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Gilead Sciences Announces First Quarter 2023 Financial Results

– Product Sales Excluding Veklury Increased 15% Year-Over-Year to $5.7 billion

Biktarvy Sales Increased 24% Year-Over-Year to $2.7 billion

Oncology Sales Increased 59% Year-Over-Year to $670 million –

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

"Gilead's track record of strong commercial and clinical execution continued through the first quarter of 2023. A 15% year-over-year revenue increase reflects growth in each of our core areas," said Daniel O'Day, Gilead's Chairman and Chief Executive Officer. "Biktarvy outperformed once again, and Oncology revenue increased 59% year-over-year, driven by Trodelvy and Cell Therapy. We look forward to helping even more people with Trodelvy following the approval for pre-treated HR+/HER2- metastatic breast cancer, making this the third U.S. approval for Trodelvy in three years."

First Quarter 2023 Financial Results

- Total first quarter 2023 revenue decreased 4% to $6.4 billion compared to the same period in 2022, due to lower Veklury® (remdesivir) sales, partially offset by increased sales in HIV and Oncology.
- Diluted Earnings Per Share ("EPS") increased to $0.80 for the first quarter of 2023 compared to $0.02 for the same period in 2022, mainly driven by the following items net of their related tax effect: a $2.7 billion in-process research and development ("IPR&D") impairment recorded in the first quarter of 2022, which did not repeat in 2023, partially offset by higher operating expenses, including higher acquired IPR&D expense and lower revenues in 2023.

- Non-GAAP diluted EPS decreased to $1.37 for the first quarter of 2023 compared to $2.12 for the same period in 2022, primarily driven by the following items net of their related tax effect: higher operating expenses, including higher acquired IPR&D expense, and lower revenues in 2023.
- As of March 31, 2023, Gilead had $7.2 billion of cash, cash equivalents and marketable debt securities, down from $7.6 billion as of December 31, 2022.
- During the first quarter of 2023, Gilead generated $1.7 billion in operating cash flow.
- During the first quarter of 2023, Gilead paid dividends of $969 million and repurchased $400 million of common stock.

Product Sales Performance

Total first quarter 2023 product sales decreased 3% to $6.3 billion compared to the same period in 2022. Total product sales, excluding Veklury, increased 15% to $5.7 billion in the first quarter of 2023 compared to the same period in 2022, primarily due to increased sales related to HIV, Cell Therapy, Trodelvy® (sacituzumab govitecan-hziy) and Liver Disease.

HIV product sales increased 13% to $4.2 billion in the first quarter of 2023 compared to the same period in 2022, primarily driven by favorable pricing dynamics, as well as higher demand and lower inventory draw-downs.

- **Biktarvy®** (bictegravir 50mg/emtricitabine 200mg ("FTC")/tenofovir alafenamide 25mg ("TAF")) sales increased 24% year-over-year in the first quarter of 2023, reflecting higher demand, as well as favorable pricing and inventory dynamics.
- **Descovy®** (FTC 200mg/TAF 25mg) sales increased 20% year-over-year in the first quarter of 2023, primarily driven by higher demand and favorable pricing dynamics.

The Liver Disease portfolio sales, which includes chronic hepatitis C virus ("HCV"), chronic hepatitis B virus ("HBV") and chronic hepatitis delta virus ("HDV"), increased

6% to $675 million in the first quarter of 2023 compared to the same period in 2022, primarily driven by higher demand and timing of purchases in the U.S.

Cell Therapy product sales increased 64% to $448 million in the first quarter of 2023 compared to the same period in 2022.

- **Yescarta®** (axicabtagene ciloleucel) sales increased 70% to $359 million in the first quarter of 2023, primarily driven by increased demand in relapsed or refractory ("R/R") large B-cell lymphoma ("LBCL").
- **Tecartus®** (brexucabtagene autoleucel) sales increased 40% to $89 million in the first quarter of 2023, primarily driven by increased demand in R/R mantle cell lymphoma and R/R adult acute lymphoblastic leukemia ("ALL").

Trodelvy sales increased by 78% to $180 million in the third quarter of 2022 compared to the same period in 2021, primarily driven by adoption in both the second- and third-line settings for the treatment of metastatic triple-negative breast cancer.

Veklury sales decreased by 63% to $573 millionfor the first 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.

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

- Product gross margin was 77.8% for the first quarter of 2023 compared to 78.2% for the same period in 2022. Non-GAAP product gross margin was 86.2% for the first quarter of 2023 compared to 87.4% in the same period in 2022.
- Research and development ("R&D") expenses and non-GAAP R&D expenses for the first quarter of 2023 were $1.4 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 activities.

