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## **Gilead Sciences Announces Second Quarter 2023 Financial Results**

***– Product Sales Excluding Veklury Increased 11% Year-Over-Year to \$6.3 billion***

***Biktarvy Sales Increased 17% Year-Over-Year to \$3.0 billion***

***Oncology Sales Increased 38% Year-Over-Year to \$728 million***

***Net Income Reflects \$525 million Legal Settlement Accrual (\$0.32 per share) –***

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) announced today its results of operations for the second quarter of 2023.

“It was another strong quarter for Gilead, with continued commercial and clinical momentum,” said Daniel O’Day, Gilead’s Chairman and Chief Executive Officer. “11% year-over-year growth across our base business was driven by our diverse portfolio of therapies for HIV, Oncology, and Liver Disease. We received positive regulatory updates for six of our therapies and presented a large body of data on our pipeline, reinforcing our growing potential to help more patients and communities worldwide.”

### **Second Quarter 2023 Financial Results**

- Total second quarter 2023 revenue increased 5% to \$6.6 billion compared to the same period in 2022, primarily driven by increased sales in HIV and Oncology, partially offset by lower Veklury® (remdesivir) sales.
- Diluted Earnings Per Share (“EPS”) decreased to \$0.83 for the second quarter of 2023 compared to \$0.91 for the same period in 2022, mainly driven by a \$525 million litigation accrual for settlements with certain plaintiffs in the HIV antitrust litigation, representing an unfavorable \$0.32 impact to diluted EPS, as well as other higher operating costs and tax expense, partially offset by higher product

revenues and unrealized gains on equity investments compared to unrealized losses in 2022.

- Non-GAAP diluted EPS decreased to \$1.34 for the second quarter of 2023 compared to \$1.58 for the same period in 2022, primarily driven by the litigation accrual referenced earlier, representing an unfavorable \$0.32 impact to non-GAAP diluted EPS, as well as other higher operating costs, partially offset by higher product revenues.
- As of June 30, 2023, Gilead had \$8.0 billion of cash, cash equivalents and marketable debt securities, up from \$7.6 billion as of December 31, 2022.
- During the second quarter of 2023, Gilead generated \$2.3 billion in operating cash flow.
- During the second quarter of 2023, Gilead paid dividends of \$944 million and repurchased \$150 million of common stock.

## Product Sales Performance

Total second quarter 2023 product sales increased 7% to \$6.6 billion compared to the same period in 2022. Total product sales, excluding Veklury, increased 11% to \$6.3 billion in the second quarter of 2023 compared to the same period in 2022, primarily due to increased sales related to HIV, Cell Therapy and Trodelvy® (sacituzumab govitecan-hziy).

HIV product sales increased 9% to \$4.6 billion in the second quarter of 2023 compared to the same period in 2022, primarily driven by favorable pricing dynamics and higher demand, partially offset by lower channel inventory.

- **Biktarvy**® (bictegravir 50mg/emtricitabine 200mg (“FTC”)/tenofovir alafenamide 25mg (“TAF”)) sales increased 17% year-over-year in the second quarter of 2023, primarily driven by higher demand and favorable pricing dynamics, partially offset by lower channel inventory.
- **Descovy**® (FTC 200mg/TAF 25mg) sales increased 12% year-over-year in the second quarter of 2023, primarily driven by favorable pricing dynamics and higher demand, partially offset by lower channel inventory.

The **Liver Disease** portfolio sales, which includes chronic hepatitis C virus (“HCV”), chronic hepatitis B virus (“HBV”), and chronic hepatitis delta virus (“HDV”), increased 4% to \$711 million in the second quarter of 2023 compared to the same period in 2022. The

increase was primarily driven by higher demand, partially offset by unfavorable pricing dynamics.

Cell Therapy product sales increased 27% to \$469 million in the second quarter of 2023 compared to the same period in 2022.

- **Yescarta**<sup>®</sup> (axicabtagene ciloleucel) sales increased 29% year-over-year to \$380 million in the second quarter of 2023, primarily driven by strong demand in the second- and third-line settings for relapsed or refractory (“R/R”) large B-cell lymphoma (“LBCL”).
- **Tecartus**<sup>®</sup> (brexucabtagene autoleucel) sales increased 21% year-over-year to \$88 million in the second quarter of 2023, primarily driven by increased demand in R/R adult acute lymphoblastic leukemia (“ALL”) and R/R mantle cell lymphoma (“MCL”).

**Trodelvy** sales increased by 63% to \$260 million in the second quarter of 2023 compared to the same period in 2022, primarily driven by growing adoption in pre-treated HR+/HER2- metastatic breast cancer (“mBC”) in the United States.

