# GILEAD SCIENCES FIRST QUARTER 2022
# EARNINGS PREPARED REMARKS

**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 2022. 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, business and operations, financial projections and the use of capital; and 2022 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.
Now, I'll turn the call over to Dan.

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

Thank you, Jacquie, and good afternoon, everybody. We appreciate you taking the time with Gilead today, and I also want to thank those of you who joined our Virology and Oncology Deep Dives over the last few months. These two events provided a more in-depth view of our portfolio, our strategy, and the teams behind them. We shared a much broader view of our growing clinical pipeline than we had in the past, highlighting its potential to deliver a number of new therapies to address unmet needs for patients, across a diverse range of conditions.

For those of you who joined, I hope you got a deeper sense of why we're confident of sustaining our leadership in virology and growing our oncology revenue so that it becomes more than one third of our total revenue in 2030.

I'll turn now to our performance this quarter and I'm pleased to share that the year is off to a strong start in line with guidance, as shown on slide 4. Total product revenue was up 3% from last year to $6.5 billion, with cell therapy, Veklury, Trodelvy and HIV driving growth. HIV grew 2% year-over-year, primarily driven by Biktarvy, which grew 18% and reported more than 4% market share growth compared to the first quarter of 2021. This is notable given the impact of the Truvada LOE. Sequentially, HIV was down 18%, primarily as a result of first quarter seasonality. Our growing oncology portfolio performed well, with Trodelvy revenue doubling compared to the first quarter of 2021, and cell therapy delivering another strong quarter of growth.

We recently expanded our portfolio of marketed cancer therapies following the FDA approval of Yescarta for second line relapsed or refractory LBCL. I'm also pleased to highlight the FDA approval of our new cell therapy facility in Maryland, which is part of the expected 50% increase in our manufacturing capacity by the end of 2022. The new facility will support our cell therapy growth expectations over the next several years.

Moving to the pipeline, we shared the Phase 3 topline readout from TROPiCS-02 in March showing that the study met its primary endpoint with a statistically significant improvement in progression-free survival vs physician's choice of chemotherapy. Additionally, the first interim analysis of the key secondary endpoint of overall survival demonstrated a trend in improvement. As you know, we are exploring potential pathways for approval with regulatory authorities to bring Trodelvy to these later-stage patients. The details of the study results will be shared at ASCO in June.

At the Oncology Deep Dive earlier this month, we highlighted the broad potential for Trodelvy across multiple tumor types and lines of therapy, with plans to initiate 13 more Trodelvy trials through 2023, including 4 more in 2022.

Turning to slide 5, as you know, the timing for TROPiCS-02 and the NDA decision for CAPELLA are subject to change. In the case of CAPELLA, this is due to the vial compatibility issue that we're working to resolve and we're fully confident in lenacapavir itself. Other than that, we are on track with the remaining targeted milestones we shared with you in January.

We have added some of the newly disclosed trials from our Oncology Deep Dive. Additionally, we're pleased to note that the partial clinical holds for the pivotal magrolimab trials – including ENHANCE-3 for 1L unfit AML shown on this slide – have been lifted. I'm also pleased to share that – despite the hold - there's no change to the timing of the first interim readout for ENHANCE for 1L high risk MDS, which we expect in the first half of 2023. Merdad will share more pipeline details later in the call.

Before I pass over to Johanna, I want to take a moment to thank the Gilead and Kite teams who are putting the full weight of their expertise, passion, and commitment behind all of this work that you're seeing. It is thanks to our 14 thousand employees across the world that we're delivering for patients with diverse conditions and diseases today and advancing a pipeline of innovative new therapies for the future. We have some bold ambitions for the coming years and we're confident of achieving them given the level of innovation and capabilities we have in place today.

Now I'll invite Johanna to share an update on our first quarter commercial performance. Johanna?

**Johanna Mercier, *Chief Commercial Officer***

Thanks Dan, and good afternoon everyone.

Turning to slide 7, we had a solid start to the year with total product sales, excluding Veklury, of $5.0 billion for the quarter, up 2% year-over-year, driven by cell therapy, Trodelvy and HIV, offset in part by HCV pricing dynamics. Quarter-over-quarter, total product sales, excluding Veklury, were down 14%, as a result of the seasonality we typically see in the first quarter of the year, primarily in our HIV business.

