GILEAD SCIENCES SECOND QUARTER 2023
EARNINGS PREPARED REMARKS

Jacquie Ross, CFA, *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 second quarter of 2023. 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 the call to Q&A, where the team will be joined by Cindy Perettie, the Executive Vice President of Kite.

[CLICK to SLIDE 2] Before we get started, let me remind you that we will be making forward-looking statements, including those related to 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 2023 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.

With that, I'll turn the call over to Dan. [CLICK through SLIDE 3 to SLIDE 4].

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

Thank you, Jacquie, and good afternoon, everyone. As always, we appreciate you taking the time to catch up with Gilead in the midst of a busy earnings period.

This was another very strong quarter for Gilead in terms of both business performance and clinical execution. Thank you to the Gilead teams that drove this progress with their dedication to improving the health of individuals and communities worldwide.

Total product sales, excluding Veklury, grew 11% year-over-year, and closed a very strong first half performance in the base business. As we look to the full year, we are increasing guidance for total product sales. We now expect even stronger growth in our base business of 6.5 to 8%, which is expected to more than offset our revised expectations for Veklury. As a result, our guidance for base business product sales has increased $550 million at the midpoint.

In the second quarter, HIV contributed about two thirds of the $615 million growth in our core business, growing 9% year-over-year. Oncology grew 38% year-over-year, and with product sales of $728 million in the second quarter, now has an annual run-rate of approximately $3 billion.

Moving to clinical progress, the second quarter was very active on the regulatory front with approvals, positive opinions or recommendations for six of our therapies: Trodelvy, Yescarta, Tecartus, Sunlenca, Hepcludex, and Veklury. This regulatory progress highlights the strength of our increasingly diverse portfolio. It also reflects the ability of our teams to successfully navigate regulatory processes across the therapeutic areas and key geographies, with speed and efficiency.

In addition to this progress, we shared positive pipeline updates at ASCO, which included:

- Overall survival data for Yescarta, the only large B-cell lymphoma cell therapy to demonstrate significant overall survival benefit versus standard of care in the second-line setting,
- Promising Trodelvy data in endometrial cancer, reinforcing our belief in Trodelvy as a cornerstone asset with pan-tumor potential, and
- Updated TIGIT data from the full study population of ARC-7, establishing domvanalimab's proof-of-concept in lung cancer.

We have also shared long term data for Hepcludex for hepatitis delta virus, showing improved response rates at Week 96 compared to Week 48. These data support new guidelines recommending Hepcludex for people living with chronic HDV in the EU.

With a broad portfolio of novel mechanisms, and a commitment to pursuing areas of high unmet need, we know that some pipeline setbacks are to be expected. As we announced last month, we have discontinued the Phase 3 ENHANCE study in higher-risk MDS, due to futility in a second interim analysis. As you know, MDS is one of the most intractable forms of blood cancer and we are disappointed that this study was not able to deliver new hope for patients with the disease. We will take a thorough, data-driven approach regarding next steps as we carry out the ongoing analyses of magrolimab.

Overall, we are executing well on our clinical commitments, and our current performance speaks to the strength of our combined oncology portfolio. We have a rich pipeline of activity in the second half,

including an initial look at a subset of EVOKE-02 data on Trodelvy plus pembro in first line metastatic non-small cell lung cancer.

Before I hand over to Johanna, I'd like to welcome Cindy Perettie, our head of cell therapy to her first Gilead earnings conference call. Cindy has now been with Gilead for two months, and brings a wealth of oncology and leadership experience from Roche, Foundation Medicine, and the Sarah Cannon Research Institute. We are delighted to have Cindy join our Gilead leadership team, and it's great to have her with us on the call today.

With that, I'll hand the call over to Johanna for a discussion of our commercial results. Johanna?

Johanna Mercier, *Chief Commercial Officer*

Thanks Dan, and good afternoon, everyone.

