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For Immediate Distribution

FDA APPROVES TRODELVY®, THE FIRST TREATMENT FOR METASTATIC TRIPLE-NEGATIVE BREAST CANCER SHOWN TO IMPROVE PROGRESSION-FREE SURVIVAL AND OVERALL SURVIVAL

– Trodelvy Significantly Reduced the Risk of Death by 49% Compared with Single-Agent Chemotherapy in the Phase 3 ASCENT Study –

– Trodelvy is Under Regulatory Review in the EU and in the United Kingdom, Canada, Switzerland and Australia as Part of Project Orbis –

Foster City, Calif., April 7, 2021 – Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) has granted full approval to Trodelvy® (sacituzumab govitecan-hziy) for 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. The approval is supported by data from the Phase 3 ASCENT study, in which Trodelvy demonstrated a statistically significant and clinically meaningful 57% reduction in the risk of disease worsening or death (progression-free survival (PFS)), extending median PFS to 4.8 months from 1.7 months with chemotherapy (HR: 0.43; 95% CI: 0.35-0.54; p<0.0001). Trodelvy also extended median overall survival (OS) to 11.8 months vs. 6.9 months (HR: 0.51; 95% CI: 0.41-0.62; p<0.0001), representing a 49% reduction in the risk of death.

Trodelvy is directed to the Trop-2 receptor, a protein frequently expressed in multiple types of epithelial tumors, including TNBC, where high expression is associated with poor survival and relapse. Prior to the FDA approval of Trodelvy, patients with previously treated metastatic TNBC had few treatment options in this high unmet-need setting. The FDA granted accelerated approval to Trodelvy in April 2020 based on objective response rate and duration of response results in a Phase 1/2 study. Today's approval expands the previous Trodelvy indication to include treatment in 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.

"Women with triple-negative breast cancer have historically had very few effective treatment options and faced a poor prognosis," said Aditya Bardia, MD, MPH, Director of Breast Cancer Research Program, Mass General Cancer Center and Assistant Professor of Medicine at Harvard Medical School, and global principal investigator of the ASCENT study. "Today's FDA approval reflects the statistically significant survival benefit seen in the landmark ASCENT study and positions sacituzumab govitecan-hziy as a potential standard of care for pre-treated TNBC."

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"A metastatic TNBC diagnosis is frightening. As an aggressive and difficult-to-treat disease, it's a significant advance to have an FDA-approved treatment option with a proven survival benefit for patients with metastatic disease that continues to progress," said Ricki Fairley, Founder and CEO of Touch, the Black Breast Cancer Alliance. "For far too long, people with metastatic TNBC had very few treatment options. Today's news continues the progress of bringing more options to treat this devastating disease."

Among all patients evaluable for safety in the ASCENT study (n=482), Trodelvy had a safety profile consistent with the previously approved FDA label. The most frequent Grade ≥3 adverse reactions for Trodelvy compared to single-agent chemotherapy were neutropenia (52% vs. 34%), diarrhea (11% vs. 1%), leukopenia (11% vs. 6%) and anemia (9% vs. 6%). Adverse reactions leading to treatment discontinuation occurred in 5% of patients receiving Trodelvy.

"Today's approval is the culmination of a multi-year development program and validates the clinical benefit of this important treatment in metastatic TNBC," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. "Building upon this milestone, we are committed to advancing Trodelvy with worldwide regulatory authorities so that, pending their decision, Trodelvy may become available to many more people around the world who are facing this difficult-to-treat cancer."

Regulatory submissions for Trodelvy in metastatic TNBC have been filed in the United Kingdom, Canada, Switzerland and Australia as part of Project Orbis, an initiative of the FDA Oncology Center of Excellence (OCE) that provides a framework for concurrent submission and review of oncology products among international partners, as well as in Singapore through our partner Everest Medicines. The European Medicines Agency has also validated a Marketing Authorization Application for Trodelvy in the European Union. All filings are based on data from the Phase 3 ASCENT study.

Trodelvy Boxed Warning

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.

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), where high expression is associated with poor survival and relapse.

Trodelvy is also being developed as an investigational treatment for metastatic urothelial cancer, 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 Triple-Negative Breast Cancer (TNBC)

TNBC is an aggressive type of breast cancer, accounting for approximately 15% of all breast cancers. The disease is diagnosed more frequently in younger and premenopausal women and is more prevalent in African American and Hispanic women. TNBC cells do not have estrogen and progesterone receptors and have limited HER 2. Medicines targeting these receptors therefore are not typically effective in treating TNBC.

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About the ASCENT Study

The Phase 3 ASCENT study, an open-label, active-controlled, randomized confirmatory trial, enrolled more than 500 patients with relapsed/refractory metastatic triple-negative breast cancer (TNBC) who had received two or more prior systemic therapies (including a taxane), at least one of them for metastatic disease. Patients were randomized to receive either Trodelvy or a chemotherapy chosen by the patients' treating physicians. The primary efficacy outcome was progression-free survival (PFS) in patients without brain metastases at baseline, as measured by a blinded, independent, centralized review using RECIST v1.1 criteria. Additional efficacy measures included PFS for the full population (all patients with and without brain metastases) and overall survival (OS). More information about ASCENT is available at http://clinicaltrials.gov/show/NCT02574455.

Important Safety Information for Trodelvy

BOXED WARNING: NEUTROPENIA AND DIARRHEA

- **Severe, life-threatening, or fatal neutropenia may occur. Withhold TRODELVY for absolute neutrophil count below 1500/mm3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patient 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 to TRODELVY

WARNINGS AND PRECAUTIONS

Neutropenia: Dose modifications may be required due to neutropenia. Neutropenia occurred in 62% of patients treated with TRODELVY, leading to permanent discontinuation in 0.5% of patients. Grade 3-4 neutropenia occurred in 47% of patients. Febrile neutropenia occurred in 6%.

Diarrhea: Diarrhea occurred in 64% of all patients treated with TRODELVY. Grade 3 diarrhea occurred in 12% of patients. 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: TRODELVY can cause severe and life-threatening hypersensitivity and infusion-related reactions, including anaphylactic reactions. Hypersensitivity reactions within 24 hours of dosing occurred in 37% of patients. Grade 3-4 hypersensitivity occurred in 1% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.4%. 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.

Nausea and Vomiting: Nausea occurred in 67% of all patients treated with TRODELVY. Grade 3-4 nausea occurred in 5% of patients. Vomiting occurred in 40% 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 69% in patients homozygous for the UGT1A1*28, 48% 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 24% in patients homozygous for the UGT1A1*28 allele, 8% in patients heterozygous for the UGT1A1*28 allele, and 10% 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 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 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.

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 urothelial cancer, 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.

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