GILEAD SCIENCES FIRST QUARTER 2021 EARNINGS CONFERENCE CALL

Jacquie Ross, *VP, Investor Relations*

Thank you, Operator, and good afternoon everyone. Just after market close today, we issued a press release with earnings results for the first quarter of 2021. 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 O'Day, our Chief Commercial Officer, Johanna Mercier, our Chief Medical Officer, Merdad Parsey, and our Chief Financial Officer, Andrew Dickinson. After that, we'll open up the call to Q&A, where the team will be joined by Christi Shaw, the Chief Executive Officer of Kite.

Before we get started, let me remind you that we will be making forward-looking statements, including those related to the impact of the COVID-19 pandemic on Gilead's business, financial condition and results of operations; plans and expectations with respect to products, product candidates, corporate strategy, financial projections and the use of capital; and 2021 financial guidance, all of which involve certain assumptions, risks and uncertainties that are beyond our control and could cause actual results to differ materially from these statements.

A description of these risks can be found in the earnings press release and our latest SEC disclosure documents. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

Non-GAAP financial measures will be used to help you understand the company's underlying business performance. The GAAP to non-GAAP reconciliations are provided in the earnings press release, in our supplementary data sheet, as well as on the Gilead website.
I will now turn the call over to Dan.

Daniel O'Day, *Chairman and Chief Executive Office*

Thank you, Jacquie, and good afternoon, everyone. We appreciate you taking the time to join us today. Before I hand over to the team to go into the details of our commercial, pipeline and financial results, I wanted to share our overall assessment of Gilead's first quarter. 2021 is a pivotal year for Gilead and – as you can see on slide [4], we are off to a solid start.

- Our first quarter total product sales were in-line with our internal expectations. While our core business was more impacted by COVID-19 than we anticipated, this was offset by higher Veklury sales. In the United States, 1 in 2 hospitalized patients are receiving Veklury, and – worldwide - Veklury continues to play a key role as a standard of care treatment for patients who are hospitalized with COVID-19.

- Given the desperate situation in India, Gilead has been working with the Indian government, health authorities and our voluntary licensees to increase supply of remdesivir and provide donated medicine. As the trajectory of the pandemic evolves globally, we will continue to invest in multiple clinical studies of Veklury, including alternative formulations.

- Earlier this month, we received two FDA approvals for Trodelvy. The full approval for metastatic triple negative breast cancer extended the label to second-line plus patients. This means Trodelvy could help many more patients, as there are more than double the number of patients in this category as there are in the third line setting. We also received accelerated approval in second-line plus metastatic urothelial cancer.

In March, we announced a new partnership to combine investigational lenacapavir with Merck's investigational islatravir for long-acting HIV treatment, accelerating the path to the next wave of therapies. While many people living with HIV may prefer a daily regimen like Biktarvy, we believe that broadening their options to include weekly oral therapies and infrequent injections every three months or longer addresses a significant patient need, and sets up strong, sustainable HIV leadership into the late 2030s. Long-acting formulations, such as lenacapavir as monotherapy, are also likely to unlock further PrEP usage and reach many more people at risk of HIV.

We are also pleased with our progress in advancing lenacapavir in both treatment and prevention settings as part of our internal clinical development. This past quarter, we reported compelling long-acting efficacy data for lenacapavir in heavily treatment-experienced people with multi-drug resistant HIV.

We are fully confident that lenacapavir will be the foundation for our long-acting HIV treatment and prevention portfolio.

And while we advance lenacapavir, Biktarvy usage continues to grow, with 1 in 2 people living with HIV starting their treatment on Biktarvy in the US. In addition, Biktarvy is capturing 1 in 2 switches, and approximately half of those are switching from a regimen that includes a non-Gilead agent.
In addition to securing regulatory approvals in oncology, we have already achieved several other pipeline milestones, including EMA validation of the Trodelvy MAA for metastatic triple-negative breast cancer and submission of the supplemental biologics license application to FDA for Tecartus in relapsed or refractory ALL.

Building on the work we did last year, we continue with the disciplined prioritization of our pipeline across Gilead. To share one example, Kite completed an optimization exercise this past quarter to ensure that resources are focused on the most promising opportunities to make a difference for patients.

