



## **GILEAD SCIENCES FIRST 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 first quarter 2023. The press release, slides, and supplementary data are available on the investors section of our website at [gilead.com](http://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.

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 is 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.

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

Thank you, Jacquie, and good afternoon, everyone.

The Gilead team continued its track record of strong commercial and clinical execution in the first quarter of 2023. Our base business grew at 15% excluding Veklury with total product sales of \$6.3 billion, reflecting outperformance across the portfolio.

On a year-over-year basis, roughly two-thirds of the \$735 million increase in our base business sales was driven by HIV, and the other third was driven by Oncology. Once again, we're seeing the tangible impact of our transformation and the successful diversification of our business.

We saw year-over-year growth in HIV up 13%; Liver Disease – which includes therapies for HCV, HBV and HDV – up 6%, Cell Therapy up 64%, and Trodelvy up 52%. As expected, Veklury revenues continued to track lower rates of COVID-19 hospitalizations. As a result, revenue of \$573 million was down 63% from the first quarter of last year.

On the clinical side, we received another FDA approval for Trodelvy in early February. This latest approval was for a third indication, pre-treated HR+/HER2- metastatic breast cancer. It's early days, but this has been a very strong commercial launch for Trodelvy in the U.S. so far. This further highlights the critical patient need that Trodelvy is addressing in this late-stage population, as well as the effectiveness of our commercial oncology team. We continue to prepare for Trodelvy's approval in pre-treated HR+/HER2- metastatic breast cancer in Europe in the second half of this year.

Another key milestone for the quarter was the announcement of the primary overall survival data from the landmark Phase 3 ZUMA-7 study. Yescarta is now the first and only treatment in nearly 30 years to show a statistically significant improvement in overall survival for initial treatment of relapsed or refractory large B-Cell Lymphoma patients versus historical standard of care in a curative setting. Full results will be presented at this year's ASCO.

Turning to clinical progress in Virology, we continue to add to the body of evidence for lenacapavir's effectiveness as part of a six-month, subcutaneous therapy. At this year's CROI, the team shared positive Phase 1b data on the investigational lenacapavir and bNAbs combination. The bNAbs combination is, of course, just one of the eight long-acting treatment combination options that we're exploring for lenacapavir and we are pleased with our progress so far.

In the meantime, following our first approval of lenacapavir as Sunlenca for heavily treatment-experienced people living with HIV, we are seeing strong engagement from KOLs and physicians who are interested in the full potential of lenacapavir for prevention and treatment. As you know, this first approval addresses a significant unmet need for a small number of people living with HIV who have very limited options available to them. And we look forward to making lenacapavir available to many more people, beginning with the potential approval in prevention in the 2025 timeframe.

We see lenacapavir as having the most promising potential yet in the ongoing efforts to end the HIV epidemic and we're looking forward to working with others to make it broadly available, as soon as possible.

With that, I'll hand over to Johanna for a review of our first quarter commercial performance. Johanna?

**Johanna Mercier, Chief Commercial Officer**

Thanks Dan, and good afternoon, everyone.

The commercial organization delivered a very strong start to the year, and continued to build on the momentum we saw in 2022 to set a firm foundation for continued execution and growth in 2023. As our results show on slide [7], each of our core franchises delivered year-over-year growth, led by HIV and Oncology, and total product sales, excluding Veklury, totaled \$5.7 billion, up 15% year-over-year. Including Veklury, total product sales were \$6.3 billion, down 3%, driven by lower Veklury sales associated with fewer COVID-19 hospitalizations.

On slide [8], HIV sales were up 13% year-over-year to \$4.2 billion, driven by favorable pricing dynamics, higher demand, and lower inventory draw-downs. Quarter-over-quarter, sales were down 12%, associated with the normal seasonality we typically experience in the first quarter.

As a reminder:

- At the start of the year, patient copays and deductibles reset, which have an impact on average realized prices and market growth. We expect these pricing impacts to normalize through the remainder of the year; and,
- We also typically see a build-up in inventory in the fourth quarter followed by meaningful inventory draw-downs in the first quarter. Following a focused effort to better manage this dynamic, we're pleased to see less of an impact than we have historically on both a quarter-over-quarter and year-over-year basis, highlighting our goal of better matching product delivery with end-user demand.

We expect these efforts to contribute to a more stable quarter-over-quarter growth in our HIV business, as compared to prior years.

Turning to Sunlenca, first quarter sales of \$4 million were very much in-line with our expectations. Sunlenca is an important option for the small number of people living with HIV who have developed resistance and have few – if any – other options. We're leveraging the launch to engage with providers and the community ahead of lenacapavir's potential launches in prevention and treatment.