The second quarter was another strong quarter for Gilead, with solid performance across our commercial portfolio leading to an increase in our full year expectations for both the base and overall business. For the second quarter of 2023, as shown on slide 7, total product sales, excluding Veklury grew 11% year-over-year to $6.3 billion, with year-over-year growth in each of our core franchises. This represents the seventh consecutive quarter of year-over-year growth for our base business – reinforcing the strength of our Virology and Oncology portfolios. This strong growth more than offset the decline in Veklury sales which were as expected given the lower hospitalizations. Altogether, total product sales including Veklury was $6.6 billion, up 7% year-over-year.

Starting with HIV on slide 8, second quarter sales of $4.6 billion were up 9% year-over-year, driven by higher average realized price in part due to channel mix, and higher demand, partially offset by lower channel inventory. Quarter-over-quarter, sales were up 10%, driven by favorable pricing and inventory build following the typical first quarter dynamics.

Overall, the global *HIV treatment market* continues to grow in-line with our expectations of 2% to 3% annually. Specifically, in the U.S., the market overall grew more than 2% in the first half of the year compared to the first half of 2022, reflecting growth in the non-retail channels more than offsetting a roughly flat retail market.

HIV product sales grew 11% in the first half of 2023 compared to the first half of 2022, helped by favorable pricing dynamics, including the phasing of certain government purchases and channel mix. Looking forward, we expect HIV product sales growth to more closely mirror market growth in the second half. Therefore, we are increasing our full year expectations for HIV, and now expect full year HIV product growth for 2023 to be modestly higher than the 5% we reported in 2022.

Turning to slide 9, Biktarvy sales of $3.0 billion were up 17% year-over-year, driven by higher demand and favorable pricing dynamics, partially offset by lower channel inventory.

With a market share up almost 3% year-over-year in the U.S., Biktarvy remains the treatment of choice for HIV with more than 46% market share. This represents the 20th consecutive quarter of share gains in the U.S., with a year-over-year growth rate that has – once again – outpaced new and existing regimens.

Similarly, we continue to see solid share gains across other major markets as Biktarvy maintains its leading position for new starts, as well as for those switching therapies.

Descovy sales were $516 million, up 12% year-over-year. With awareness and utilization of HIV prevention higher than ever, the U.S. market grew once again. And amidst this growth, we're pleased to see strong demand for Descovy for PrEP, up 14% year-over-year in the U.S. – with a strong market share that has remained over 40%. With this strong foundation, we look forward to potentially adding lenacapavir as a six-monthly subcutaneous option for prevention as early as 2025.

Moving to the Liver Disease portfolio on slide 10, sales were up 4% year-over-year and 5% quarter-over-quarter to $711 million. We remain committed to eliminating HCV globally with our market-leading portfolio of medicines, and our efforts to increase awareness contributed to higher patient starts in the U.S., Europe, and Asia in the second quarter. HBV and HDV also contributed to growth in the Liver Disease portfolio, driven by higher demand.

Liver Disease remains an important part of our portfolio, benefiting hundreds of thousands of patients. We're pleased to have received full marketing authorization for Hepcludex in HDV in Europe, a further recognition of the benefit this medicine brings to patients who have very limited therapeutic options. Across our portfolio of HCV, HBV, and HDV products, the Liver Disease contribution to our commercial performance continues to stabilize overall to a run-rate of more than $2.5 billion in sales a year.

Onto slide 11, Veklury sales declined in the second quarter, as expected reflecting lower hospitalization rates, with sales of $256 million, down 43% year-over-year.

For those patients hospitalized and treated for COVID-19, a majority continue to receive Veklury – a testament to Veklury's robust clinical profile. Most recently, this has included decisions by the U.S. FDA and the European Commission to expand Veklury's indication to reach patients with renal impairment, including those on dialysis.

Moving to Oncology on slide 12, it is remarkable to observe that – in less than five years – our oncology business has grown from less than $300 million and is now approaching an annualized run rate of $3 billion, with tens of thousands of patients treated with Gilead and Kite oncology therapies to date. Beyond our well-established leadership in cell therapy, we have the only TROP2-directed ADC on the market with Trodelvy, and – combined – our oncology portfolio extends the options for patients in 8 indications.