Finally, we're looking forward to a full year of clinical news flow for Gilead. Our pipeline list for 2021 includes over 20 milestones across therapeutic areas. While they are all important steps in Gilead's journey to serve more patients and diversify our business, slide [5] lists the most significant items so you can track our progress more clearly.

These include:

- The Phase 3 TROPiCS-02 PFS readout for Trodelvy in HR+/HER2- metastatic breast cancer.
- Yescarta's Phase 3 ZUMA-7 readout for second-line DLBCL, which could result in sBLA submission later this year.
- The Phase 3 readout for Hepcludex that could lead to BLA filing.
- Arcus' domvanalimab Phase 2 ARC-7 interim read out in NSCLC, which could inform an opt-in decision.
- Magrolimab's Phase 1b data readout in MDS, which could lead to a submission for accelerated approval later this year.
- Potential Phase 2 trial initiation of lenacapavir and islatravir as a long-acting oral HIV treatment in second half 2021

Our aspirations for patients are bold, and our pipeline offers diversity across indications and risk profiles. While execution will continue to be a focus, these milestones give us a great deal of optimism about the future and our ability to deliver therapies that make a meaningful difference for patients.

Before I hand off, I wanted to take a moment to thank Dr. Bill Lee, who is retiring from his role as Executive Vice President of Research after 30 years at Gilead. On behalf of all of us, I want to offer my sincere gratitude to Bill for his outstanding contributions that have helped to benefit millions of patients around the world. I would also like to welcome Dr. Flavius Martin who joined Gilead as the new EVP of Research on April 12th. Flavius has an impressive track record in overseeing industry-leading research and advancing new therapeutic candidates.

With that, I'll invite Johanna to update you all on our commercial operations in the first quarter.

Johanna Mercier, *Chief Commercial Officer*

Thanks, Dan, and good afternoon, everyone.

Starting on slide [7], it was a solid quarter of execution for the commercial team, with total product revenue of $6.3 billion, up 16% from the first quarter of last year. This was in-line with our internal expectations as Veklury sales offset a more substantial pandemic-related impact on our core business than we had anticipated. Excluding Veklury, total product revenue was $4.9 billion, reflecting inventory and pricing seasonality, the anticipated HIV loss of exclusivity in the US, and ongoing pandemic-related dynamics in HIV and HCV.

Moving to HIV on slide [8], revenue was down sequentially, as expected, primarily due to seasonal trends. As a reminder, two things happen every year to our HIV business that contribute to a sequential decline from Q4 to Q1:

- First, the channel builds inventory in the fourth quarter and then draws it down in Q1. In the first quarter of 2021, this inventory impact contributed an estimated $410 million to the sequential decline.

- Second, we realize lower net HIV prices in the first quarter due to items such as increased copay support and Part D discounts which tend to normalize through the year.

This quarter, we had two additional impacts.

- A year-over-year decline of $335 million in Truvada and Atripla revenue associated with the LOEs in the US; and

- A difficult comparison in the first quarter of 2020 given the pandemic-related HIV stocking we saw in March of 2020 as well as the impact of the pandemic on HIV market demand.

Our focus is on share driven by demand. Overall, 3 in 4 people living with HIV initiate or switch to Gilead products, highlighting the strength and demand for our life-changing medicines. While the pandemic dampened market size and switch volumes, we **maintained** share in line with prior quarter across our total HIV portfolio despite generic erosion.

In terms of product lines:

- **Biktarvy** was up 8% year over year but down sequentially, as expected, driven by seasonal inventory and pricing dynamics. Despite the pandemic impacting the new starts and switch volume in HIV, demand fundamentals for Biktarvy remain strong, with 5 share point growth compared to the same time last year, and 2 share point growth just in the last quarter in the US. As Dan mentioned earlier, 1 out of 2 people living with HIV initiating or switching therapy is prescribed Biktarvy. Further, nearly half of Biktarvy switches come from incremental sources.

- **Descovy** revenue was down sequentially and year-over-year, largely driven by seasonal inventory and pricing dynamics. Although PrEP volume continues to be impacted by the pandemic, Descovy share remains stable around 45% and positions us well as the PrEP market recovers post-pandemic.

