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PHASE 3 TROPiCS-02 STUDY MET THE PRIMARY ENDPOINT OF PROGRESSION-FREE SURVIVAL IN LATE-LINE HR+/HER2- METASTATIC BREAST CANCER

– Study Will Continue to Follow Patients for Overall Survival, a Key Secondary Endpoint –

Foster City, Calif., March 7, 2022 – Gilead Sciences, Inc. (Nasdaq: GILD) today announced results from the Phase 3 TROPiCS-02 study evaluating Trodelvy® (sacituzumab govitecan-hziy) in patients with HR+/HER2- metastatic breast cancer who received prior endocrine therapy, CDK4/6 inhibitors and two to four lines of chemotherapy. The study met its primary endpoint with a statistically significant improvement in progression-free survival (PFS) versus physician's choice of chemotherapy. The trial targeted a 30% reduction in the risk of disease progression or death. The primary endpoint results were consistent with those observed in the Phase 1/2 IMMU-132-01 study in a subset of HR+/HER2- metastatic breast cancer patients.[1] The first interim analysis of the key secondary endpoint of overall survival in the TROPiCS-02 study demonstrated a trend in improvement for overall survival. Patients will be followed for a subsequent overall survival analysis. The safety profile for Trodelvy was consistent with prior studies, and no new safety concerns emerged in this patient population.

"Trodelvy demonstrated consistent activity in this difficult-to-treat patient population," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. "We are evaluating the data and will explore potential pathways with regulatory authorities to bring Trodelvy to this group of patients. As we work to expand the patient benefit of Trodelvy beyond its current indications for second-line metastatic triple-negative breast cancer and accelerated approval in second-line metastatic bladder cancer, we are pursuing studies across multiple tumor types and earlier lines of therapy."

"HR+/HER2- breast cancer accounts for approximately 70% of all breast cancer cases. Patients with advanced breast cancer may eventually develop endocrine resistance, then resistance to a limited set of sequential chemotherapy options," said Hope Rugo, MD, Professor of Medicine and Director, Breast Oncology and Clinical Trials Education at the University of California San Francisco Comprehensive Cancer Center. "These data show the potential for Trodelvy to address an important unmet need for patients with HR+/HER2- metastatic breast cancer who have been heavily pretreated."

Detailed results from TROPiCS-02 will be presented at an upcoming medical conference.

[1] Kalinsky et al, 2020

Gilead has filed a current report on Form 8-K that includes this press release and some FAQs related to the information in this release. The information in this press release should be read in conjunction with the FAQs.

Trodelvy has not been approved by any regulatory agency for the treatment of HR+/HER2- metastatic breast cancer. Its safety and efficacy have not been established for this indication. Trodelvy has a Boxed Warning for severe or life-threatening neutropenia and severe diarrhea; please see below for additional Important Safety Information.

About the TROPiCS-02 Study

The TROPiCS-02 study is a global, multicenter, open-label, Phase 3 study, randomized 1:1 to evaluate Trodelvy versus physician's choice of chemotherapy (eribulin, capecitabine, gemcitabine, or vinorelbine) in 543 patients with HR+/HER2- metastatic breast cancer who were previously treated with endocrine therapy, CDK4/6 inhibitors and two to four lines of chemotherapy. The primary endpoint is progression-free survival per Response Evaluation Criteria in Solid Tumors (RECIST 1.1) as assessed by blinded independent central review for participants treated with Trodelvy compared to those treated with chemotherapy. The trial targets a 30% reduction in the risk of disease progression or death and is powered to detect a statistically significant difference of at least 0.9 months in median PFS. Secondary endpoints include overall survival, duration of response, clinical benefit rate and overall response rate as well as assessment of safety and tolerability and quality of life measures. More information about TROPiCS-02 is available at https://clinicaltrials.gov/ct2/show/NCT03901339.

About HR+/HER2- Breast Cancer

Hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) breast cancer is the most common type of breast cancer and accounts for approximately 70% of all new cases, or nearly 400,000 diagnoses worldwide each year. Almost one in three cases of early-stage breast cancer eventually become metastatic, and among patients with HR+/HER2- metastatic disease, the five-year relative survival rate is 30%. As patients with HR+/HER2- metastatic breast cancer become resistant to endocrine-based therapy, their primary treatment option is limited to single-agent chemotherapy. For patients treated with single-agent chemotherapy, the prognosis remains poor.