Overall, the *HIV treatment market* grew approximately 2% year-over-year in the U.S., and almost 4% in Europe – tracking in-line with our expectations for annual growth of 2-3%. And in *prevention*, awareness continues to grow with the U.S. PrEP market up over 19% year-over-year.

Moving to slide [9]. Biktarvy sales of \$2.7 billion were up 24% year-over-year, driven by higher demand, as well as favorable pricing and inventory dynamics.

Biktarvy continues to cement itself as the therapy of choice for people living with HIV, now capturing a treatment market share of 46% in the U.S., up 3% year-over-year, and representing a growth rate that has impressively outpaced new and existing regimens. Moreover, Biktarvy has maintained its leading position for new starts across the U.S., Europe, and other major markets – as well as in treatment-switches across most major markets, including the U.S.

On Descovy, sales were \$449 million in the quarter, up 20% year-over-year. Demand for Descovy for PrEP remains strong – up 14% year-over-year. Descovy for PrEP once again maintained its greater than 40% market share. The continued resilience of our PrEP business, despite availability of other prevention options, including generics, provides a solid foundation as we make progress towards the potential approval and launch of lenacapavir for PrEP.

Moving to slide [10]. The Liver Disease portfolio was up 6% year-over-year to \$675 million, highlighting the continuing contribution of our viral hepatitis medicines to patients and the Gilead portfolio. In HCV, sales were \$445 million, up 12% year-over-year, driven by favorable pricing dynamics and timing of purchases by the Department of Corrections. HBV and HDV sales were \$230 million, down 2% year-over-year primarily due to pricing dynamics outside the U.S.

We continue to expect HCV starts to trend down over time, given the curative nature of therapy, with some offset from HBV and HDV. In the meantime, we are pleased to observe solid and stable market shares across all of our liver portfolio.

Onto slide [11] and, as we expected, Veklury sales of \$573 million were down year-over-year and sequentially as COVID-related infections became less severe and hospitalizations remain below peak levels. As a reminder, the winter surge occurred earlier than we had expected – beginning in the fourth quarter and lasting only through the beginning of Q1. As Veklury's use tracks hospitalizations, its sales are volatile and highly subject to surges and the overall path of the pandemic.

Veklury is backed by clinical data and real-world evidence that reinforces its clinical profile, and despite the lower hospitalization rates in the quarter, Veklury's share of hospitalized patients treated for COVID-19 grew modestly, maintaining well over 50% share in the U.S.

Moving to Oncology, and beginning with Trodelvy on slide [12]. Sales of \$222 million were up 52% year-over-year, and 14% sequentially, driven by strong growth both in the U.S. and Europe.

Following U.S. approval in early February, we're off to a strong start with Trodelvy in pre-treated HR+/HER2- metastatic breast cancer, as some clinicians move quickly to make this new option available for patients in this setting. We look forward to extending Trodelvy's reach to these patients in Europe, where a decision is expected later this year.

Of course, our efforts here are underpinned by the successes and learnings in metastatic triple-negative breast cancer, or TNBC. From our expansion of the field force last year, and the strong body of data across a number of tumor types, more physicians are recognizing Trodelvy's clinically meaningful overall survival benefit. This recognition is not just in metastatic TNBC, but also in HR+/HER2- metastatic breast cancer regardless of HER2-negative status.

Now onto slide [13]. Cell Therapy sales in the first quarter were \$448 million, up 64% year-over-year and 7% quarter-over-quarter.

We're pleased with the continued growth of Yescarta, with sales up 70% year-over-year to \$359 million, primarily driven by growth in the second- and third-line settings for relapsed or refractory large B-cell lymphoma. Sequentially, sales were up 6%, driven in part by strong demand and favorable pricing dynamics, both primarily in Europe.

Turning to Tecartus, sales were \$89 million, up 40% year-over-year and 8% sequentially, driven by growing demand for both relapsed or refractory mantle cell lymphoma and adult acute lymphoblastic leukemia.

Looking ahead, we continue to work to raise awareness of cell therapies and increase class share. We believe that compelling data, including ZUMA-7's recent positive overall survival results, in addition to peer datasets in the cell therapy space, will support broader adoption over time.

In summary, it's been a positive start to the year with our current product portfolio of Virology and Oncology medicines delivering strong performance. We look forward to maintaining this momentum through the rest of the year, and beyond.

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. We are off to a strong start in 2023, with our first regulatory approval of the year for Trodelvy for certain HR+/HER2- metastatic breast cancer patients in the U.S., and an additional 10 trials initiated so far this year, including 4 Phase 3 studies. This brings our clinical pipeline to 61 ongoing clinical programs.

Starting with Virology on slide [15], we presented late-breaking data among 83 abstracts at CROI in Seattle in February, highlighting Gilead's continued expertise and leadership across HIV, viral hepatitis, and COVID-19.

In HIV, we shared several data readouts from our lenacapavir-based development programs in prevention and treatment.