On slide 8, you can see that HIV sales were down 18% quarter-over-quarter to $3.7 billion, consistent with our guidance, given the seasonality we customarily experience in the first quarter every year.

> First, the channels build their inventories over the fourth quarter and then draw them down during Q1. On a dollar basis, the majority of the sequential decline was associated with inventory-drawdown.
>
> Second, we realized lower net prices in part due to increased co-pay support, Part D discounts, and other efforts to maintain access and affordability of our HIV medicines as patients' insurance plans reset. This is a customary Q1 dynamic that we expect to normalize throughout the rest of this year.

Year-over-year, HIV sales were up 2% driven by market growth for both treatment and PrEP, offset in part by the impact of the loss of exclusivity for Truvada in 2020. The year-over-year impact of this LOE is expected to be minimal starting in the second quarter of this year. Excluding the LOE impact, HIV sales increased 5%.

Overall, we're encouraged by the signs of recovery seen in the HIV treatment market, despite screening and diagnosis rates still below pre-pandemic levels and the continued impact on market growth due to

the Omicron surge in Q1. As a result, both the U.S. and European HIV treatment markets were down slightly on a sequential basis. On a year-over-year basis, the European market was roughly flat and the U.S. market grew a little over 3%.

The PrEP market grew 33% year-over-year and 3% sequentially. Notably, Descovy continued to hold approximately 45% market share, and we'll continue to engage with payers to ensure those who benefit from PrEP have access to their preferred regimen. We believe Gilead remains well-positioned in PrEP, and – as highlighted during our Virology Deep Dive in February – we expect the market to double by 2030, catalyzed by the launch of long-acting regimens such as lenacapavir.

Descovy sales in the first quarter were $374 million, up 4% year-over-year, driven by continued PrEP market growth, partially offset by generic competition and switches to newer treatment medicines such as Biktarvy.

Turning to slide 9, Biktarvy sales of $2.2 billion in the first quarter were up 18% year-over-year, driven by U.S. market growth and notably, continued share gains in both U.S. and in Europe. Biktarvy remains the leading regimen for new starts and switches in the U.S., and new starts in Europe. In fact, Biktarvy's share is up 4.5% year-over-year to 43% share in the U.S. – almost 8 times larger than the next leading promoted medicine, and representing the highest share of any complete regimen for the treatment of HIV.

Moving to slide 10, in HCV, we maintained steady market share, and the 22% decline year-over-year was primarily driven by unfavorable pricing dynamics. Sequentially, HCV was up 2%, while the overall market and new patient starts continue to be impacted by the pandemic.

HBV and HDV, on slide 11, were up 7% year-over-year, due to higher demand for Vemlidy, namely in Asia. Sequentially, HBV and HDV declined 11% driven by the same HBV seasonal inventory and pricing dynamics impacting HIV.

Hepcludex sales were $11 million for the quarter, primarily reflecting sales in Germany and France where full reimbursement has been established. Our discussions with regulatory bodies in other countries across Europe are ongoing, and of course, we look forward to potential approval in the U.S. in the second half of this year.

Veklury revenues in the first quarter were $1.5 billion as shown on slide 12. Veklury utilization tracks hospitalization rates and therefore – due to the timing of Omicron surges – was lower in the U.S. after January, but higher in Europe and Asia later in the quarter.

We are optimistic that there will not be another surge this year in the U.S. And overall, we will maintain our readiness to support hospitalized and non-hospitalized patients. There is no change to our commitment to COVID-19 patients globally and, in that regard, we were very pleased to receive the World Health Organization's revised COVID-19 guidelines. These guidelines now conditionally recommend Veklury for the treatment of patients with non-severe COVID-19 at highest risk of hospitalization. And earlier this week, Veklury received FDA approval for the treatment of certain pediatric patients who are at least 28 days old, highlighting our ongoing commitment to extend the reach of Veklury where we can.

Now turning to Oncology. Trodelvy sales were up 103% year-over-year and 24% sequentially, as shown on slide 13. We're encouraged by adoption not just in the U.S., but notably in Germany and France and continue to work with health authorities and reimbursement bodies to extend Trodelvy's reach to patients globally. We've completed the expansion of our field force to support the U.S. and Europe and believe we are now at right scale to support physicians and make Trodelvy available across all approved indications to patients who could benefit from it.