About Trodelvy

Trodelvy® (sacituzumab govitecan-hziy) is a first-in-class Trop-2 directed antibody-drug conjugate. Trop-2 is a cell surface antigen highly expressed in multiple tumor types, including in more than 90% of breast and bladder cancers. Trodelvy is intentionally designed with a proprietary hydrolyzable linker attached to SN-38, a topoisomerase I inhibitor payload. This unique combination delivers potent activity to both Trop-2 expressing cells and the microenvironment.

Trodelvy is approved in more than 35 countries, with multiple additional regulatory reviews underway worldwide, for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease. Trodelvy is also approved in the U.S. under the accelerated approval pathway for the treatment of adult patients with locally advanced or metastatic urothelial cancer (UC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.

Trodelvy is also being developed for potential investigational use in other TNBC and metastatic UC populations, as well as a range of tumor types where Trop-2 is highly expressed, including hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) metastatic breast cancer, metastatic non-small cell lung cancer (NSCLC), metastatic small cell lung cancer (SCLC), head and neck cancer, and endometrial cancer.

U.S. Indication for Trodelvy

In the United States, Trodelvy is indicated for the treatment of:

- Adult patients with unresectable locally advanced or metastatic TNBC who have received two or more prior systemic therapies, at least one of them for metastatic disease.
- Adult patients with locally advanced or metastatic UC who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

U.S. Important Safety Information for Trodelvy

BOXED WARNING: NEUTROPENIA AND DIARRHEA

- **Severe or life-threatening neutropenia may occur. Withhold Trodelvy for absolute neutrophil count below 1500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.**
- **Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. Administer atropine, if not contraindicated, for early diarrhea of any severity. At the onset of late diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold Trodelvy until resolved to ≤Grade 1 and reduce subsequent doses.**

CONTRAINDICATIONS

- Severe hypersensitivity reaction to Trodelvy.

WARNINGS AND PRECAUTIONS

Neutropenia: Severe, life-threatening, or fatal neutropenia can occur and may require dose modification. Neutropenia occurred in 61% of patients treated with Trodelvy. Grade 3-4 neutropenia occurred in 47% of patients. Febrile neutropenia occurred in 7%. Withhold Trodelvy for absolute neutrophil count below 1500/mm^3 on Day 1 of any cycle or neutrophil count below 1000/mm^3 on Day 8 of any cycle. Withhold Trodelvy for neutropenic fever.

Diarrhea: Diarrhea occurred in 65% of all patients treated with Trodelvy. Grade 3-4 diarrhea occurred in 12% of patients. One patient had intestinal perforation following diarrhea. Neutropenic colitis occurred in 0.5% of patients. Withhold Trodelvy for Grade 3-4 diarrhea and resume when resolved to ≤Grade 1. At onset, evaluate for infectious causes and if negative, promptly initiate loperamide, 4 mg initially followed by 2 mg with every episode of diarrhea for a maximum of 16 mg daily. Discontinue loperamide 12 hours after diarrhea resolves. Additional supportive measures (e.g., fluid and electrolyte substitution) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment can receive appropriate premedication (e.g., atropine) for subsequent treatments.

Hypersensitivity and Infusion-Related Reactions: Serious hypersensitivity reactions including life-threatening anaphylactic reactions have occurred with Trodelvy. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions. Hypersensitivity reactions within 24 hours of dosing occurred in 37% of patients. Grade 3-4 hypersensitivity occurred in 2% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of Trodelvy was 0.3%. The incidence of anaphylactic reactions was 0.3%. Pre-infusion medication is recommended. Observe patients closely for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Medication to

treat such reactions, as well as emergency equipment, should be available for immediate use. Permanently discontinue Trodelvy for Grade 4 infusion-related reactions.