Moving to slide [9], **HCV** first quarter revenue was $510 million. We continue to maintain a leading share of about 60% in the US and 50% in Europe. Despite COVID continuing to impact patient starts, we did see a very modest sequential improvement overall in patient volume, although it remains depressed versus pre-COVID levels. HCV also benefited from a pricing adjustment in France.

As shown on slide [10], in Q1, **HBV and HDV** sales totaled $220M with HBV sales of $214M, growing 15% year-over-year, driven by strong Vemlidy demand, most notably in China and in the US. We continue to expect the HBV franchise sales to reach $1B by FY 2022.

With the completion of the MYR acquisition during the first quarter, our portfolio now includes Hepcludex. There are currently no available treatments for HDV, making Hepcludex, which has received conditional approval by the EMA, a first-in-class treatment. This innovative drug blocks viral entry into liver cells. We are targeting a BLA submission later this year, and are excited by the opportunity to make Hepcludex more broadly available and address the unmet need for people who are infected with HDV.

Moving to slide [11], Trodelvy delivered $72 million in its first full quarter as part of the Gilead portfolio. In a span of just three weeks this month, Trodelvy received FDA full approval for second-line plus metastatic triple negative breast cancer, received accelerated approval in second-line plus metastatic urothelial cancer, and had its ASCENT Phase 3 data published in The New England Journal of Medicine just a week ago.

We can now leverage treatment efficacy data from the full trial population in our discussions with physicians, and build even greater confidence to consider this potentially transformative therapy. This more than doubles the patient population, extending our reach to 6,000 second line metastatic triple negative breast cancer patients in the US, in addition to over 4,000 patients in the third-line plus population. Given the poor prognosis and difficulty in treating both second and third line metastatic triple negative breast cancer patients, Trodelvy could extend median overall survival by almost a year while also nearly tripling the median progression free survival compared to chemotherapy.

Outside the US, we submitted the TNBC Marketing Authorization Application based on the ASCENT Phase 3 clinical study for an accelerated review process. We look forward to continuing discussions with the European Medicines Agency and anticipate approval as early as December of this year. Additionally, Trodelvy is under review for TNBC in the UK, Canada, Switzerland and Australia as part of Project Orbis.

On slide [12], Christi is on the call to answer your questions shortly, but you can see that our Cell Therapy business had a strong quarter, with revenue of $191 million up 36% from the same quarter last year, driven by growing adoption of Yescarta in Europe, with our industry-leading 4-year 44% overall survival. The recent approval for Yescarta in follicular lymphoma will broaden our addressable patient population and support our ongoing growth. Tecartus continues to see strong launch demand as physicians and patients adopt the first and only cell therapy approved for relapsed or refractory mantle cell lymphoma.

Moving to Veklury on slide [13], first quarter revenue was $1.5 billion, with demand tracking hospitalization rates. Although we saw lower hospitalization rates and increasing vaccination rates in certain parts of the world, overall progress was more gradual than expected over the first quarter and as such, we are now assuming a slower pandemic-recovery for the second quarter. As the pace of recovery builds momentum in the second half of the year, this should contribute to a modest recovery in patient starts for our HCV and HIV franchises.

We will continue to play our part to support broader access for eligible patients in need of remdesivir. We are working with our voluntary licensees to accelerate production capacity for India, while also donating 450,000 vials of Veklury to help patients as the supply of licensed generics increases. Our thoughts are with those who continue to tackle the worst of this pandemic.
With that, I'll hand the call over to Merdad.

Merdad Parsey, MD, PhD, *Chief Medical Officer*

Thank you, Johanna. As both Dan and Johanna mentioned, we are off to a solid start in a catalyst heavy 2021, and my comments today will focus on the nearer-term events and changes to our pipeline. A comprehensive update on our broader pipeline is included in the appendix of the slide deck available on our IR website.

I'll start with our virology pipeline. We remain as focused as ever on driving innovation in HIV therapies, and there are no changes to the expected timelines associated with our lenacapavir programs.
In HIV prevention:

- We are activating sites for our first Phase 3 study for lenacapavir as monotherapy for the prevention of HIV and will begin screening patients later this quarter. This study will focus on preventing infection in cisgender men, transgender women and men, and gender non-binary people who have sex with men.