We're extremely excited by the feedback from physicians about Trodelvy's impact on patients, both those who are prescribing Trodelvy today and those who expect to have access to it soon. With strong physician uptake and our expanded field footprint starting in April, we believe Trodelvy will benefit more than the 1 in 4 second line mTNBC patients we're reaching in the U.S. today. We look forward to sharing more updates as we progress through the year.

Turning to slide 14, on behalf of Christi and the Kite team, Cell Therapy sales for first quarter of 2022 were $274 million, up 43% year-over-year and 15% sequentially. For the quarter, Yescarta sales of $211 million were up 32% year-over-year and 16% sequentially driven by continued global demand in relapsed or refractory large B-cell lymphoma, as well as in follicular lymphoma. This highlights the growing recognition of the durable long-term survival benefit showcased at last December's American Society of Hematology meeting.

For Tecartus, sales of $63 million were up 103% year-over-year due to strong demand in relapsed or refractory mantle cell lymphoma. We are pleased with the strong early uptake for adult acute lymphoblastic leukemia in the U.S. following approval last October, which contributed to the 11% sequential growth in Tecartus.

The strong momentum we've seen across our Cell Therapy portfolio continued with the approval of Yescarta in second-line relapsed or refractory LBCL earlier this month – as well as FDA's approval for our new Maryland manufacturing facility announced last week. Through capacity improvements across our existing in-house CAR-T manufacturing sites, in addition to the new Maryland site, we expect our manufacturing capacity to increase by up to 50% and support our aspiration to serve a cumulative 25,000 plus patients by the end of 2025.

Second-line orders started coming in the day after the FDA approval and have been steady ever since. It is truly heartening to see the immediate help we provide to patients. Given Yescarta's 2L inclusion in the NCCN guidelines and robust clinical data, we expect Yescarta to shift the paradigm in the standard of care for LBCL patients.

Christi is here with the team and is available to take any questions on Cell Therapy during the Q&A.

With that, I'll hand the call over to Merdad for an update on our clinical pipeline. Merdad?

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

Thank you, Johanna.

2022 is full of clinical activity here at Gilead, and I hope the Virology and Oncology Deep Dives were helpful in highlighting the breadth and depth of our portfolio. By the end of 2022, we expect to have

more than 90 clinical trials underway across oncology, virology, and inflammation. With such a broad portfolio, our focus is firmly on innovation and execution to ensure that we fully leverage its potential.

Moving to HIV on slide 16, we shared exciting one year data from the CAPELLA trials at CROI in February, reporting 83% virologic suppression in heavily treatment experienced people living with multi-drug resistant HIV. Given the significant unmet need of this patient population, the lenacapavir NDA was designated Priority Review by the FDA, and we are planning to re-submit the NDA as soon as we have resolved the clinical hold and Complete Response Letter.

As you know, the basis of these FDA actions was the compatibility of lenacapavir with the vials in use at that time, not lenacapavir itself. We are in ongoing dialogue with the agency to consider an alternative vial, and look forward to updating you of our progress in due course. Separately, we are on track for the HTE MAA approval in Europe in the second half of the year

At our Virology Deep Dive in February, we shared details of the 8 internal candidates that could partner with lenacapavir for treatment, and highlighted the additional early development or discovery assets shown on slide 17. In addition to our PrEP programs, these assets give us a high degree of confidence that Gilead will sustain its leadership in HIV through the 2020s and beyond.

In the immediate term, we continue to generate very strong data for Biktarvy. At CROI, we showed virologic suppression at or above 98% in the M=E analysis, and zero cases of treatment failure due to resistance to any components of the single tablet regimen in two 5-year Phase 3 trials. Of note, this 5-year duration is unprecedented for an HIV regimen.

Moving to slide 18, Veklury is playing an important role in the fight against COVID-19 and is the only antiviral approved for use in both hospitalized and non-hospitalized patients. Just in the last few days, the FDA approved an sNDA for Veklury for the treatment of pediatric patients who are at least 28 days old, and either hospitalized with COVID-19 or with mild-to-moderate COVID-19 and considered high risk for progression to severe COVID-19.

In addition to Veklury, we have an ongoing Phase 1 trial of GS-5245, our investigational oral COVID-19 nucleoside that, once metabolized, works in the same way as remdesivir. Results from this study could lead to a registrational trial, so – even while we hope the worst of this pandemic is behind us – we will continue to work to ensure that COVID-19 therapies are available to as many patients as possible.

