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Gilead Sciences Announces Third Quarter 2023 Financial Results

– Product Sales Excluding Veklury Increased 5% Year-Over-Year to \$6.4 billion

Biktarvy Sales Increased 12% Year-Over-Year to \$3.1 billion

Oncology Sales Increased 33% Year-Over-Year to \$769 million –

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

“Gilead has now delivered two years of consistent growth in our base business. In the third quarter, this continued growth was driven by both Virology and Oncology,” said Daniel O’Day, Gilead's Chairman and Chief Executive Officer. “Our clinical momentum also remains strong, and highlights this quarter included new data on Trodelvy with pembrolizumab in first-line metastatic non-small cell lung cancer. In Virology, we completed enrollment for Phase 3 trials of lenacapavir for HIV prevention and oral obeldesivir for COVID-19. We are looking forward to advancing these and other potential new options for patients over the coming months.”

Third Quarter 2023 Financial Results

- Total third quarter 2023 revenue of \$7.1 billion was flat compared to the same period in 2022, primarily driven by increased sales in Oncology and HIV, offset by lower Veklury® (remdesivir) and chronic hepatitis C virus (“HCV”) product sales.
- Diluted Earnings Per Share (“EPS”) increased to \$1.73 for the third quarter of 2023 compared to \$1.42 for the same period in 2022, and non-GAAP diluted EPS increased to \$2.29 for the third quarter of 2023 compared to \$1.90 for the same period in 2022. The increases in GAAP and non-GAAP diluted EPS were primarily

driven by lower tax expense, partially offset by net higher total costs and expenses.

- As of September 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 third quarter of 2023, Gilead generated \$1.8 billion in operating cash flow.
- During the third quarter of 2023, Gilead repaid \$2.3 billion of debt, paid dividends of \$953 million and repurchased \$300 million of common stock. Additionally, Gilead issued senior unsecured notes in an aggregate principal amount of \$2.0 billion.

Product Sales Performance

Total third quarter 2023 product sales of \$7.0 billion was flat compared to the same period in 2022, reflecting continued growth in the base business, offset by lower Veklury sales. Total product sales, excluding Veklury, increased 5% to \$6.4 billion in the third quarter of 2023 compared to the same period in 2022, primarily due to increased sales in Oncology and HIV, partially offset by lower HCV sales.

HIV product sales increased 4% to \$4.7 billion in the third quarter of 2023 compared to the same period in 2022, primarily driven by higher demand and channel inventory dynamics, partially offset by lower average realized price due to a shift in channel mix.

- **Biktarvy**[®] (bictegravir 50mg/emtricitabine 200mg (“FTC”)/tenofovir alafenamide 25mg (“TAF”)) sales increased 12% year-over-year in the third quarter of 2023, primarily driven by higher demand, as well as favorable channel inventory.
- **Descovy**[®] (FTC 200mg/TAF 25mg) sales increased 2% year-over-year in the third quarter of 2023, primarily driven by higher demand, partially offset by pricing dynamics in the United States.

The **Liver Disease** portfolio sales, which includes HCV, chronic hepatitis B virus (“HBV”), and chronic hepatitis delta virus (“HDV”), decreased 10% to \$706 million in the third quarter of 2023 compared to the same period in 2022, as higher HCV patient starts were more than offset by unfavorable pricing dynamics, primarily due to the resolution of a rebate claim in HCV in the third quarter of 2022.

Cell Therapy product sales increased 22% to \$486 million in the third quarter of 2023 compared to the same period in 2022.

- **Yescarta**[®] (axicabtagene ciloleucel) sales increased 23% year-over-year to \$391 million in the third 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”) outside of the United States.
- **Tecartus**[®] (brexucabtagene autoleucel) sales increased 18% year-over-year to \$96 million in the third quarter of 2023, primarily driven by increased demand in R/R mantle cell lymphoma (“MCL”) and R/R adult acute lymphoblastic leukemia (“ALL”).