**Veklury** sales decreased by 43% to \$256 million for the second quarter of 2023 compared to the same period in 2022, primarily driven by lower rates of COVID-19 related hospitalizations in all regions. Veklury sales generally reflect COVID-19 related rates and severity of infections and hospitalizations, as well as the availability, uptake and effectiveness of vaccinations and alternative treatments for COVID-19.

## **Second Quarter 2023 Product Gross Margin, Operating Expenses and Effective Tax Rate**

- Product gross margin was 78.0% for the second quarter of 2023 compared to 76.5% for the same period in 2022. Non-GAAP product gross margin was 86.9% for the second quarter of 2023 compared to 85.6% in the same period in 2022.
- Research and development (“R&D”) expenses and non-GAAP R&D expenses for the second quarter of 2023 were \$1.4 billion compared to \$1.1 billion in the same period in 2022. The increases in GAAP and non-GAAP R&D expenses were primarily driven by higher clinical activities.

- Acquired in-process R&D (“IPR&D”) expenses for the second quarter of 2023 were \$236 million, primarily driven by the acquisition of XinThera, Inc. (“XinThera”) and the expanded collaboration with Arcus Biosciences, Inc. (“Arcus”).
- Selling, general and administrative (“SG&A”) expenses for the second quarter of 2023 were \$1.8 billion compared to \$1.4 billion in the same period in 2022. Non-GAAP SG&A expenses for the second quarter of 2023 were \$1.8 billion compared to \$1.3 billion in the same period in 2022. The increases in GAAP and non-GAAP SG&A expenses were primarily driven by the litigation accrual referenced earlier, as well as increased commercial activities in Oncology and HIV, partially offset by lower corporate expenses.
- The effective tax rate (“ETR”) for the second quarter of 2023 was 34.6% compared to 24.5% for the same period in 2022, primarily driven by a remeasurement of certain deferred tax liabilities. Non-GAAP ETR for the second quarter of 2023 was 21.0% compared to 19.3% for the same period in 2022.

### **Guidance and Outlook**

For the full-year, Gilead expects:

- Total product sales between \$26.3 billion and \$26.7 billion, compared to \$26.0 billion and \$26.5 billion previously.
- Total product sales, excluding Veklury, between \$24.6 billion and \$25.0 billion, compared to \$24.0 billion and \$24.5 billion previously.
- Total Veklury sales of approximately \$1.7 billion, compared to approximately \$2.0 billion previously.
- Diluted earnings per share between \$4.50 and \$4.85, compared to \$4.75 and \$5.15 previously.
- Non-GAAP diluted earnings per share between \$6.45 and \$6.80, compared to \$6.60 and \$7.00 previously.

Additional information and a reconciliation between GAAP and non-GAAP financial information for the 2023 guidance is provided in the accompanying tables. Also see the Forward-Looking Statements described below. The financial guidance is subject to a

number of risks and uncertainties, including uncertainty around the duration and magnitude of the COVID-19 pandemic.

## **Key Updates Since Our Last Quarterly Release**

### **Virology**

- Received U.S. Food and Drug Administration (“FDA”) and European Commission (“EC”) approval to extend the use of Veklury to treat COVID-19 in people with severe renal impairment, including those on dialysis.
- Presented data on Biktarvy at the International AIDS Society Conference that further demonstrate the safety and efficacy profile in different subgroups of people with HIV, such as virologically suppressed pregnant women. Also presented patient-reported outcomes from the Phase 2/3 CAPELLA study of lenacapavir in heavily treatment-experienced people with HIV as well as data from use of oral lenacapavir as a bridging regimen. Note that the use of lenacapavir for oral bridging is not approved by any regulatory authority.
- Presented new long-term data at the European Association for the Study of the Liver Congress 2023 from the MYR301 Phase 3 trial evaluating bulevirtide for HDV, showing improved response rates at Week 96 compared to Week 48. Additionally, abstracts across viral hepatitis and liver fibrosis were highlighted.
- Received full marketing authorization from the EC for Hepcludex® (bulevirtide) for the treatment of adults with chronic HDV and compensated liver disease. Hepcludex was initially granted conditional marketing authorization in July 2020. Bulevirtide remains the only approved treatment for HDV in the EU and is not approved in the U.S.
- Announced partnerships with the Clinton Health Access Initiative and Penta to improve treatment and adherence rates among children with HIV in low and middle income countries.

### **Oncology**

- Received EC approval for Trodelvy as monotherapy for the treatment of adult patients with unresectable or metastatic HR+/HER2- mBC who have received

endocrine-based therapy, and at least two additional systemic therapies in the advanced setting.

