



## **GILEAD SCIENCES THIRD 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 third quarter of 2021. 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. 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. Starting on slide 4, this was a very strong third quarter with significantly higher than expected demand for Veklury and positive HIV share gains as the market continues to recover.

The high demand for Veklury was associated with the latest surge in cases of COVID-19. The therapy has now been provided to more than *nine* million people worldwide, including 6.5 million people in 127 middle- and low-income countries through our voluntary licensing program. All of us at Gilead are proud of the role that Veklury continues to play. I wanted to acknowledge the way our teams have navigated the unpredictable path of the pandemic, flexing our own operations and supporting our partners' efforts to ensure Veklury and remdesivir are available to meet patient demand.

At the same time, we're applying our three decades of expertise in virology to advance new options that can be taken outside the hospital and earlier in the disease. We recently filed an sNDA for IV outpatient use of Veklury. This is based on data from our Phase 3 PINETREE study that demonstrated a significant reduction in the risk of hospitalizations after a 3-day IV treatment of Veklury in the outpatient setting. In order to meet additional treatment needs, we also continue to advance our oral programs to develop a novel best-in-class therapy.

Turning to HIV performance, we saw positive gains in the treatment market for the second quarter in a row and reported record revenue for Biktarvy. While treatment prescription volumes remain below pre-pandemic levels, we maintained total U.S. and EU treatment market share and we grew Biktarvy share sequentially in both geographies. The PrEP market continues to recover and our PrEP market share is holding steady despite generic entry. Overall, our third quarter results give us confidence that the HIV market is recovering from the pandemic and our market share clearly highlights Gilead's strong market position.

As a result of the strong quarter, we have increased our full year revenue and earnings per share guidance. Veklury now looks set to deliver close to twice the revenue we expected at the start of the year. While our base business has clearly been affected by COVID, it has also shown resilience. At the guidance midpoint - we are now expecting full-year *total* revenue to be \$1.75 billion higher than we expected at the start of the year.

Our confidence in the longevity of our HIV business is in part based on our progress in developing the next generation of HIV therapy and prevention. Lenacapavir is the cornerstone of that work and we have four clinical trials evaluating lenacapavir across treatment and prevention, highlighting our efforts to extend the options available to people living with or at risk of HIV. This quarter, lenacapavir was granted FDA priority review for the heavily-treatment experienced population. As a reminder, lenacapavir has Breakthrough Therapy Designation and, if approved, would be the first long-acting treatment for people living with HIV who have multi-drug resistance, as well as the first available 6-month, long-acting subcutaneous injection treatment for HIV.

Separately, as you know, we signed an agreement with Merck earlier this year to explore combinations of lenacapavir with islatravir in long-acting treatment. Earlier this week, we announced the start of a Phase 2 study with Merck evaluating a lenacapavir and islatravir long-acting oral combination treatment. Our approach to long-acting is very much shaped by people living with HIV. We have heard that they would welcome weekly oral or infrequent subcutaneous injections that could coincide with routine office visits or even be taken at home. The advantages of these options include greater convenience, the potential for stronger adherence and privacy. Lenacapavir has shown promising potential in both oral and subcutaneous injections and we will continue to advance both options while updating you on our progress throughout.

While extending our leadership in HIV, we are also executing on the significant potential in our broad and diverse oncology portfolio. This is potential that could bring transformational benefits for people with cancer and value for all stakeholders.

Third quarter highlights include:

- The initiation of two solid tumor trials for magrolimab – head and neck cancer and a multi-tumor basket study. We plan to initiate an additional Phase 3 study in first line unfit acute myeloid leukemia, or AML, in early 2022;
- The FDA approval of Tecartus for adult relapsed or refractory acute lymphoblastic leukemia, or ALL, is our fourth approved indication in cell therapy. Additionally, the Kite team has filed an sBLA for Yescarta in second-line LBCL which, if approved, would be the first CAR T therapy in an earlier line setting; and
- A positive CHMP opinion for Trodelvy in second-line metastatic TNBC earlier this month. We expect an approval decision from the European Commission later this year and this could potentially be our 6th approval for Trodelvy in TNBC in 2021.

Additionally, we have just announced a new clinical trial collaboration and supply agreement with Merck to evaluate the combination of Gilead's TROP2 antibody drug conjugate Trodelvy with Merck's anti-PD1 therapy Keytruda for the treatment of first line metastatic triple negative breast cancer. When we acquired Immunomedics last year, we said that we would explore the use of Trodelvy across a wide range of tumor types and that we would pursue combinations with both internal and external molecules. You can see this start to play out now, with this Merck partnership as an early example of our approach.