Trodelvy (sacituzumab govitecan-hziy) sales increased 58% to \$283 million in the third quarter of 2023 compared to the same period in 2022, primarily driven by higher demand in both the United States and Europe.

Veklury sales decreased 31% to \$636 million for the third 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

Third Quarter 2023 Product Gross Margin, Operating Expenses and Effective Tax Rate

- Product gross margin was 77.6% for the third quarter of 2023 compared to 80.0% for the same period in 2022, primarily driven by intangible asset amortization expenses related to the pretreated HR+/HER2- metastatic breast cancer indication for Trodelvy following its approval in February 2023, as well as product mix. Non-GAAP product gross margin was 85.9% for the third quarter of 2023 compared to 86.8% in the same period in 2022, primarily driven by product mix.
- Research & development (“R&D”) expenses for the third quarter of 2023 were \$1.5 billion compared to \$1.1 billion in the same period in 2022. Non-GAAP R&D expenses for the third quarter of 2023 were \$1.5 billion compared to \$1.2 billion in the same period in 2022. The increases in GAAP and non-GAAP R&D expenses

were primarily driven by increased clinical activity, as well as costs associated with the discontinuation of two Phase 3 magrolimab studies.

- Acquired in-process research and development (“IPR&D”) expenses for the third quarter of 2023 were \$91 million, driven by an upfront payment related to the Tentarix Biotherapeutics Inc. (“Tentarix”) collaboration and other collaboration-related activities.
- Selling, general and administrative (“SG&A”) expenses and non-GAAP SG&A expenses for the third quarter of 2023 were \$1.3 billion compared to \$1.2 billion in the same period in 2022. The increases in GAAP and non-GAAP SG&A expenses were primarily driven by increased commercial activities in Oncology.
- The effective tax rate (“ETR”) for the third quarter of 2023 was 6.3% compared to 26.6% for the same period in 2022, and non-GAAP ETR for the third quarter of 2023 was 7.0% compared to 22.4% for the same period in 2022. Both ETR and non-GAAP ETR decreases were primarily driven by a decrease in tax reserves as a result of reaching agreement with a tax authority on certain tax positions.

Guidance and Outlook

For the full-year, Gilead expects:

- Total product sales between \$26.7 billion and \$26.9 billion, compared to \$26.3 billion and \$26.7 billion previously.
- Total product sales, excluding Veklury, between \$24.8 billion and \$25.0 billion, compared to \$24.6 billion and \$25.0 billion previously.
- Total Veklury sales of approximately \$1.9 billion, compared to approximately \$1.7 billion previously.
- Diluted earnings per share between \$4.55 and \$4.75, compared to \$4.50 and \$4.85 previously.
- Non-GAAP diluted earnings per share between \$6.65 and \$6.85, compared to \$6.45 and \$6.80 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 approval to extend the use of Veklury to treat COVID-19 in appropriate patients with mild to severe hepatic impairment.
- Presented new data at the European AIDS Conference 2023, including three-year outcomes from BICSTaR, an ongoing real-world study evaluating Biktarvy in people with HIV who have a high burden of co-morbidities, and multiple analyses from the Phase 2/3 CAPELLA study of lenacapavir in people with multi-drug resistant HIV.
- Announced PURPOSE 5, a Phase 2 clinical trial to assess the persistence of lenacapavir compared with FTC/tenofovir disoproxil fumarate in people who may benefit from PrEP in Europe. The use of lenacapavir for PrEP is investigational.
- Presented new data at Infectious Disease Week 2023 demonstrating Biktarvy’s efficacy and safety profile across a broad range of people with HIV as well as two-year outcomes from the CAPELLA study of lenacapavir. Additionally, presented data on the safety profile of Veklury across vulnerable populations and the drug-drug interaction profile of the investigational oral antiviral obeldesivir, as well as new in vitro data on antiviral activity of Veklury and obeldesivir against recent SARS-CoV-2 Omicron subvariants.
- Discontinued the Phase 3 BIRCH trial of obeldesivir in non-hospitalized participants who are at high risk for developing severe COVID-19. The decision was based on lower-than-expected COVID-19 incidence rates and related hospitalizations or all-cause death by Day 29, and does not reflect any safety or efficacy concerns.