Nausea and Vomiting: Nausea occurred in 66% of all patients treated with Trodelvy and Grade 3 nausea occurred in 4% of these patients. Vomiting occurred in 39% of patients and Grade 3-4 vomiting occurred in 3% of these patients. Premedicate with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK1 receptor antagonist as well as other drugs as indicated) for prevention of chemotherapy-induced nausea and vomiting (CINV). Withhold Trodelvy doses for Grade 3 nausea or Grade 3-4 vomiting and resume with additional supportive measures when resolved to Grade ≤1. Additional antiemetics and other supportive measures may also be employed as clinically indicated. All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting.

Increased Risk of Adverse Reactions in Patients with Reduced UGT1A1 Activity: Patients homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia, febrile neutropenia, and anemia and may be at increased risk for other adverse reactions with Trodelvy. The incidence of Grade 3-4 neutropenia was 67% in patients homozygous for the UGT1A1*28, 46% in patients heterozygous for the UGT1A1*28 allele and 46% in patients homozygous for the wild-type allele. The incidence of Grade 3-4 anemia was 25% in patients homozygous for the UGT1A1*28 allele, 10% in patients heterozygous for the UGT1A1*28 allele, and 11% in patients homozygous for the wild-type allele. Closely monitor patients with known reduced UGT1A1 activity for adverse reactions. Withhold or permanently discontinue Trodelvy based on clinical assessment of the onset, duration and severity of the observed adverse reactions in patients with evidence of acute early-onset or unusually severe adverse reactions, which may indicate reduced UGT1A1 function.

Embryo-Fetal Toxicity: Based on its mechanism of action, Trodelvy can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. Trodelvy contains a genotoxic component, SN-38, and targets rapidly dividing cells. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with Trodelvy and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Trodelvy and for 3 months after the last dose.

ADVERSE REACTIONS

In the ASCENT study (IMMU-132-05), the most common adverse reactions (incidence ≥25%) were fatigue, neutropenia, diarrhea, nausea, alopecia, anemia, constipation, vomiting, abdominal pain, and decreased appetite. The most frequent serious adverse reactions (SAR) (>1%) were neutropenia (7%), diarrhea (4%), and pneumonia (3%). SAR were reported in 27% of patients, and 5% discontinued therapy due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the ASCENT study were reduced neutrophils, leukocytes, and lymphocytes.

In the TROPHY study (IMMU-132-06), the most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, neutropenia, nausea, any infection, alopecia, anemia, decreased appetite, constipation, vomiting, abdominal pain, and rash. The most frequent serious adverse reactions (SAR) (≥5%) were infection (18%), neutropenia (12%, including febrile neutropenia in 10%), acute kidney injury (6%), urinary tract infection (6%), and sepsis or bacteremia (5%). SAR were reported in 44% of patients, and 10% discontinued due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in

the TROPHY study were reduced neutrophils, leukocytes, and lymphocytes.

DRUG INTERACTIONS

UGT1A1 Inhibitors: Concomitant administration of Trodelvy with inhibitors of UGT1A1 may increase the incidence of adverse reactions due to potential increase in systemic exposure to SN-38. Avoid administering UGT1A1 inhibitors with Trodelvy.

UGT1A1 Inducers: Exposure to SN-38 may be substantially reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with Trodelvy.

Please see full Prescribing Information, including BOXED WARNING.

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.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including Gilead's ability to initiate, progress or complete clinical trials involving Trodelvy within currently anticipated timelines or at all; the possibility of unfavorable results from ongoing or additional clinical trials involving Trodelvy; Gilead's ability to submit regulatory applications for new or expanded indications for Trodelvy, including for the treatment of metastatic HR+/HER2- breast cancer, in the currently anticipated timelines or at all; Gilead's ability to receive regulatory approvals in a timely manner or at all, including regulatory approvals of Trodelvy for the treatment of metastatic HR+/HER2- breast cancer and other indications, and the risk that any such approvals may be subject to significant limitations on use; the possibility that Gilead may make a strategic decision to discontinue development of Trodelvy for the treatment of metastatic HR+/HER2- breast cancer and as a result, Trodelvy may never be commercialized for this indication; and any assumptions underlying any of the foregoing. These and other risks, uncertainties and other factors are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the U.S. Securities and Exchange Commission. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The reader is cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and is cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation and disclaims any intent to update any such forward-looking statements.

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*U.S. Prescribing Information for Trodelvy including **BOXED WARNING**, is available at www.gilead.com.*

For more information about Gilead, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.