Next on slide 5, I'm pleased to note we delivered on three of our target milestones for the quarter. You will also note that the timelines for TROPiCS-02 and the Phase 1b magrolimab trial have shifted, as we now expect to have the PFS readout for TROPiCS-02 in late January or early February and the topline readout for the Phase 1b magrolimab in the first quarter of 2022. Merdad will also touch on this later in the call, but as you know these modest timeline adjustments are quite normal in oncology especially event-driven trials like TROPiCS-02. We look forward to sharing these updates in Q1 2022.

Taken as a whole, our oncology portfolio now spans some of the most promising targets in the field today. In addition to Trodelvy for TROP2, CD47, and cell therapy, these include TIGIT, adenosine and many others. We are very encouraged by the momentum across these programs and look forward to sharing much more in the coming quarters.

The positive momentum overall in the third quarter gives us great confidence in the direction we are taking and the pace of our progress. We are well on our way with the plans to sustain our leadership in HIV and, while there is much more to come in oncology, we have already begun to execute on the potential in our highly promising portfolio. Veklury is making a significant impact as the pandemic continues to evolve and we are well-placed for when the HIV market bounces back. I want to thank all the Gilead and Kite employees around the world who are making all this possible with their passion for scientific excellence and their commitment to global public health.

With that, I'll hand over to Johanna who will share an update on our commercial performance in the third quarter.

**Johanna Mercier, Chief Commercial Officer**

Thank you Dan, and good afternoon everyone.

As you can see on Slide [7], total product sales of \$7.4B grew 13% year over year, primarily driven by Veklury. Excluding Veklury, total products sales were \$5.4B, down 3% year over year, primarily due to the impact of the Truvada and Atripla LOEs, offset by continued growth in Biktarvy and contributions from our new medicines such as Trodelvy.

On slide [8], Veklury sales of \$1.9B were up 132% sequentially, and reflected strong US demand consistent with the recent surge in COVID cases including the Delta variant. Over 60% of patients hospitalized with COVID-19 in the US receive Veklury, and we continue to expect Veklury sales to track hospitalizations, which you can see peaked at the end of August and have been declining ever since.

Moving to HIV on Slide [9], revenue of \$4.2B grew 6% sequentially driven by favorable net pricing and strong demand for Biktarvy, partially offset by a continuation of the trend towards a less favorable payer mix.

While sequential trends were strong, total HIV revenues were down 8% year-over-year given the impact of the Truvada and Atripla LOEs and lower channel inventory, primarily driven by pandemic-related stocking in the prior year. Excluding the impact of the LOEs, HIV revenues were up 4% year-over-year.

Overall, we are encouraged by the improving trends in HIV treatment. The U.S. HIV treatment market grew about 3% sequentially, suggesting a modest pick-up from the recovery that started in Q2.

- Our share of the overall U.S. HIV treatment market continues to hold steady at approximately 75%. And reflecting the modest pandemic recovery and strong share gains, Biktarvy revenues grew 20% year-over-year and 14% sequentially to a record \$2.3 billion.
- Descovy revenue of \$433 million was flat quarter-over-quarter, driven by increased demand and inventory, offset by lower net price. We continue to see recovery year-to-date with the PrEP market growing 12% quarter-over-quarter and are encouraged to see Descovy share holding steady around 45% despite the availability of multi-source generic versions of Truvada.

Next, on slide [10], Biktarvy continues to gain market share sequentially and year-over-year both in the US and the EU5. We are particularly pleased to see sequential quarterly growth of 1.5% in the U.S. and 1.0% in the EU5, especially given Biktarvy's leading market share. We are proud to see continued uptake of Biktarvy, now capturing 41% of the total treatment market in the U.S. with more than 57% of people living with HIV starting treatment on Biktarvy.

On slide [11], HCV revenue of \$429M was down 8% year-over-year, primarily driven by a favorable settlement in the third quarter of 2020 that did not repeat, fewer patient starts outside the U.S., and the timing of Department of Corrections purchases on a relative basis. Sequentially, HCV revenue declined 22% due to inventory dynamics, including a sizeable purchase by the Department of Corrections in the prior quarter, and fewer patient starts. Although starts improved in some geographies year-over-year,

we saw sequential declines in the US and EU5 driven by continued pandemic-related impact on patient visits and lower testing volumes in addition to normal seasonality. However, we continue to be pleased that Gilead HCV market share is holding steady around 60% in the US and just about 50% in the EU5.

Moving to slide [12], HBV and HDV revenues of \$247M were up 17% year-over-year, driven by Vemclidly demand in international markets and the addition of Hepcludex to our portfolio. Q3 revenue for Hepcludex was \$12M reflecting sales now in Germany, France, Austria, and Greece. We are actively working with government authorities to secure full reimbursement in the major European markets in 2022.