- In the second half of 2021, we plan to initiate a study looking at lenacapavir for the prevention of HIV infections in adolescent girls and young women.

In treatment:

- We presented additional data from Phase 2/3 CAPELLA trial for lenacapavir at CROI and we continue to expect our first lenacapavir filing for use with other antiretrovirals in heavily-treatment experienced individuals in the second half of the year;

- We anticipate data later this year from the Phase 2 CALIBRATE study in the treatment-naïve population to support a virologically suppressed indication; and

- We plan to launch a Phase 2 trial for a long-acting oral treatment combination of Gilead's lenacapavir and Merck's islatravir in the second half of this year. Both medicines have shown long half-lives and high potency at low doses; as such, we believe that the lenacapavir plus islatravir combination is promising. We are excited by our new partnership and working with our colleagues at Merck to bring the maximum benefit possible to people living with HIV.

Based on our commitment to HIV, we continue to work towards a potential cure. We have several early-stage programs evaluating combinations to understand the biology and identify a path for this important mission. Leveraging our internal expertise as well as external partnerships, including Aelix and Gritstone.

On slide [16], moving onto the oncology pipeline, which has over 20 internal clinical stage programs including many built around Trodelvy.

- We're excited to have received full FDA approval of Trodelvy in second line plus metastatic triple negative breast cancer based on the confirmatory Phase 3 ASCENT trial data. In the US alone, this indication expands upon the accelerated approval for third line metastatic triple negative breast cancer to now include second line patients who have had at least one prior treatment for metastatic disease. Trodelvy has the potential to significantly improve overall survival and progression free survival outcomes for patients. In the US, there is a population of 10,000 patients who may benefit from Trodelvy.

- We also received FDA accelerated approval for second-line metastatic urothelial carcinoma based on positive data from the Phase 2 TROPHY study. With almost one-third of patients responding to treatment and a 7.2-month median duration of response, Trodelvy offers a much-needed new treatment option for the many patients with metastatic urothelial cancer whose disease continues to progress despite receiving available first and second-line treatment. In the US alone, we estimate there are roughly 8,000 addressable patients.

2021 will continue to be an exciting year for Trodelvy, and there have been no changes to the 2021 timelines we shared previously:

- We submitted the MAA to the EMA for Trodelvy in second-line plus metastatic TNBC in March, and it is now under accelerated review. We continue to target EU approval in the second half of the year.

- Later this year, we anticipate a Phase 3 TROPiCS-02 progression free survival readout for HR+/HER2- metastatic breast cancer. Pending data, we will evaluate and determine next steps from a regulatory perspective. We estimate there are roughly 17,000 patients in the US who could benefit from Trodelvy in this setting.

- We are now actively recruiting additional patients for the Phase 2 TROPiCS-03 basket study in solid tumors to expand eligibility to patients regardless of TROP2 expression. We have already decided to initiate a Phase 3 trial in NSCLC in the second half of this year, and will share updates on additional planned studies later this year.

Moving to cell therapy on slide [17], with the FDA's accelerated approval of Yescarta for patients with 3L+ follicular lymphoma in March, we have now added a third indication for the Kite portfolio. ZUMA-5 study data showed that 91% of patients responded to a single infusion, with an estimated 74% of patients in continued remission at 18 months. We are working towards making this option available to patients outside the US and continue to target an MAA filing in the next several months.

There are no changes to the expected timelines for the ZUMA-7 study assessing Yescarta for second-line Diffuse Large B-Cell Lymphoma – or DLBCL – patients. We expect to announce the top-line Phase 3 outcome later this quarter, followed by sBLA and MAA submissions in the second half of the year. Additionally, FDA has approved the inclusion of ZUMA-1 Cohort 4's updated safety data into Yescarta's label for 3L DLBCL. Cohort 4 demonstrated that early use of corticosteroids and/or tocilizumab led to reductions in cytokine release syndrome or neurologic events.

