October 27, 2022

Gilead Sciences Announces Third Quarter 2022 Financial Results

– Product Sales Excluding Veklury Increased 11% Year-Over-Year to $6.1 billion –

– Biktarvy Sales Increased 22% Year-Over-Year to $2.8 billion –

– Oncology Sales Increased 79% Year-Over-Year to $578 million –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Gilead Sciences, Inc. (Nasdaq: GILD) announced today its results of operations for the third quarter of 2022.

Chairman and Chief Executive Officer of Gilead Sciences, Daniel O'Day said: "This was another very strong quarter across the business. In HIV, treatment and prevention markets continue to grow with further share gains for Biktarvy in treatment, and we received our first approval for our long-acting HIV agent, lenacapavir, in Europe. In oncology, there is increasing demand for cell therapies and Trodelvy. Yescarta and Tecartus received two approvals in Europe and Trodelvy was granted FDA Priority Review for HR+/HER2- metastatic breast cancer. Overall, we are seeing terrific progress from a commercial and clinical perspective and look forward to building on this momentum."

Third Quarter 2022 Financial Results

- Total third quarter 2022 revenue decreased 5% to $7.0 billion compared to the same period in 2021, primarily due to lower Veklury®(remdesivir) sales, partially offset by increased sales in HIV and oncology products.
- Diluted Earnings Per Share ("EPS") decreased to $1.42 for the third quarter of 2022 compared to $2.05 for the same period in 2021, mainly driven by higher acquired in-process research and development ("IPR&D") expenses of $389 million primarily due to the acquisition of MiroBio Ltd. ("MiroBio") and lower product gross margin and revenues, partially offset by lower income tax expense.
- Non-GAAP diluted EPS decreased to $1.90 for the third quarter of 2022 compared to $2.65 for the same period in 2021, primarily driven by the MiroBio acquisition, as well as lower product gross margin and revenues.

- As of September 30, 2022, Gilead had $6.9 billion of cash, cash equivalents and marketable debt securities down from $7.8 billion as of December 31, 2021.
- During the third quarter of 2022, Gilead generated $2.9 billion in operating cash flow.
- During the third quarter of 2022, Gilead repaid $1.0 billion of debt, made a cash payment of $414 million to acquire MiroBio, paid dividends of $928 million and repurchased $180 million of common stock.

Product Sales Performance

Total third quarter 2022 product sales decreased 5% to $7.0 billion compared to the same period in 2021. Total product sales, excluding Veklury, increased 11% to $6.1 billion in the third quarter of 2022 compared to the same period in 2021, primarily due to increased product sales related to HIV, cell therapy, hepatitis C virus ("HCV") and Trodelvy®(sacituzumab govitecan-hziy).

HIV product sales increased 7% to $4.5 billion in the third quarter of 2022 compared to the same period in 2021, primarily driven by favorable channel mix associated with government utilization leading to higher average realized price, as well as higher demand.

- Biktarvy® (bictegravir 50mg/emtricitabine 200mg ("FTC")/tenofovir alafenamide 25mg ("TAF")) sales increased 22% year-over-year in the third quarter of 2022, primarily due to higher demand and channel mix.
- Descovy® (FTC 200mg/TAF 25mg) sales increased 16% year-over-year in the third quarter of 2022, primarily driven by channel mix and higher demand, partially offset by inventory dynamics.

HCV product sales increased 22% to $524 million in the third quarter of 2022 compared to the same period in 2021, primarily due to a favorable resolution of a prior year rebate claim in Europe and other favorable pricing dynamics in the United States, partially offset by fewer patient starts.

Hepatitis B virus ("HBV") and hepatitis delta virus ("HDV") product sales increased 7% to $264 million in the third quarter of 2022 compared to the same period in 2021, primarily driven by Vemlidy® (TAF 25mg). **Vemlidy** sales increased 10% in the third quarter of 2022 compared to the same period in 2021, primarily driven by favorable inventory dynamics.

Cell therapy product sales increased 79% to $398 million in the third quarter of 2022 compared to the same period in 2021.