Moving to Trodelvy on slide [13], third quarter revenue of \$101M grew 13% quarter-over-quarter driven by increased share in mTNBC in part due to the expansion to second line. Trodelvy was approved for second line mTNBC in the US in April, and we already estimate that approximately 15% of second line patients are receiving Trodelvy. In the third line or later setting, we estimate that about one third of patients with mTNBC are receiving Trodelvy. In urothelial cancer, at least 1 in 4 bladder cancer patients in the third line or later setting start treatment on Trodelvy. And with adoption in second-line still early, there is continued opportunity for growth across both settings.

We are pleased with the uptake so far and remain focused on broadening physician awareness in community settings. Following recent NCCN Breast Cancer and ESMO clinical guideline updates, Trodelvy is now included as a preferred regimen in second line metastatic TNBC in both guidelines, and we expect this will drive further adoption. We are preparing the first commercial launches of Trodelvy for mTNBC in Great Britain, Australia, Canada, and Switzerland. And later this year, we are expecting a decision from the European Commission following the recent positive opinion from the CHMP. Next, on slide [14] and on behalf of Christi and the Kite team, our cell therapy products grew 51% year-over-year to \$222M. This was driven by LBCL demand and strong launches in both mantle cell lymphoma and follicular lymphoma, more than offsetting the expected impact of new U.S. entrants in LBCL.

With the addition of our new MCL and FL indications, we are particularly proud that we have maintained our best-in-class manufacturing operations with a 97% reliability rate. To support our expected growth, we are working to bring our new Maryland facility online in mid-2022, which will automate many of our manual processes and reduce COGS.

We also wanted to highlight the recent FDA approval of Tecartus in adult ALL. This makes Tecartus the first and only CAR T therapy now available to these eligible patients in the US. The Kite team has also filed a supplemental BLA for Yescarta in second line LBCL, which would bring us one step closer to potentially curing even more patients.

Christi is here with the team and available to take questions on cell therapy during the Q&A. With that, I'll hand it over to Merdad for pipeline updates.

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

Thank you, Johanna. As always, I'll focus today on the most important updates and refer you to the appendix of the earnings presentation for a more comprehensive view of our pipeline programs.

First, on slide [16] in HIV prevention, we have initiated the 5,000-plus participant Phase 3 PURPOSE 1 trial studying lenacapavir for prevention in adolescent girls and young women who are at risk of HIV infection. We are also in the initial stage of recruiting for PURPOSE 2 to evaluate lenacapavir for prevention in over 3,000 cisgender men, transgender, & gender non-binary who have sex with men, and we will provide updated timelines once enrollment is further along.

In HIV treatment, the FDA granted priority review in August for lenacapavir for the treatment of people living with HIV who have developed multi-drug resistance to other anti-retrovirals. This is based on compelling CAPELLA data that demonstrated 81% of heavily treatment-experienced individuals achieved viral suppression when lenacapavir was combined with an optimized background regimen. The PDUFA action date has been set for February 28, 2022 and, if approved, lenacapavir would become the first available 6-month, long-acting subcutaneous injection treatment for HIV.

Earlier this week, we announced enrollment has started for the Phase 2 trial for the long-acting oral combination of lenacapavir and islatravir. This is part of our collaborative work with Merck to develop more flexible options for people living with HIV with a once-weekly oral pill. Gilead is leading the development and clinical work for this oral combination, and Merck is leading the clinical work for the injectable combination that is expected to enter Phase 1 clinical trials next year.

Moving to Veklury on slide [17], we presented a late-breaker at the IDWeek 2021 conference last month based on the Phase 3 PINETREE study evaluating Veklury as an outpatient, IV treatment for COVID-19. The results demonstrated that a three-day course of Veklury significantly reduced the risk of hospitalization for high-risk patients with COVID-19. In particular, Veklury demonstrated a statistically significant 87% reduction in risk for the composite primary endpoint of COVID-19 related hospitalizations or all-cause mortality by Day 28 compared with placebo. There were no deaths in either arm of the study by Day 28.

We stopped PINETREE enrollment at the halfway mark of 584 patients in April due to the COVID-19 landscape at the time, but the study remained blinded and collected outcome data in the enrolled patients. Upon analysis of those data, the results were highly statistically significant and clinically meaningful – yet again demonstrating the efficacy of Veklury. It also emphasizes the importance of early treatment with antiviral therapies. We have submitted these data as an sNDA filing to FDA and are in discussions with other regulatory agencies to explore approval for IV Veklury in an outpatient setting. We are also continuing our work to develop novel oral antivirals for the treatment of COVID-19.