- In prevention, we presented pre-clinical *in vivo* data providing further validation that a subcutaneous injection of lenacapavir can confer long-acting protection in an animal model. We believe lenacapavir as a single agent has the potential to be the first, once every 6-month option for HIV prevention. We are currently testing this in our pivotal Phase 3 PURPOSE trials.
- In treatment, we shared Phase 1b proof-of-concept data on twice-yearly lenacapavir in combination with two investigational broadly neutralizing antibodies. At Week 26, 90% of trial participants receiving this combination maintained virologic suppression. Further, treatment with the investigational regimen was generally well-tolerated.

Moving to COVID-19 on slide [16], we also shared positive data from three retrospective real-world analyses of Veklury at CROI. These analyses showed that initiation of Veklury within the first two days of hospital admission reduced death and hospital readmission rates among all patients with COVID-19.

The right-hand side of the slide highlights that both of our oral Phase 3 trials evaluating GS-5245, or obeldesivir, our investigational oral COVID nucleoside, in standard-risk patients and in high-risk patients are now enrolling. Given uncertainties in the global epidemiology of COVID-19, we continue to be cautious with regards to the length of time it could take to fully enroll these trials.

Moving onto slide [17], Trodelvy continues to build momentum as the cornerstone of our solid tumor portfolio.

As expected, the FDA approved Trodelvy for its third indication. Trodelvy is now approved in adults with HR+/HER2- metastatic breast cancer who have previously received endocrine-based therapy and at least two additional systemic therapies for metastatic disease. FDA approval is based on the overall survival benefit seen in the Phase 3 TROPiCS-02 trial. We have already received acceptance of our European filing and continue to expect a regulatory decision from the European Commission in the second half of this year.

The Phase 3 EVOKE-01 trial evaluating the potential for Trodelvy in second line non-small cell lung cancer is ongoing. Additionally, we recently had FPI for the Phase 3 EVOKE-03 study – also known as KEYNOTE-D46. This trial is being led by Merck to evaluate Trodelvy in combination with pembrolizumab in first line PD-L1 high non-small cell lung cancer.

Additionally, we're excited to announce that over 30 abstracts, including an oral presentation of the updated ARC-7 trial data, have been accepted at ASCO this year. Not only do these data highlight elements of our investigational Trodelvy and domvanalimab programs in breast, bladder, and lung cancers, the abstracts include new insights on many of our promising targets, including our Cell Therapy portfolio.

Speaking of which, on slide [18], I'm pleased to discuss the clinical progress we've made within Cell Therapy.

Recently, we highlighted new overall survival data from the Phase 3 ZUMA-7 trial evaluating Yescarta for the initial treatment of adults with relapsed or refractory large B-cell lymphoma. These data will be presented as an oral late-breaker at ASCO. Yescarta is the first and only therapy of any kind to show a statistically significant overall survival benefit versus standard of care in almost 30 years.

As we work to extend our leadership in Cell Therapy within our current portfolio, we are also building out our earlier stage programs. As mentioned in our last earnings call, we closed our agreement to co-develop and co-commercialize Arcellx's CART-ddBCMA for the treatment of patients with relapsed or refractory multiple myeloma.

Also, we closed our acquisition of Tmunity Therapeutics in February, extending our pre-clinical and clinical pipeline in blood cancers and solid tumors. We're currently working to integrate the Tmunity team and their assets into our broader innovation pipeline.

Wrapping up, on slide [19], we're sharing the updated key pipeline milestones that we expect in 2023, which as you can see span FPIs, data readouts, updates, and regulatory approvals across Oncology, Virology, and Inflammation.

Overall, this highlights the progress that Gilead has made on its transformation journey, with 61 clinical programs that are well diversified across indication and stage. We have an ambitious clinical program, and I'd like to thank the Gilead team that has worked tirelessly to execute and accelerate the progress of our portfolio. 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.

Starting on slide [21], the first quarter was a strong commercial start to the year, with total product sales, excluding Veklury, up 15% year-over-year – despite continued FX headwinds. Overall, our base business demonstrated growth in each of our product families, including almost 60% growth in Oncology and 13% growth in HIV.

Total product sales were \$6.3 billion, down 3% due to lower Veklury sales, partially offset by growth in our base business. FX negatively impacted first quarter total product sales by \$106 million, representing approximately 160 basis points of growth.

Turning to slide [22], non-GAAP product gross margin was 86.2%, down 1.2 percentage points from last year, due to – among other things – the timing of the Biktarvy royalty initiation in the first quarter of 2022 and product mix, partially offset by inventory benefits.

Moving to opex, expenses were higher than we anticipated in the first quarter due to R&D investments and inflationary pressures.