Moving to Oncology and specifically Trodelvy on slide 19, we will share more detailed data from the TROPiCS-02 study at ASCO in June. As a reminder, we announced that the study met its primary endpoint, with statistically significant PFS versus physician's choice of chemotherapy in late-line patients, and results consistent with the Trodelvy arm in the IMMU-132-01 Phase 1/2 trial. OS showed a trend in improvement at the first interim analysis, and we are now targeting a final OS analysis in 2024, depending on the timing of events.

In the meantime, we are engaging with regulatory authorities to explore potential pathways given the high unmet need. As a reminder, TROPiCS-02 targeted a more advanced patient population than DESTINY-Breast04. The encouraging clinical data we have seen in this more challenging patient group has strengthened our excitement in exploring earlier stage patients. As we shared two weeks ago, we are planning a pivotal study for front-line HR+/HER2- patients, and will share more information in due course.

In addition to TROPiCS-02, we are targeting First Patient In, or FPI, for a number of new Trodelvy trials this year. In the first half of 2022, this includes front line studies for non-small cell lung cancer, PD-L1+ and PD-L1- mTNBC. And, in the second half of the year, we are targeting FPI for the EVOKE-03 Phase 3 trial for 1L NSCLC. TROPiCS-04 for metastatic urothelial carcinoma is ongoing and we anticipate a readout in the 2023/24 timeframe.

You can see from this slide, shared for the first time at our Oncology Deep Dive earlier this month, that we are in the earliest stages of evaluating how Trodelvy – either alone or in combination – could bring new options to people with cancer. In total, we are studying more than 25 combinations, including 7 Phase 3 combination studies.

On behalf of my Kite colleagues, and on slide 20, I'm pleased to highlight the FDA approval of Yescarta for the 2L treatment of relapsed or refractory large B-cell lymphoma earlier this month. The approval is based on ZUMA-7 trial data that showed that 2.5 times more patients receiving Yescarta were alive at two years without disease progression or need for additional cancer treatment versus the standard of care. This was the first cell therapy approved by FDA for initial treatment of refractory or relapsed LBCL within 12 months of initial treatment. Yescarta was also added to the NCCN's B-cell Lymphomas treatment guidelines for these patients.

Moving to magrolimab on slide 21, we're very pleased that the FDA lifted the partial clinical holds for our MDS and AML trials, and we have resumed enrollment in our three pivotal studies. I'll note that the remaining partial clinical holds on DLBCL and multiple myeloma are being reviewed by a different division of FDA, and we are actively working to resolve them as quickly as possible. In the meantime, the impact of these remaining partial holds is limited, since the DLBCL trial was already fully enrolled at the time of the partial clinical hold, and the multiple myeloma trial had just initiated.

Overall, we are excited by magrolimab's potential to be the first new treatment for first line, high-risk MDS patients in 15 years, and have completed patient enrollment for the first interim analysis that we expect to share in early 2023. In the meantime, we look forward to sharing data from our Phase 1b trial for high-risk MDS and first line TP53 AML with more patients and longer follow up at ASCO in June.

Finally, on slide 22, and noting that the timing for the potential submission for TROPiCS-02 and the NDA decision for CAPELLA are subject to change, there are no updates to the targeted milestones shared with you in January. With our partner, Arcus, we are targeting a number of data readouts in the second half of the year, and have added some new trials, including STAR-121 evaluating zimberelimab and domvanalimab in combination with chemotherapy for front-line non-small cell lung cancer, and ARC-21 to evaluate the same combination in upper GI malignancies.

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

### **Andrew Dickinson,** ***Chief Financial Officer***

Thank you Merdad, and good afternoon everyone.

Before I get into the Q1 P&L review and the guidance update, I wanted to touch on the $2.7 billion partial in-process R&D impairment related to assets acquired from Immunomedics in 2020. This had a

$1.63 per share impact on our Q1 GAAP results and on our full year GAAP EPS guidance. There is no impact to our non-GAAP EPS in Q1, or to our non-GAAP EPS guidance for the full year.