Moving to slide [18], we continue to view Trodelvy as a pipeline in a product. Trodelvy targets TROP2, which is overexpressed in many solid tumor cells, so we believe that Trodelvy can have meaningful impact on a wide range of cancers in addition to the second line metastatic TNBC and second line bladder indications that are approved today.

We are all eagerly anticipating the readout from the Phase 3 TROPiCS-02 study, our randomized Phase 3 trial in HR+/HER2- metastatic breast cancer. As a reminder, this is an event-driven trial evaluating

disease progression and we have not yet achieved the target number of events. As such, we now expect to have the topline data readout in late January or early February. To be clear, data analysis will only begin once we achieve the required number of events; we remain confident of the potential for Trodelvy to deliver a clinically meaningful benefit to patients with HR+/HER2- metastatic breast cancer.

We continue to advance Trodelvy into registrational studies for other indications. For example, as recently posted on [clinicaltrials.gov](https://clinicaltrials.gov), we plan to initiate the Phase 3 trial in second to third-line non-small cell lung cancer at-risk and look forward to sharing updates for other solid tumors as we expand the program. As Dan mentioned, we'll also start to work with Merck on a new clinical study looking at Trodelvy in combination with Merck's Keytruda for first line metastatic TNBC, and plan to initiate the trial in 1H22.

Moving to slide [19], we continue to believe that with its synergistic potential and the safety profile observed to date, magrolimab could benefit patients with a variety of hematological and solid tumors. As you know, our initial focus has been MDS and AML. While our commitment to these patients remains unchanged, we continue to evolve our clinical programs in the context of recent developments in the MDS therapeutic landscape. The ongoing Phase 3 ENHANCE trial evaluating magrolimab in higher-risk MDS is on-track and enrolling well. We will discuss our development plans and regulatory path forward with the FDA before the end of the year. Meanwhile, the data from our Phase 1b trial continues to mature, and we now expect to share topline data in the first quarter of 2022.

Looking beyond MDS, our ENHANCE-02 trial for magrolimab in 1L TP53 mutant AML is ongoing, targeting a new therapeutic option for nearly 2,000 patients in the US. In addition, an estimated 6,000 patients in the US are diagnosed and treated annually with unfit AML, so we are expanding our development efforts to initiate a Phase 3 trial for 1L unfit AML by early next year.

Over the past few months, we have initiated 2 solid tumor trials, namely head and neck cancer and a solid-tumor basket-study for non-small cell lung cancer, small cell lung cancer, and urothelial cancer, and plan to initiate a third study in metastatic TNBC. Based on the broad CD47 expression observed in the literature, we are excited by magrolimab's potential to be an effective therapy for solid tumors and look forward to sharing more updates as they become available.

Next, on behalf of Christi and the Kite team, I also wanted to highlight the most recent approval for Tecartus in adults with relapsed or refractory ALL on slide [20]. There is an incredibly high unmet need for these patients with 50% of adult patients relapsing on currently available treatment. The approval was based on data from ZUMA-3, which demonstrated 65% of patients achieved complete remission.

Additionally, as Johanna mentioned earlier, Kite has filed the sBLA for Yescarta in second line LBCL. With a median follow-up of two years, the study met the primary endpoint of event-free survival with a hazard ratio of 0.398 and p value of less than 0.0001, representing a potential significant advance in the standard of care for LBCL patients. We look forward to reviewing the entire dataset at ASH and expect an update next year on approval status.

Lastly, moving to slide [21], we remain very excited about our oncology partners, whose work spans many promising new pathways in oncology. For example, our partner Arcus has a pipeline that includes not only anti-TIGIT candidates, but also CD73 and adenosine receptor inhibitors to promote immune responses and inhibit tumor growth. We continue to expect to trigger the opt-in review period for Arcus' domvanalimab likely later this year or early next year, pending the review of more mature data.

Additionally, through our partnerships, we have access to several candidates that could help modulate immunosuppressive and tumor-permissive cell types and pathways, including:

- Tizona's HLA-G checkpoint inhibitor, which recently expanded to a Phase 1b; and
- Jounce's CCR8 inhibitor, which received IND clearance last quarter.

Other potential opt-in programs from partners include:

- Pionyr's TREM1 and TREM2 antibodies, which are in Ph 1 trials and actively enrolling patients; and
- Agenus's CD137 agonist, which is expected to be evaluated in a combination trial that will be initiated later this year.