- Announced the Phase 3 OAKTREE trial of obeldesivir in non-hospitalized participants without risk factors for developing severe COVID-19 is approaching full enrollment, and remains unaffected by the BIRCH decision.
- Announced plans to present at the American Association for the Study of Liver Diseases 2023 annual meeting. Presentations will include new and long-term data across Gilead's Liver Disease portfolio.
- Announced a collaboration with Assembly Biosciences, Inc. ("Assembly") to advance the research and development of novel antiviral therapies, including in herpesviruses, HBV and HDV.

Oncology

- Presented promising early data at the 2023 World Conference on Lung Cancer from the Phase 2 EVOKE-02 study evaluating the investigational use of Trodelvy in combination with Keytruda® (pembrolizumab) as a first-line treatment in patients with advanced or metastatic non-small cell lung cancer without actionable genomic alterations. The study demonstrated clinical activity in patients with PD-L1 tumor proportion score ("TPS")>50% in Cohort A and PD-L1 TPS<50% in Cohort B, including early and durable responses, as well as safety consistent with the known safety profile of each agent.
- Presented data at the European Society of Medical Oncology 2023 meeting from the Phase 2 TROPiCS-03 basket study demonstrating encouraging activity of Trodelvy for investigational use in both advanced head and neck squamous cell carcinoma and extensive stage small cell lung cancer cohorts, as well as other data in breast and urothelial cancer. Additionally, presented a comparative analysis, adjusting for trial differences, on Yescarta relative to bispecific antibodies in 3L+ R/R LBCL.
- Announced abstracts for the American Society of Hematology 2023 Annual Meeting, including updated Phase 1 data evaluating the Arcellx, Inc. ("Arcellx") partnered CART-ddBCMA in R/R multiple myeloma, demonstrating continued deep and durable responses with 22 months follow-up. Additionally announced abstracts for long-term follow-up across Yescarta trials in R/R LBCL, first-line high-

risk LBCL, and R/R follicular lymphoma, as well as real-world data for Tecartus in R/R MCL and B-cell ALL.

- Announced results from the Phase 2 ALYCANTE study, led and sponsored by the French collaborative group LYSA/LYSARC, evaluating Yescarta in transplant-ineligible patients with second-line R/R LBCL, which demonstrated high response rates and durable remission.
- Presented initial data, alongside Arcus Biosciences, Inc. (“Arcus”) at the American Society of Clinical Oncology Monthly Plenary Session from the Phase 2 EDGE-Gastric study of domvanalimab in combination with zimberelimab and chemotherapy in first-line locally advanced unresectable or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma. The results showed encouraging overall response rates and six-month landmark progression-free survival rate.
- Discontinued the Phase 3 ENHANCE-2 study of magrolimab in first-line acute myeloid leukemia (“AML”) with TP53 mutations based on an ad hoc analysis and following review by an independent data monitoring committee. Additionally announced that the U.S. FDA placed a partial clinical hold on magrolimab studies in AML that paused enrollment, though previously enrolled patients may continue to receive the study medicine.
- Announced a collaboration with Tentarix to discover and develop novel therapies across oncology and inflammation, using Tentarix’s proprietary Tentacles platform.
- Announced a collaboration with Epicrispr Biotechnologies, Inc. (“Epic Bio”) to develop next-generation cancer cell therapies using Epic Bio’s proprietary gene regulation platform.

Corporate

- Issued \$2.0 billion aggregate principal amount of senior unsecured notes in a registered offering, comprised of \$1.0 billion principal amount of 5.25% senior notes due in 2033 and \$1.0 billion principal amount of 5.55% senior notes due in 2053, and repaid debt of \$2.3 billion.
- The company’s Board of Directors declared a quarterly dividend of \$0.75 per share of common stock for the fourth quarter of 2023. The dividend is payable on

December 28, 2023, to stockholders of record at the close of business on December 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 1:30 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 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, COVID-19 and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.