Moving to Tecartus, we submitted our sBLA for relapsed or refractory adult B-cell precursor acute lymphocytic leukemia, or ALL, just after the end of the first quarter. If approved, Tecartus would add a much-needed treatment option for patients 18 and older. We plan to share the ZUMA-3 data at ASCO this summer, and we continue to enroll patients for ZUMA-4 to evaluate Tecartus for ALL in the pediatric population.

Consistent with our ongoing diligence across both Gilead and Kite,, we will continue to focus and streamline the Kite portfolio to align with our key strategic priorities and expertise in hematologic malignancies, specifically in lymphoma and leukemia.

Moving to slide [18], in addition to the previously mentioned milestones for virology, Trodelvy, and Kite, we have several other notable upcoming events.

First, I want to take a moment to highlight magrolimab's progress and outlook in myelodysplastic syndrome and acute myeloid leukemia. In MDS, we expect to see Phase 1b data in the second half of the year and, pending results, those data could lead to a BLA submission before the end of the year. If approved, magrolimab would be the first-in-class macrophage checkpoint inhibitor targeting CD47, and Gilead's first frontline oncology indication. There is a significant unmet need for MDS with no new treatments approved in 14 years despite 15,000 new patients diagnosed each year in the US alone.

We are also exploring pivotal studies in frontline AML. Additionally, we continue to evaluate multiple solid tumor indications for magrolimab, most recently initiating a Ph1b/2 2L+ solid tumor basket study and a randomized Phase 2 for head and neck cancer in combination with chemotherapy and Merck's Keytruda.

Second, in virology, we are thrilled to officially add Hepcludex into our portfolio and look forward to a Phase 3 data readout later this quarter, with a potential BLA filing in the second half.

As for potential opt-in programs, Arcus' ARC-7 NSCLC study is expected to evaluate interim data in the second quarter. We and the Arcus team have indicated the interim analysis is targeting an ORR of 50% or greater, and a clear separation in ORR from the zimberelimab monotherapy arm compared to the domvanalimab + zimberelimab combination arm.

Last, on slide [19] you can see our robust, and diversified pipeline across oncology, virology, and inflammation. In addition to the readouts on the previous slide, we have multiple collaboration programs that we are monitoring closely, including:

- Arcus's ARC-8 in pancreatic ductal adenocarcinoma and ARC-6 for castration-resistant prostate cancer, both of which expect initial readouts later this year; and

- The Galapagos SIK2/3 Toledo proof-of-concept trials across psoriasis, ulcerative colitis, and RA are expected to have readouts later this year.

In closing, we are pleased to see how our portfolio has grown from about 30 clinical stage programs 2 years ago to 47 today while maintaining our focus on disciplined management of R&D expenses. We have also gone from 6 molecules approved, filed, or in registrational studies to 15. Our teams have worked tirelessly to continuously evaluate and accelerate priority programs. We are thrilled to see how our portfolio is developing and look forward to accelerating innovation to help transform patient care.

With that, I'll hand the call to Andy.

Andrew Dickinson, *Chief Financial Officer*

Thank you Merdad, and good afternoon everyone. As you can see, we are building momentum in our clinical pipeline, and we expect to have plenty of data to share as we move through the rest of 2021.

Moving to slide [21], the first quarter was a good start to the year, with total product sales in-line with our internal expectations overall as modestly higher Veklury sales offset a slower pandemic-recovery than we had anticipated. In addition to pandemic impacts, our HIV business reflected the inventory seasonality we typically see in the first quarter.

Total product sales were $6.3 billion, up 16% year-over-year, driven primarily by Veklury. The first quarter reflects continued growth from Biktarvy, our first full quarter of Trodelvy sales, and strong growth in HBV as well as Cell Therapy. This growth was offset by ongoing COVID-related softness across our business, in addition to the Truvada and Atripla LOE. As also indicated by Johanna, there is the difficult comparison to the first quarter of 2020 given the pandemic-related HIV stocking observed. As a result, total product sales excluding Veklury were $4.9 billion, down 11% year-over-year.

Non-GAAP product gross margin was 86.5%, 60 basis points lower year-over-year primarily associated with product mix and a small inventory charge, partially offset by favorable royalty adjustments.