In closing, on slide [22], our teams are focused on executing across our oncology, virology, and inflammation pipeline. And while it's still early days for our inflammation portfolio, we remain committed and invested in continuing to advance our pipeline across various mechanisms of action, such as IRAK-4, alpha-4-beta-7, and TPL2.

In combination with our opt-in partners, our pipeline portfolio spans many of the most promising targets across our three key therapeutic focus areas. We are excited and committed to build out best-in-class and industry-leading franchises.

I'll now hand it over to Andy.

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

Thank you Merdad, and good afternoon everyone.

Moving to slide [24], as you've heard from Johanna, our financial performance in the third quarter overall was strong, with total product sales up 13% year-over-year, driven by Veklury's continued role in the pandemic.

Year-over-year, total product sales excluding Veklury fell 3% due to lower Truvada and Atripla sales following their loss of exclusivity late last year, offset in part by continued demand for Biktarvy and contributions from our new medicines such as Trodelvy.

Sequentially, total product sales excluding Veklury were up 2%, highlighting the ongoing pandemic recovery in HIV treatment and PrEP. This was partially offset by HCV where new starts in both the US and Europe continued to be impacted by the pandemic.

Turning to the rest of the P&L:

- Non-GAAP product gross margin was 90%, 350 basis points higher year-over-year, reflecting the reversal of a previously recorded \$175 million litigation reserve, as well as lower royalty expense and a change in product mix.

- Non-GAAP R&D was \$1.1 billion, down 4% year-over-year, reflecting lower remdesivir and inflammation related expenses, offset in part by increased clinical investment in Trodelvy and magrolimab.
- Non-GAAP SG&A was \$1.2 billion, up 8% year-over-year, driven by increased promotional and marketing activities across all geographies, primarily for Trodelvy.
- On tax, we realized a higher effective tax rate of 18.9% for the third quarter, or up 50 basis points year-over-year, primarily due to a prior year net discrete tax benefit.

Overall, our non-GAAP diluted earnings per share was \$2.65 for the quarter, compared to \$2.11 for the same period last year. The year-over-year increase primarily reflects higher Veklury sales and product gross margin, offset by higher SG&A, lower interest income, and higher effective tax rate.

On slide [25], you can see that Veklury has already exceeded our prior guidance for the year, with total revenues of \$4.2 billion in the first nine months. As a result, and with modestly updated expectations for the rest of our business, we are increasing our revenue and earnings per share guidance for the full-year by 6% and 13% at the midpoint, respectively, as shown on slide [26].

After the wave of infections and hospitalizations in recent months, we believe we have moved past the peak of the pandemic for this year. We continue to expect Veklury will play an important role in the treatment of patients with COVID-19 globally, however, assuming we do not experience another surge, we expect Veklury revenue to step down *significantly* in the fourth quarter. As a result:

- We are raising our full year total product sales in the range of \$26.0 to \$26.3 billion, compared to our previous range of \$24.4 to \$25.0 billion, reflecting results year-to-date and Veklury performance.
- We now expect full-year Veklury revenues to be in the range of \$4.5 to \$4.8 billion, up from our prior outlook of \$2.7 to \$3.1 billion. We continue to expect that sales of Veklury will continue to track COVID-19 related hospitalizations.
- We now expect full-year total product sales excluding Veklury to be approximately \$21.5 billion, compared to the prior range of \$21.7 to \$21.9 billion, reflecting our performance year-to-date and continued pandemic-related impact.

As for the rest of the P&L:

- We expect our non-GAAP product gross margin to be approximately 87%, compared to 86% to 87% previously, primarily reflecting the strong gross margin in the third quarter.
- For non-GAAP operating expenses,
  - We now expect R&D to decline mid single digit percentage compared to 2020 levels as compared to our prior expectations of low to mid single digit percentage decline.

- We expect SG&A to be flat on a dollar basis compared to 2020, versus prior expectations of flat to low single digit percentage decline.
- Our non-GAAP effective tax rate is still expected to be approximately 21% this year.
- Finally, with the updates to our revenue, product gross margin, and operating expenses, we now expect our non-GAAP diluted EPS to be between \$7.90 and \$8.10 for the full-year, and GAAP diluted EPS to be between \$5.50 and \$5.70.

On capital allocation, our priorities have not changed. We continue to invest in our business and, at the same time, we've returned over \$1 billion in the third quarter and \$3.2 billion year-to-date to our shareholders, through dividends and share repurchases.

We have also repaid \$3.75 billion in debt this year. And earlier today, we notified our 3 non-call 1 bondholders that we would exercise our ability to repay \$1 billion of the notes early. Taken together, we now expect to pay down \$4.75 billion of debt this year, significantly exceeding our prior guidance to pay down at least \$4 billion.

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

***[Q&A]***