Looking in more detail at Trodelvy on slide 13, sales were up 63% year-over-year and 17% sequentially, to $260 million – representing an annual run-rate that exceeds a billion dollars. We continue to be very pleased with the launch in pre-treated HR+/HER2- metastatic breast cancer, with strong awareness of our approval in the U.S. We look forward to reaching even more patients in Europe following last week's marketing authorization from the European Commission. Additionally, we're beginning discussions with health authorities in Japan with plans to file for approval in metastatic triple-negative breast cancer later this year.

With a strong field force in place and robust datasets across multiple tumor types, Trodelvy remains well-positioned to maintain and expand its reach. And Gilead continues to build on our experience in breast and bladder cancers, with a view to other indications over time as the development program evolves.

Turning to Cell Therapy on slide 14, sales in the second quarter were $469 million, up 27% year-over-year and 5% quarter-over-quarter.

Yescarta showed continued growth, with sales up 29% year-over-year to $380 million, primarily driven by strong underlying demand in the second- and third-line settings for relapsed or refractory large B-cell lymphoma, both in existing as well as new markets.

Tecartus sales were $88 million, up 21% year-over-year, reflecting increased demand for relapsed or refractory adult acute lymphoblastic leukemia, as well as mantle cell lymphoma, primarily outside the U.S.

We are excited about the opportunity ahead as the body of evidence supporting broader adoption of cell therapies continues to grow. The work that Kite has been leading to raise awareness and adoption of cell therapy will be accelerated by other providers as they ramp up their manufacturing capabilities. This overall expansion in supply will – predictably – impact our market share in the near-term, but overall class share is the most important driver of our business over time. As cell therapy is offered and delivered to more patients, we are confident that Kite cell therapies will remain differentiated in terms of our manufacturing reliability and efficacy.

Wrapping up the second quarter, I'd like to acknowledge the commercial teams and our partners across Gilead and Kite that – once again – delivered an extremely strong performance, reflecting both solid execution and the compelling portfolio of Gilead products that positively impacts millions of people around the world.

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

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

Thank you, Johanna.

I am pleased to highlight the ongoing progress our teams have made with 64 ongoing clinical programs, and 21 Phase 3 trials. Notably, we presented multiple positive data readouts at medical conferences in the second quarter, such as updated overall survival data for Trodelvy in pre-treated HR+/HER2- metastatic breast cancer, OS data for Yescarta in second-line relapsed or refractory large B-cell lymphoma, and long-term data from bulevirtide in HDV. As we move in to the second half of 2023, we remain focused on execution, investing in capabilities to increase our productivity, and portfolio prioritization. We also look forward to sharing an update on Trodelvy in non-small cell lung cancer, including EVOKE-02 data at World Conference on Lung Cancer in September.

Turning first to Virology on slide 16, we are proud of the role Gilead has played in transforming HIV care. We continue to innovate based on our commitment to both the HIV community and to those who could benefit from a prevention regimen with our ongoing work to deliver new, effective, and convenient options.

The unique profile of lenacapavir, our first-in-class capsid inhibitor, enables the 8 prevention and treatment clinical programs we are focused on.

- In HIV treatment, the ARTISTRY-1 trial evaluating an oral, once daily bictegravir and lenacapavir combination regimen is progressing well. We expect to provide an update on the Phase 2 portion of the study later this year. This novel regimen aims to provide an effective and simpler regimen for the 6-8% of virologically suppressed individuals who are currently on complex, multi-tablet regimens to manage their HIV.

- We continue to advance in our goal of providing longer-acting HIV treatment options through the development of lenacapavir combination regimens with integrase inhibitors, NRTIs, an NNRTI, as well as the Phase 2 study of our 2 broadly neutralizing antibodies.