Non-GAAP R&D was $1 billion, up 4% year-over-year, primarily driven by investment in new pipeline products including Trodelvy and magrolimab, offset by timing of certain clinical studies and lower Veklury-related expenses. Non-GAAP SG&A was $1 billion, down 4% from Q1 2020, due to timing of grants and sales and marketing activities. This was partially offset by higher commercialization investments associated with Veklury, Trodelvy, Cell Therapy, and HBV and HIV in China.

Moving to tax, we realized a lower rate of 18% for the quarter due to recognition of favorable settlements with tax authorities.

Overall, our non-GAAP diluted earnings per share were $2.08 in the first quarter of 2021, compared to $1.68 for the same period last year. The year-over-year improvement was primarily due to Veklury revenues, flat operating expenses, and a lower tax rate, offset in part by lower interest income.

You can see, on slide [22], that there is no change to our full-year non-GAAP guidance. While the pandemic remains unpredictable, and as we realized a more substantial impact to our core business in the first quarter than we had anticipated, we are nonetheless encouraged by the lower hospitalization rates and increased vaccinations. We have modified our assumptions on the timing of pandemic recovery to allow a more gradual improvement starting in the second quarter.

- We continue to expect total product sales, excluding Veklury, of $21.7 to $22.1 billion.

- We continue to expect full year non-GAAP R&D and SG&A expenses each to be flat to down low-single digit percentage year-over-year.

- Given our first quarter results, you can see our R&D expenses are somewhat back-end loaded in 2021 based on the timing of clinical activities which include the anticipated initiation of the solid tumor study with magrolimab, advancing internal long-acting combinations with lenacapavir for the treatment of HIV, and other pipeline activities. Our work with Merck on a long-acting treatment regimen for people living with HIV is also underway, and will ramp up during 2021, although we are able to absorb this program into our current R&D expense guidance.

- In SG&A, we are ramping up sales and marketing to support efforts such as the ongoing and expected launches such as Trodelvy in the US for bladder cancer and in Europe for triple-negative breast cancer. Additionally, we expect to start seeing higher travel and other costs scale up in the second half of the year as social distancing restrictions lighten up in some geographies.

- Despite the lighter expenses in the first quarter, we're leaving our operating expense guidance unchanged as we expect to catch up on this to some extent later in the year and, for now, to retain the flexibility to manage the timing of clinical and commercial investments.

- We continue to expect our non-GAAP tax rate to be 21% this year. While we are carefully monitoring the discussions on a higher corporate tax rate here in the US, we believe any impact is more likely in 2022 and beyond, although of course a more immediate change could alter our current tax guidance.

- Finally, with no changes to our revenue or operating expense guidance, we continue to expect non-GAAP diluted EPS of $6.75 to $7.45 for the year.

We have updated our GAAP diluted EPS guidance, and now expect to be in the range of $4.75-5.45, down from $5.25-5.95, reflecting fair value losses for our equity holdings in the first quarter, donation expenses, and other pre-tax charges including upfront payments related to collaborations.

On slide 23, you can see that we remain diligent in our capital allocation priorities. Already this year, we have repaid $1.25 billion in debt and are on-track to pay down at least $4 billion by year-end. We have also returned $1.2 billion to shareholders, through dividends and repurchase of shares.

To close, we remain committed to delivering for patients and for shareholders as we look to invest in our business and R&D pipeline while paying close attention to our expenses.

With that, I'll hand back to Dan for a few closing comments. Dan?

Daniel O'Day, *Chairman and Chief Executive Office*

Thanks, Andy. Before we open up for questions, I'd like to thank the broader Gilead team who accomplished a great deal in the first quarter, setting the stage, I think, for quite an exciting year, rich in catalysts across our clinical portfolio.

Of course, Gilead would not be the company it is today without the vision of John Martin, Gilead's Chief Executive Officer for 20 years, who passed away in March. Under his leadership, Gilead transformed the treatment of HIV and viral hepatitis, and became a global organization firmly rooted in its commitment to science and to patients. That commitment will be a constant as we work to take John's legacy forward in Gilead's next chapter.

With that, I'll invite the Operator to begin the Q&A.

Jacquie Ross, *VP, Investor Relations*

Thank you, Operator, and thank you all for joining us today. We appreciate your continued interest in Gilead, and look forward to updating you on our continued progress.