- Acquired IPR&D expenses for the first quarter of 2023 were $481 million compared to $8 million in the same period in 2022, primarily driven by the acquisition of Tmunity Therapeutics Inc. ("Tmunity"), as well as upfront and milestone payments related to the collaborations with Arcellx, Inc. ("Arcellx") and Nurix Therapeutics, Inc. ("Nurix").
- Selling, general and administrative ("SG&A") expenses and non-GAAP SG&A expenses for the first quarter of 2023 were $1.3 billion, compared to $1.1 billion in the same period in 2022. The increases in GAAP and non-GAAP SG&A expenses were primarily due to Oncology commercial expansion and investments, higher Branded Prescription Drug fee, as well as higher corporate activities.
- The effective tax rate ("ETR") for the first quarter of 2023 was 24.3% compared to 107.9% for the same period in 2022. The decrease in ETR was primarily due to a $2.7 billion IPR&D impairment taken in the first quarter of 2022 related to assets acquired by Gilead from Immunomedics Inc. that did not repeat in 2023. Non-GAAP ETR for the first quarter of 2023 was 18.9% compared to 18.4% for the same period in 2022.

Guidance and Outlook

For the full-year, Gilead expects:

- Total product sales between $26.0 billion and $26.5 billion, unchanged from prior guidance.
- Total product sales, excluding Veklury, between $24.0 billion and $24.5 billion, unchanged from prior guidance.
- Total Veklury sales of approximately $2.0 billion, unchanged from prior guidance. Veklury sales are expected to be highly variable, depending on the frequency and severity of surges, and our guidance will continue to be updated on a quarterly basis as necessary.
- Diluted earnings per share between $4.75 and $5.15, compared to $5.30 and $5.70 previously.

- Non-GAAP diluted earnings per share between $6.60 and $7.00, unchanged from prior guidance.

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

- Presented positive Phase 1b proof-of-concept data for an investigational combination regimen of lenacapavir with broadly neutralizing antibodies teropavimab and zinlirvimab as a potential long-acting treatment regimen for HIV with twice-yearly dosing at the Conference on Retroviruses and Opportunistic Infections ("CROI") 2023. In addition, announced results from multiple collaborative studies evaluating novel investigational combinations and strategies as part of the HIV cure research program.
- Announced new real-world study data at CROI demonstrating Veklury use in hospitalized patients with COVID-19 was associated with a statistically significant reduction in mortality in the overall patient population, including immunocompromised patients. Real-world data analyses of Veklury from other sources are ongoing and may vary in their results or conclusions. Separate in vitro analyses were also presented that showed Veklury retains potent antiviral activity against recent Omicron subvariants.
- Presented new COVID-19 data at the European Congress of Clinical Microbiology and Infectious Diseases, including results from a Phase 1 study of obeldesivir (GS-5245), as an investigational oral therapy for the treatment of COVID-19. Additionally, presented findings from a Phase 3 study of Veklury in patients with severe renal impairment, as well as new real-world studies.

Oncology

- Received FDA approval of Trodelvy for the treatment of adult patients with unresectable locally advanced or metastatic HR+/HER2- breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.
- Presented positive results from a three-year follow-up analysis of Tecartus in the Phase 2 ZUMA-3 study of patients with R/R ALL at the European CAR T-cell Meeting.
- Presented positive data from the Phase 2 TROPHY-U-01 study of Trodelvy for the treatment of metastatic urothelial cancer at the American Society of Clinical Oncology Genitourinary Cancers Symposium.
- Completed the acquisition of Tmunity, a clinical stage private biotech company, which provides preclinical and clinical programs, including an investigational "armored" CAR T technology platform that has the potential to be applied to a variety of CAR Ts to enhance anti-tumor activity, as well as rapid manufacturing processes.
- Announced primary overall survival results from the Phase 3 ZUMA-7 study for initial treatment of adult patients with R/R LBCL, which showed a statistically significant improvement for Yescarta in overall survival versus historical treatment.

Inflammation

- Exercised option to license investigational targeted protein degrader molecule NX-0479 ("GS-6791") from Nurix. GS-6791 is a potent, selective, oral IRAK4 degrader with potential applications in the treatment of rheumatoid arthritis and other inflammatory diseases.

Corporate

- The company's Board of Directors declared a quarterly dividend of $0.75 per share of common stock for the second quarter of 2023. The dividend is payable on June 29, 2023, to stockholders of record at the close of business on June 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 and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.