrey Christopher Meacham: Yet another one on Yeztugo. It seems like the OUS contribution, I think, is going to be much bigger when you compare to Descovy or Truvada and PrEP. Johanna, I'm

not asking for guidance, but when you think about the U.S. versus OUS contribution for HIV treatment, could that ultimately mirror what you will see in PrEP kind of at the peak. I guess that's what I'm asking is the -- outside the U.S. market is one that is sort of novel and new for you guys, and I want to get some context there.

Johanna Mercier: Thanks, Geoff. I do think that you're right. I think there is a broader opportunity with Yeztugo ex-U.S. And a lot of that has to do, right, with Descovy, we were kind of challenged in many markets, the comparator with Truvada and Truvada was generic in many of those markets. With Yeztugo, I think with the innovation, the transformational value that we are bringing for markets that truly recognize the need for something else in HIV prevention and recognize the value of lenacapavir and what it brings to their population or their specific target populations where you see an HIV incidence that is very high. I really do think there's an opportunity for us to have broader footprint than just where we are today with Descovy, for example. And so I think to your point, at stable -- at steady state or at peak, I do think maybe that will take a little bit of time because I think the challenge from a reimbursement standpoint will not be simple. But I do think for the countries that have literally said and been very outspoken that they want to bend the curve or that they're not meeting their 2030 target, which nobody is. This is really an opportunity for us to partner with those stakeholders and make sure that Yeztugo is available for those countries.

Operator: Our next question comes from Mohit Bansal at Wells Fargo.

Mohit Bansal: Great. Thank you very much. And Johanna, you are very popular today so one more for you. So the question is regarding the logistics as well as the safety side of it. So just wanted to understand for Yeztugo, the logistics dynamic because this is a prescriber base that is used to orals and now they're going to use an injection, which is also at doctor's offices. So how are you navigating that? And would it take some time to help understand prescribers the entire dynamic. Would love to understand that.

Johanna Mercier: Sure. And as we were preparing for this launch, we were leveraging a lot of the learnings of past launches in this space or launches that went from an oral to injectable just to understand what we needed to do to prepare for it. And one of the key things was education and making sure there's optionality, flexibility for where they go. So the -- at launch, we were able to offer our customers, our HCPs, the clinics to make sure that they understood that they could prescribe it and do buy and bill in their office. We also offer them to make sure that they could prescribe it and then send the script to specialty pharmacy, and they would do all the background work and then send the product back for the injection with the user, consumer. And -- or if they didn't want any of that, they could go to an alternate site of care and basically just send with the script, the consumer to that alternate site of care for their injection and do all the reimbursement background work. So I think we've set it up with a lot of flexibility. And what we're seeing, although very early -- what we're seeing is exactly kind of what we thought. We thought at the beginning, we're going to see a lot heavier towards specialty pharmacy [unless] the buy and bill would be more of the clinics that were already doing buy and bill in the past and a little bit of alternate site of care is happening as well, but few and far between. And so I think it's still very early to kind of assess where that's looking for. But I will say one of the biggest differentiation is I talked a little bit earlier around cross-functional network and partnership. The teams are set up across the U.S. so that they have a full cross-functional team, whether it comes with nurse educators, field reimbursement, the medical representative, the commercial sales representative, and they work together in pods. So what they've done is actually set up meetings with a lot of these clinics around the country together so that they can answer all the questions at the same time to navigate the process, the logistics for Yeztugo. And that has apparently had incredible success. Our customers aren't used to that, and they've been incredibly appreciative and satisfied with what we've been bringing so that they have all their answers when they need it so that they can put pen to paper and prescribe for their patients. And so I think we're managing it incredibly cross-functionally and making sure that we understand the complexity of the logistics but making sure the customers see it as simple. And so that's our goal.

Operator: Our next question comes from Courtney Breen at Bernstein. Courtney?

Courtney Breen: Probably another one for Johanna I think. You spoke a little bit about kind of you've been surprised positively so far in the Yeztugo launch around access and around kind of the connecting

of the dots that the team has been able to achieve and the scripts and the actual injection rates. Why didn't you raise the launch expectations or the guidance as you thought about kind of the Yeztugo launch for the remainder of this year. What are the things that are still question marks in your mind that would give you confidence to kind of raise your own expectations in terms of this launch for the early parts and what we might see this year?

Johanna Mercier: Courtney, great question. And I think I would answer it with two ways. One is, it's still very early, right? We're 6 weeks into the launch. So that's one. Two is access is critical here. And so we're managing one-offs on medical exceptions every time our field reimbursement team hears that there is a little bit of a block somewhere, and we're working through it with the plan. But I think more importantly, we really need to see the number of covered lives increase over the next quarter or two to really see that momentum and really pull through those intake calls into scripts and injections. And so that's kind of the piece that we're waiting to see. And so I think you can ask me that question again in a couple of quarters, and we'll go from there.

Operator: Our last question comes from Carter Gould at Cantor.

Carter Lewis Gould: Congrats on the Yeztugo progress. Maybe to switch things up. I just wanted to ask on sort of your continued confidence on anito-cel approvability based on a single-arm study. I'm familiar with the feedback your partner received some time ago. But since then, there's been bispecific approvals, competitor CAR Ts have had confirmatory data, coupled with obviously no shortage of disruption across CBER and FDA. So just how do you get comfortable with the feedback from years past still applies? And if there's been ongoing feedback that bolsters that confidence.

Unidentified Company Representative: Yes. I know we're not communicating our regulatory strategy other than to say that we are continuing to have conversations with the FDA and are looking forward to launching in 2026. We don't have any major shifts in the things that we've communicated before and are looking forward to filing anito-cel.

Daniel P. O'Day: Great. This is Dan. I just want to thank everybody for your questions today and for joining the call. Maybe just a couple of closing comments from my side. As we've shared today, this has been a really successful second quarter with growth drivers from all three of our therapeutic areas contributing to the 4% growth in the base business, more than offsetting the anticipated headwinds we had from the Medicare Part D redesign, just to remind you all, we're incredibly proud of -- and much of the call was devoted to this to have delivered the world's first twice yearly prevention for HIV with lenacapavir. In the U.S., it's really off to a very strong start. We'll continue to update on the quarters with that. But in addition, of course, we had the positive CHMP opinion on Yeztugo and a great start overall with the launch. So we're incredibly impressed and proud of where we believe this will go. And overall, it's also been one of our strongest clinical quarters we've ever had. We didn't speak about it so much today. But in addition to that, we had the back-to-back positive Phase III results for Trodelvy and we just finished with the last question on the anito-cel and cell therapy and the broader cell therapy pipeline, I would say, and this top line performance is transforming down to the bottom line. And it's a really special time at Gilead with so many launches, imminent launches, Yeztugo, Livdelzi, Trodelvy first line potentially coming up as well as the needle cell. So it's a strong time for the team. So I just want to take this opportunity to thank the Gilead team for their incredible efforts they're putting into driving this level of innovation. I want to thank all of you for joining us today. As usual, our IR team is available for follow-up and any questions that you have. We wish you a great rest of your day, and thank you for your interest in Gilead.