- In HIV prevention, recruitment for our Phase 3 PURPOSE-1 and -2 clinical trials evaluating every 6 months, single-agent subcutaneous lenacapavir continues to exceed our expectations in the second quarter. We look forward to potentially providing a data update in the late 2024 to early 2025 timeframe as we target approval in late 2025.

Moving onto slide 17, I'm pleased to note that the European Association for the Study of the Liver, or EASL, has updated its HDV guidelines to recommend that all patients in the EU with chronic HDV infection should be considered for antiviral treatment. Recently, Hepcludex was granted full approval by the European Commission, and remains the only approved therapy for chronic HDV infection in the EU. The updated guidelines were supported by Hepcludex's 48-week data, which were published in the *New England Journal of Medicine* in June.

Gilead also presented data demonstrating that 96-week treatment with bulevirtide improved virologic and biochemical responses with no evidence of treatment-emergent resistance – including in those who were previously non- or partial responders. These data reinforce our confidence in bulevirtide and its potentially longer-term benefit for patients with HDV. As a reminder, bulevirtide is not yet approved in the U.S.

Turning to Oncology on slide 18, Trodelvy remains the first and only approved TROP2-directed ADC, with indications across three tumor types. It's also the only TROP2-directed ADC to show overall survival benefit versus chemotherapy in two tumor types. We have now treated over 20,000 patients and evaluated more than 2,300 patients in our clinical trials, Trodelvy's robust dataset informs a well-characterized safety profile, with low discontinuation rates observed across multiple indications and no required increase in monitoring for severe interstitial lung disease.

At ASCO, we presented additional data demonstrating Trodelvy's potential, including:

- In pre-treated HR+/HER2- metastatic breast cancer, we presented the final analysis from our Phase 3 TROPiCS-02 trial, supporting the marketing authorization we just received from the European Commission last week.

- In bladder cancer, we shared an analysis of TROPHY-U-01, supporting Trodelvy's efficacy in post-platinum, post-IO metastatic urothelial cancer, across a range of TROP2 expression. With our accelerated approval in bladder cancer, we hope to provide a data update from the ongoing, confirmatory Phase 3 TROPiCS-04 trial and initiate global filings for Trodelvy in metastatic urothelial cancer by the end of next year.

- In heavily pre-treated endometrial cancer, we presented promising efficacy data from our Phase 2 TROPiCS-03 basket trial, demonstrating the expanding pan-tumor potential of Trodelvy.

Moving to slide 19, our comprehensive clinical development program in non-small cell lung cancer includes several signal-seeking and ongoing Phase 3 clinical trials. We know non-small cell lung cancer is not only an area of significant unmet need – as the number one cause of cancer-related deaths – but also an area we believe Trodelvy has the potential to transform standard of care as a combination partner to an IO backbone in the first-line setting, as well as a single agent in the post-IO setting.

On slide 20, we highlight the growing number of lung-related catalysts.

I'm particularly excited to highlight that we have added a new milestone with a preliminary readout from our Phase 2 EVOKE-02 trial at the World Conference on Lung Cancer. This study is evaluating Trodelvy plus pembrolizumab with or without chemo in first-line non-small cell lung cancer. We will be sharing data from the first two cohorts evaluating Trodelvy in combination with pembro in PD-L1-high and in PD-L1-low patients.

The abstract, expected to be released later in August, will be an initial subset of a small number of patients. Our presentation, scheduled for Sunday, September 10th at World Lung, will include data at a later cutoff date, with more patients.

Turning to domvanalimab, or dom, on slide 21, we presented data from the last interim analysis of the full 150-patients enrolled in the Phase 2 ARC-7 study at ASCO in June. The data continue to show consistent and clinically meaningful improvement in progression-free survival in first-line PD-L1 high non-small cell lung cancer, when dom – our Fc silent anti-TIGIT – is combined with an investigational anti-PD1 agent as compared to the PD1-inhibitor alone. These data form the basis for our dom program encompassing Phase 3 trials in first-line non-small cell lung cancer and upper GI cancers.