- Presented longer-term overall survival (“OS”) data from the Phase 3 TROPiCS-02 study evaluating Trodelvy in pre-treated HR+/HER2- mBC at the 2023 American Society of Clinical Oncology (“ASCO”) meeting, demonstrating durable and clinically meaningful improvement in median OS versus comparator chemotherapy. Data were also presented from a Phase 2 trial evaluating Trodelvy as a potential therapy in advanced endometrial cancer.
- Presented OS data at ASCO from the Phase 3 ZUMA-7 trial of Yescarta in second-line R/R LBCL, which demonstrated significantly longer OS versus standard of care. Additionally, real-world evidence data for Tecartus in MCL were reported, which showed consistently high complete response and overall response rates, regardless of the type of prior treatment received.
- Presented data at the European Hematology Association Annual Congress evaluating Yescarta, Tecartus, and magrolimab in a number of hematologic malignancies.
- Received a recommendation from the National Institute for Health and Care Excellence in the United Kingdom for use of Yescarta in the second-line setting for diffuse LBCL and high-grade B-cell lymphoma, and Tecartus in R/R B-cell precursor ALL in England’s National Health Service.
- Announced, through Fosun Kite Biotechnology Co., Ltd., a joint venture between Kite and Shanghai Fosun Pharmaceutical (Group) Co., Ltd., the approval of axicabtagene ciloleucel (under the trade name Yikaida®) by the China National Medical Products Administration for the treatment of adult patients with R/R LBCL who failed first-line immunochemotherapy or relapsed within 12 months after first-line immunochemotherapy.
- Completed the transfer of Yescarta’s marketing authorization in Japan from Daiichi Sankyo Co., Ltd. (“Daiichi Sankyo”) to Gilead Sciences K.K.
- Announced data from an interim analysis at ASCO from the Phase 2 ARC-7 study of domvanalimab, zimberelimab and etrumadenant in first-line, metastatic PD-L1-high non-small cell lung cancer, demonstrating consistent improvement in

progression-free survival and a clinically meaningful reduction in the risk of progression or death in the domvanalimab-containing arms, as compared to the zimberelimab monotherapy arm.

- Announced the Phase 3 ENHANCE trial of magrolimab in combination with azacitidine in higher-risk myelodysplastic syndromes was discontinued due to futility based on a planned analysis. Data from the trial will be presented at an upcoming medical meeting.
- Announced the acquisition of XinThera, adding additional pipeline assets including rights to a portfolio of small molecule inhibitors targeting PARP1 for oncology as well as MK2 for inflammatory diseases.

### **Inflammation**

- Announced expansion of the Arcus collaboration to include research programs in inflammatory diseases.

### **Corporate**

- Appointed Cindy Perettie as Executive Vice President of Kite, who joins with more than 20 years of scientific and commercial leadership experience in global biopharmaceutical organizations.
- The company's Board of Directors declared a quarterly dividend of \$0.75 per share of common stock for the third quarter of 2023. The dividend is payable on September 28, 2023, to stockholders of record at the close of business on September 15, 2023. Future dividends will be subject to Board approval.

Certain amounts and percentages in this press release may not sum or recalculate due to rounding.

### **Conference Call**

At 2:00 p.m. Pacific Time today, Gilead will host a conference call to discuss Gilead's results. A live webcast will be available on <http://investors.gilead.com> and will be archived on [www.gilead.com](http://www.gilead.com) for one year.

### **Non-GAAP Financial Information**

The information presented in this document has been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”), unless otherwise noted as non-GAAP. Management believes non-GAAP information is useful for investors, when considered in conjunction with Gilead’s GAAP financial information, because management uses such information internally for its operating, budgeting and financial planning purposes. Non-GAAP information is not prepared under a comprehensive set of accounting rules and should only be used to supplement an understanding of Gilead’s operating results as reported under GAAP. Non-GAAP financial information generally excludes acquisition-related expenses including amortization of acquired intangible assets and inventory step-up charges, and other items that are considered unusual or not representative of underlying trends of Gilead’s business, fair value adjustments of equity securities and discrete and related tax charges or benefits associated with changes in tax related laws and guidelines. Although Gilead consistently excludes the amortization of acquired intangible assets from the non-GAAP financial information, management believes that it is important for investors to understand that such intangible assets were recorded as part of acquisitions and contribute to ongoing revenue generation. Non-GAAP measures may be defined and calculated differently by other companies in the same industry. Reconciliations of the non-GAAP financial measures to the most directly comparable GAAP financial measures are provided in the accompanying tables.

### **About Gilead Sciences**

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis, coronavirus disease 2019 (“COVID-19”), and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.