CONTACTS: Jacquie Ross, Investors
(650) 358-1054

Shant Salakian, Media
(424) 384-1841

For Immediate Release

U.S. FDA GRANTS ACCELERATED APPROVAL TO TRODELVY® FOR THE TREATMENT OF METASTATIC UROTHELIAL CANCER

– Accelerated Approval Granted for Locally Advanced or Metastatic Urothelial Cancer Following a Platinum-Containing Chemotherapy and a PD-1/PD-L1 Inhibitor –

– New Indication Marks Second FDA Approval for Trodelvy in 2021 –

Foster City, Calif., April 13, 2021 – Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) has granted accelerated approval of Trodelvy® (sacituzumab govitecan-hziy) for use in adult patients with locally advanced or metastatic urothelial cancer (UC) who have previously received a platinum-containing chemotherapy and either a programmed death receptor-1 (PD-1) or a programmed death-ligand 1 (PD-L1) inhibitor. The accelerated approval was based on data from the international Phase 2, single-arm TROPHY study. Of the 112 patients who were evaluable for efficacy, 27.7% of those treated with Trodelvy responded to treatment, with 5.4% experiencing a complete response and 22.3% experiencing a partial response. The median duration of response was 7.2 months (95% CI: 4.7-8.6). The Trodelvy U.S. Prescribing Information has a BOXED WARNING for severe or life-threatening neutropenia and severe diarrhea; see below for Important Safety Information.

The FDA's accelerated approval mechanism enables drugs that treat serious diseases with unmet medical need to be approved based on a surrogate or intermediate clinical endpoint. Continued approval is contingent upon verification and description of clinical benefit in a confirmatory trial.

"Only a fraction of patients derives long-term benefit from previously approved cytotoxic therapy or immunotherapy, leaving a great unmet need for treatment options for patients with advanced urothelial cancer who have progressed on first- and second-line therapies," said Scott T. Tagawa, MD, MS, FACP, Professor of Medicine and Urology at Weill Cornell Medicine, an oncologist at New York-Presbyterian/Weill Cornell Medical Center and principal investigator of the TROPHY study.[i] "The response rate and tolerability seen with sacituzumab govitecan-hziy may provide physicians an effective new treatment option for patients whose cancer continues to progress even after multiple therapies."

UC is the most common type of bladder cancer and occurs when the urothelial cells that line the inside of the bladder and other parts of the urinary tract grow unusually or uncontrollably. An estimated 83,000 Americans will be diagnosed with bladder cancer in 2021, and almost 90% of those diagnoses will be UC. The relative five-year survival rate for patients with metastatic UC is 5.5%.

"Cases of urothelial cancer continue to rise in the U.S., yet prognosis remains the same for the vast majority of patients," said Andrea Maddox-Smith, CEO of the Bladder Cancer Advocacy Network (BCAN). "Bladder cancer patients need as many treatment options as possible, and we are pleased that Trodelvy can be a potentially viable treatment for them."

-more-

Trodelvy's safety profile in the TROPHY study is consistent with previous observations in metastatic UC and other tumor types. Among all evaluable treated metastatic UC patients (n=113), the most common (≥25%) adverse reactions were diarrhea (72%), anemia (71%), fatigue (68%), neutropenia (67%), nausea (66%), alopecia (49%), decreased appetite (41%), constipation (34%), vomiting (34%) and abdominal pain (31%). Adverse reactions leading to treatment discontinuation occurred in 10% of those receiving Trodelvy, with 4% discontinuing treatment due to neutropenia.

"Today's accelerated approval is thanks to the patients and healthcare professionals involved in the TROPHY study, and we appreciate their partnership," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. "This achievement, coupled with last week's full FDA approval in unresectable locally advanced or metastatic triple-negative breast cancer, underscores our commitment toward rapidly delivering Trodelvy to patients facing some of the most difficult-to-treat cancers."

A global, randomized Phase 3 confirmatory clinical trial TROPiCS-04 (NCT04527991) is underway and is also intended to support global registrations. More information on TROPiCS-04 is available at https://clinicaltrials.gov/ct2/show/NCT04527991.

About Trodelvy

Trodelvy (sacituzumab govitecan-hziy) is a first-in-class antibody and topoisomerase inhibitor conjugate directed to the Trop-2 receptor, a protein frequently expressed in multiple types of epithelial tumors, including metastatic triple-negative breast cancer (TNBC) and metastatic UC, where high expression is associated with poor survival and relapse.