Moving to Cell Therapy on slide 22, Yescarta continues to strengthen its position as the cell therapy of choice for large B-cell lymphoma.

At ASCO in June, we presented overall survival data from the landmark Phase 3 ZUMA-7 trial of Yescarta in second-line relapsed or refractory large B-cell lymphoma. At a median follow-up of 4 years, a one-time treatment with Yescarta demonstrated a statistically significant, longer overall survival compared to standard of care, with a 27% reduction in risk of death, representing a 38% relative improvement. Moreover, a majority of the patients in the standard of care arm eventually received a cell therapy off-protocol – and of those, 77% received Yescarta. Overall, Yescarta is the first treatment in nearly 30 years to demonstrate a significant improvement in survival for this patient population, and these data add to the growing body of evidence that positions cell therapy as potentially curative in some populations.

With a strong pipeline of 6 ongoing Phase 2 and 3 trials across lines of therapy, new tumor types, and earlier stage assets, Kite continues to innovate and execute on expanding the potential benefit of cell therapies to new patients, both through internal or acquired innovation and through collaborations.

We are working closely with one of these partners, Arcellx, to support their efforts regarding the iMMagine-1 clinical hold. We remain confident in the therapeutic profile for CART-ddBCMA and the

iMMagine-1 trial based on the data demonstrated to date and share in Arcellx's commitment to delivering this novel therapy to multiple myeloma patients.

Turning to slide 23, we highlight our progress against key clinical milestones for 2023 so far.

We are, of course, disappointed by the outcome of the interim analysis of the ENHANCE trial evaluating magrolimab in higher-risk MDS, given the need for treatment options. We will continue to monitor and report on the other magrolimab trials.

Importantly, while not every trial will be positive, our efforts at building a well-diversified portfolio gives us multiple opportunities to improve the lives of patients. We're excited about our momentum in making oncology and inflammation important contributors to our future, and continue to make strong progress on delivering our key clinical catalysts for this year.

Beyond our near-term milestones, I'd also like to highlight our growing pipeline of early-stage inflammation assets, including our oral alpha-4-beta-7 and the progression of our IRAK4 inhibitor, edecesertib, into Phase 2, as well as the advancement of the BTLA agonist program from the MiroBio acquisition into Phase 1. We're excited by this differentiated inflammation pipeline and the potential to impact important gaps in the treatment of inflammatory diseases.

Overall, we believe we have a very ambitious clinical portfolio that is well-diversified across indication and stage. We look forward to updating you as we progress through 2023.

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

Andrew Dickinson, *Chief Financial Officer*

Thank you Merdad, and good afternoon, everyone.

Turning to slide 25, and as you heard from Dan and Johanna, our base business continued to perform very well in the second quarter, with total product sales, excluding Veklury, up 11% year-over-year driven by growth across all of our product families. FX was still a headwind, albeit more modest, impacting growth by approximately one percentage point.

Total product sales were $6.6 billion, up 7% year-over-year as strong execution in our base business more than offset the lower Veklury sales – as well as FX impact of $82 million.

Moving to the rest of the P&L, on a non-GAAP basis, on slide 26:

- Product gross margin was 86.9%, up 131 basis points from last year.

- R&D was $1.4 billion, up 25% year-over-year, due to higher expenses associated with our broad clinical pipeline, including the acceleration of certain late-stage clinical studies. As a reminder, we have 21 ongoing Phase 3 trials, highlighting the investment we continue to make in Gilead's near- and long-term growth profile.

As mentioned earlier this year, we will continue to manage expenses carefully. And in R&D, with a number of significant mid-to-late stage trials ongoing, we'll continue to follow the science – pivoting investment if and when the data warrant.

- Acquired IPR&D was $236 million, reflecting the XinThera acquisition and expansion of the Arcus collaboration into inflammation, in addition to milestone payments associated with ongoing partnerships.