Non-GAAP R&D was \$1.4 billion, up 25% year-over-year, due to higher expenses including the acceleration of certain late-stage clinical studies, as well as about \$50 million in one-time items. As Merdad mentioned, we have started 10 new trials so far this year, including four Phase 3 programs. This brings the total number of ongoing Phase 3 studies to 22, highlighting the investment we are making in Gilead's future growth. Clinical trial enrollment for a number of new and ongoing Trodelvy and lenacapavir trials was faster than we expected, with a notable acceleration – for example – in certain lenacapavir trials in March.

Our clinical team has been working hard to rapidly advance our studies and bring new therapeutic options to patients as fast as we can. This includes working to close the gap that some peers have in certain programs and we believe we are starting to see the impact of these acceleration efforts in our trials, although this did contribute to higher R&D expenses in the first quarter.

Consistent with past practice, we will continue to manage expenses carefully, including the ongoing process of prioritizing programs based on potential impact and data. We have taken the last several years to build the most diverse and robust clinical pipeline in Gilead's history, now with well over 100 trials across our three, targeted therapeutic areas. We are excited to see so many of these programs in later-stage trials with a number of data readouts building momentum over the next several years.

Non-GAAP acquired IPR&D was \$481 million, primarily driven by expenses related to our acquisition of Tmunity, as well as upfront and milestone payments associated with the Arcellx and Nurix collaborations.

Non-GAAP SG&A was \$1.3 billion, up 22% year-over-year, primarily due to the commercial expansion and investments in our oncology business, in addition to higher Branded Prescription Drug fee expenses, and higher corporate expenses that continue to be impacted by inflation.

Moving to tax, our non-GAAP effective tax rate in the first quarter was 18.9%, lower than expected driven by discrete tax benefits recorded in the first quarter.

Overall, our non-GAAP diluted earnings per share was \$1.37 in the first quarter of 2023, compared to \$2.12 for the same period last year, reflecting higher operating expenses and lower product gross margin.

I'll move now to guidance for the full-year 2023 on slide [23]. There is no change to our revenue guidance.

- We continue to expect total product sales in the range of \$26 billion to \$26.5 billion; and,
- We continue to expect total product sales, excluding Veklury, in the range of \$24 billion to \$24.5 billion, representing growth of 4% to 6% for our base business year-over-year.

On Veklury, the first quarter was modestly below our internal expectations, and our \$2 billion full year guidance assumes an increase in infections at some point later this year, not dis-similar from what we saw in 2022. We know from experience that COVID-19 related sales are extremely volatile and are leaving our guidance unchanged pending additional data points as we move through the year.

Moving to the rest of the P&L:

- We continue to target non-GAAP product gross margin of approximately 86%.
- As discussed, we now expect full-year 2023 non-GAAP R&D expenses to increase a low double-digit percentage compared to 2022. This results in an overall R&D investment for the full-year in the low-20s as a percentage of total revenue. We believe this is a more appropriate level of investment for a company with a broad, late-stage clinical portfolio that is targeting attractive opportunities and sustainable revenue growth.

- We continue to expect non-GAAP acquired IPR&D to be approximately \$700 million, reflecting previously committed acquired IPR&D amounts. Similar to prior quarters, we will continue to include expected acquired IPR&D expenses as we announce additional transactions over the course of the year.
- Moving to non-GAAP SG&A, there is no change to our prior guidance, where we expect a full year decline by a low-single digit percentage compared to 2022, although we will continue to look for opportunities to partially offset the higher R&D investments we now plan for this year.
- Overall, there is no change to our expectations for non-GAAP operating income in the range of \$11.0 billion and \$11.6 billion.
- Additionally, there is no change to our tax guidance, and we continue to target a non-GAAP effective tax rate of approximately 20%.
- And finally, we continue to expect non-GAAP diluted EPS in the range of \$6.60 and \$7.00 per share, reflecting, first, that the initial guidance model we shared with you in early February allowed for a broad range of potential revenue and expense scenarios and, second, that we are committed to finding room in our overall P&L to absorb the higher R&D investments that we are choosing to prioritize in 2023.
- On a GAAP basis, we expect diluted EPS to be in the range of \$4.75 to \$5.15.

Moving to slide [24], you can see there is no change to our capital allocation priorities. We returned \$1.4 billion to shareholders in the first quarter, through our dividend, and repurchase of shares.

Finally, on business development, there is no change to our philosophy. 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.

And now, I'll hand it over to Dan for some closing remarks.

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

Thanks, Andy. Before we open for Q&A, I'll just summarize our prepared remarks by noting that this is another quarter where we demonstrated the continued impact of our transformation.

Going forward, we are committed to building on the track record of strong commercial and clinical execution that we've shown in recent quarters, thanks to the dedication of the Gilead and Kite teams around the world. With this positive momentum, we look forward to delivering on our portfolio while maintaining financial discipline.

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