In addition to the accelerated approval of Trodelvy for the treatment of locally advanced or metastatic UC, Trodelvy is approved in the U.S. to treat 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.

Beyond the regulatory approvals of Trodelvy in the U.S., regulatory reviews for Trodelvy in metastatic TNBC are currently underway in the EU, U.K., Canada, Switzerland and Australia, as well as in Singapore through our partner Everest Medicines. Trodelvy is also being developed as an investigational treatment for hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER 2-) metastatic breast cancer and metastatic non-small cell lung cancer. Additional evaluation across multiple solid tumors is also underway.

About the TROPHY U-01 Study

The Phase 2 TROPHY-U01 (also known as IMMU-132-06) trial is an ongoing, international, multi-center, open-label, multi-cohort, single-arm study evaluating Trodelvy monotherapy or combination therapy in patients with metastatic UC after progression on a platinum-based regimen and anti-PD-1/PD-L1-based immunotherapy. In Cohorts 1 and 2, patients received Trodelvy 10 mg/kg administered intravenously on Days 1 and 8 of a 21-day cycle to be continued until disease progression or loss of clinical benefit. Trodelvy is approved under accelerated approval based on the objective response rate (ORR) and duration of response (DoR) established in Cohort 1.

Cohorts 2, 3, 4 and 5 of the study are ongoing. Cohort 2 is assessing the safety and efficacy of Trodelvy monotherapy in platinum-ineligible patients after progression on anti-PD-1/PD-L1-based immunotherapy. Cohort 3 is assessing the safety and efficacy of Trodelvy on Days 1 and 8 of a 21-day cycle followed by pembrolizumab at the standard approved dose (200 mg) only on Day 1 of a 21-day cycle in patients with metastatic UC who have progressed after prior platinum therapy. Cohorts 4 and 5 are assessing the safety and efficacy of Trodelvy combination therapy in patients with treatment naive metastatic UC, with those in

Cohort 4 receiving cisplatin and those in Cohort 5 receiving cisplatin and avelumab, respectively, in addition to Trodelvy.

The primary endpoint is ORR based on RECIST 1.1 criteria evaluated by independent central review in all five cohorts. In Cohorts 1 and 2, secondary endpoints are DoR and progression-free survival (PFS) based on central review and overall survival (OS). Secondary endpoints in Cohorts 3, 4 and 5 include DoR, clinical benefit rate (CBR) and PFS based on central review by RECIST 1.1 criteria; DoR, CBR and PFS based on investigator review by RECIST 1.1 and iRECIST criteria, OS and safety and tolerability of Trodelvy in combination with pembrolizumab, cisplatin, or cisplatin and avelumab, depending on the Cohort. More information about TROPHY is available at https://clinicaltrials.gov/ct2/show/NCT03547973.

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.

-more-

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. Have medications and emergency equipment to treat such reactions available for immediate use. Observe patients closely for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. 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 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 NK-1 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: Individuals who are 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 in genotyped patients 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 in genotyped patients 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.

-more-

ADVERSE REACTIONS

In the ASCENT study (IMMU-132-05), the most common adverse reactions (incidence ≥25%) were nausea, neutropenia, diarrhea, fatigue, alopecia, anemia, vomiting, constipation, rash, decreased appetite, and abdominal pain. 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 hemoglobin, lymphocytes, leukocytes, and neutrophils.

In the TROPHY study (IMMU-132-06), the most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, neutropenia, nausea, alopecia, anemia, decreased appetite, constipation, vomiting, and abdominal pain. 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 within currently anticipated timelines or at all, including those involving Trodelvy; the possibility of unfavorable results from ongoing or additional trials, including those involving Trodelvy; Gilead's ability to receive regulatory approvals in a timely manner or at all, including additional regulatory approvals of Trodelvy for the treatment of metastatic TNBC, metastatic breast cancer, metastatic UC, metastatic non-small cell lung cancer and other solid tumors, and the risk that any such approvals may be subject to significant limitations on use; 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, 2020, 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. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties and are 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.

# # #

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 (@Gilead Sciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

[i] Dr. Tagawa is a paid consultant for Gilead Sciences, Inc.