- SG&A was $1.8 billion, up 45% year-over-year, including the $525 million legal accrual for settlements with certain plaintiffs in the HIV anti-trust litigation, as well as increased commercial activities in Oncology and HIV. Excluding the legal settlement accrual, non-GAAP SG&A expense was $1.3 billion, up 4% year-over-year.

- Moving to tax, our effective tax rate in the second quarter was 21%.

Our non-GAAP diluted earnings per share was $1.34 in the second quarter of 2023, including approximately 32 cents of expense associated with the legal settlement accrual, partially offset by higher product sales. This compared to $1.58 of earnings for the same period last year.

Overall, we had a very strong first half, as highlighted on slide 27, with solid performance in each of our core franchises across Virology and Oncology, driving 13% year-over-year growth, excluding Veklury. Given these strong first half results, we have updated our full-year sales guidance.

Moving to slide 28:

- We now expect total product sales in the range of $26.3 to $26.7 billion, up from $26 to $26.5 billion previously.

- We expect Total product sales, excluding Veklury, in the range of $24.6 to $25 billion, up from $24 to $24.5 billion, previously. This new range represents growth of 6.5% to 8% for our base business year-over-year, compared to 4% to 6% previously.

On Veklury, the second quarter and first half were below our internal expectations. Based on COVID-19 infections and hospitalizations to date, we have lowered our guidance for the full-year to approximately $1.7 billion to bring second half expectations more in-line with our first half experience. As a reminder, Veklury is highly correlated with COVID-related hospitalizations, and as such, its utilization remains variable. We will share another update with you on our third quarter call.

Moving to the rest of the P&L:

- We continue to expect non-GAAP gross margin to be approximately 86%.

- There is also no change to our non-GAAP R&D guidance, where we expect expenses to increase by a low double-digit percent compared to 2022.

- Reflecting the one-time legal settlement accrual of $525 million in the second quarter, we now expect non-GAAP SG&A expense to increase a high single-digit percent compared to 2022.

- Excluding this legal settlement accrual, non-GAAP SG&A expense for 2023 is expected to be down a low single-digit percent compared to 2022, consistent with our prior guidance.

- Non-GAAP acquired IPR&D has been updated to reflect the XinThera acquisition and expanded Arcus collaboration, adding about $200 million, or $0.17 per share. For 2023, we now expect acquired IPR&D to be approximately $900 million, reflecting previously committed acquired IPR&D amounts, as well as known milestone payments from existing collaborations. Similar to prior quarters, we will continue to include expected acquired IPR&D expenses if we announce additional transactions over the course of the year.

We now expect non-GAAP operating income in the range of $10.4 to $10.9 billion, or roughly $650 million lower at the mid-point, due to the $525 million one-time legal settlement accrual and $200 million in additional acquired IPR&D expense – neither of which were reflected in our previous full-year guidance.

Moving to tax, we now expect our non-GAAP effective tax rate to be approximately 17%, reflecting an expected decrease in our tax reserves for the second half of the year.

Altogether, we now expect non-GAAP diluted EPS in the range of $6.45 and $6.80 per share, down from $6.60 and $7.00 previously, as shown on slide 29. The chart illustrates the underlying strength of our business, with the higher product sales guidance flowing through to the bottom-line, in addition to the lower expected tax rate. This is, however, offset by both acquired IPR&D at 17-cents per share, and the legal settlement accrual at 32-cents per share – a non-recurring cost.

On a GAAP basis, we expect diluted EPS to be in the range of $4.50 and $4.85.

Moving to slide 30, you can see there is no change to our capital allocation priorities. We returned $1.1 billion to shareholders in the second quarter – through our dividend and repurchase of shares.

We believe we have built a strong pipeline that will enable Gilead to deliver near- and long-term growth. And of course, we'll continue to remain opportunistic as we look to access high quality assets through partnerships or make smaller acquisitions in the normal course of business. We remain committed to growing our dividend, and to using share repurchases primarily to offset equity dilution, although we will also be opportunistic from time to time.

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