- **Yescarta**® (axicabtagene ciloleucel) sales increased 81% to $317 million in the third quarter of 2022, primarily driven by demand in relapsed or refractory ("R/R") large B-cell lymphoma ("LBCL") in the United States and Europe.

- **Tecartus**® (brexucabtagene autoleucel) sales increased 72% to $81 million in the third quarter of 2022, primarily driven by demand in R/R mantle cell lymphoma ("MCL") in the United States and Europe as well as in adult R/R B-cell precursor acute lymphoblastic leukemia ("ALL") in the United States.

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 52% to $925 millionfor the third quarter of 2022 compared to the same period in 2021, primarily driven by lower rates of COVID-19 related hospitalizations compared to the third quarter of 2021. Veklury revenue generally reflects 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 2022 Product Gross Margin, Operating Expenses and Effective Tax Rate

- Product gross margin was 80.0% for the third quarter of 2022 compared to 83.4% for the same period in 2021. Non-GAAP product gross margin was 86.8% for the third quarter of 2022 compared to 90.0% in the same period in 2021. The decreases were primarily driven by a favorable court decision in the third quarter of 2021 that led to the reversal of the previously recorded $175 million litigation reserve during that period, as well as Biktarvy-related royalty expense that began in the first quarter of 2022 and a change in product mix.
- Research and development ("R&D") expenses for the third quarter of 2022 were $1.1 billion, relatively flat with the same period in 2021. Non-GAAP R&D expenses for the third quarter of 2022 were $1.2 billion, relatively flat with the same period in 2021(1).
- Acquired IPR&D expenses for the third quarter of 2022 were $448 million compared to $65 million(1) in the same period in 2021. The increase primarily reflects an expense of $389 million related to the MiroBio acquisition.
- Selling, general and administrative ("SG&A") expenses for the third quarter of 2022 were $1.2 billion, relatively flat with the same period in 2021. Non-GAAP SG&A expenses for the third quarter of 2022 were $1.2 billion, relatively flat with the same period in 2021.
- The effective tax rate ("ETR") for the third quarter of 2022 was 26.6% compared to 24.8% for the same period in 2021. Non-GAAP ETR for the third quarter of 2022 was 22.4% compared to 18.9% for the same period in 2021. The increases in GAAP and Non-GAAP ETR were primarily due to a non-deductible acquired IPR&D charge related to Gilead's acquisition of MiroBio.

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(1) Beginning in the second quarter of 2022, expenses related to development milestones and other collaboration payments made prior to regulatory approval of a developed product were reclassified from R&D expenses to Acquired IPR&D expenses in the Condensed Consolidated Statements of Income. We believe this presentation assists users of the financial statements to better understand the total costs incurred to acquire IPR&D projects. Prior periods have been recast for both GAAP and Non-GAAP reporting to reflect this classification, resulting in a reduction of previously-reported R&D expenses of $46 million and $93 million for the three and nine months ended September 30, 2021, respectively, and $8 million for the three months ended March 31, 2022.

Guidance and Outlook

For the full-year, Gilead has updated its guidance and now expects:

- Total product sales between $25.9 billion and $26.2 billion, compared to $24.5 billion and $25.0 billion previously.
- Total product sales, excluding Veklury, between $22.5 billion to $22.8 billion, compared to $22.0 billion and $22.5 billion previously.
- Total Veklury sales of approximately $3.4 billion, compared to approximately $2.5 billion previously.
- Non-GAAP earnings per share between $6.95 and $7.15, compared to $6.35 and $6.75 previously.
- Earnings per share between $3.35 and $3.55, compared to $2.90 and $3.30 previously.

This financial guidance excludes the impact of any expenses related to potential acquisitions or business development transactions that have not been executed, fair value adjustments of equity securities and discrete tax charges or benefits associated with changes in tax related laws and guidelines as Gilead is unable to project such amounts. A reconciliation between GAAP and non-GAAP financial information for the 2022 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. While the pandemic can be expected to continue to impact Gilead's business and broader market dynamics, the rate and degree of these impacts as well as the corresponding recovery from the pandemic may vary across Gilead's business.

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.