With the TROPiCS-02 data readout in March, we have reassessed the value of the assets acquired. While no final decisions have been made pending discussions with regulatory authorities, as a result of the data, we have taken a $2.7B impairment to reflect the likelihood of a delayed launch of Trodelvy for 3L+ HR+/HER2- breast cancer in the U.S. as well as Europe, and the possibility of a reduced market share in late line patients given the emerging competitive landscape.

Prior to today's update, Gilead was carrying $14.7 billion for the IPR&D indefinite-lived intangible assets acquired with Immunomedics. This now values these assets at $12 billion.

Recall that the carrying amount for Trodelvy reflected four potential indications in progress at the time of the acquisition: triple-negative breast cancer and HR+/HER2- breast cancer, bladder cancer, and non small cell lung cancer. At that time, we knew that Trodelvy's potential extended beyond these indications but, for accounting purposes, did not assign value for the incremental opportunities that we are exploring in prostate, endometrial, and other solid tumors, as well as potential combinations such as with magrolimab, domvanalimab, and PD-1s like pembrolizumab. As you saw at our Oncology Deep Dive earlier this month, there are 13 Trodelvy programs targeted for initiation through 2023, including a number of incremental opportunities. As a result, we remain confident Trodelvy will deliver an attractive return to our shareholders over time.

Moving to slide 24, the first quarter was a strong start to the year, despite the expected seasonality observed in our HIV business, and with stronger than expected Veklury sales.

Total product sales were $6.5 billion, up 3% YoY, with growth in Cell Therapy, Veklury, Trodelvy and HIV, offset in part by lower HCV revenue. Of note, FX negatively impacted first quarter revenue by almost $100 million, net of hedges, representing approximately 160bps of growth.

Total product sales, excluding Veklury, were up 2% from the first quarter of 2021 to $5.0 billion.

In HIV, on a sequential basis, we were impacted – as expected – by the normal seasonality associated with Q1 inventory burn following a build in Q4, in addition to the typical first quarter pricing headwinds that improve through the rest of the year. With Q1 now behind us, we expect sequential growth in HIV through the rest of the year.

Non-GAAP product gross margin was 87.4% for Q1, up 90 basis points year-over year primarily due to lower inventory reserve adjustment.

First quarter non-GAAP operating expenses were largely consistent with our expectations as we support the expansion of our oncology business. Non-GAAP R&D was $1.2 billion, up 10% year-over-year, and non-GAAP SG&A was $1.1 billion, up 5% year-over-year, both primarily due to higher costs associated with Trodelvy.

Moving to tax, our non-GAAP effective tax rate in the first quarter was 18.4%.

Overall, our non-GAAP diluted earnings per share were $2.12 in the first quarter of 2022, compared to $2.04 for the same period last year, reflecting the higher revenue and higher gross margin, offset in part by higher operating expenses.

On a GAAP basis, our effective tax rate and earnings per share were impacted by the $2.7 billion impairment.

We are excited about the strong start to the year and, as you can see on slide [25], the only revision to our outlook is to GAAP EPS, primarily to reflect the $1.63 share impact of the impairment discussed earlier.

We now expect GAAP EPS in the range of $3.00 to $3.50, from $4.70 to $5.20.

On Veklury, we note the strong revenue start to the year, but also – fortunately – the significant drop off in US hospitalizations during the first quarter and into the second quarter so far. With that in mind, we will monitor demand through the second quarter and evaluate our full year guidance in the middle of the year.

One housekeeping item before we wrap up: following recent guidance from the SEC, beginning in the first quarter and similar to our peers, Gilead will no longer exclude acquired IPR&D expenses from non-GAAP financial measures. Prior period results have been updated to reflect this new methodology, and are shared in our supplementary data posted on the Investor Relations website.

As a reminder, our full year guidance does not include the impact of any future upfront payments related to the normal course of business partnerships or licensing deals. Going forward, we plan to update our guidance on a quarterly basis to reflect the impact of any new corporate development transactions closed in the prior quarter.

Moving to slide 26, you can see there is no change to our capital allocation priorities. In the first quarter, we repaid $500 million in debt. Additionally, we returned $1.3 billion to shareholders, through our dividend and repurchase of shares.

Finally, on M&A, there is no change to our philosophy here either. We are very comfortable with the breadth and the quality of the pipeline that we have built, acquired or partnered, and the growth it will enable in the coming years. With that in mind, you can expect us to continue to opportunistically access high quality assets through partnerships, or make smaller acquisitions in the normal course of business.

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