Gilead’s Bold Ambition of Transforming Triple-Negative Breast Cancer Treatment to Be Highlighted With New Data at SABCS

November 29, 2021

– ASCENT Subgroup Analysis Provides Insights on Treatment Outcomes for Black Patients with Metastatic TNBC –

– Separate ASCENT Post Hoc Analysis Examines Outcomes in Patients Who Discontinue Treatment Due to Progressive Disease –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Nov. 29, 2021-- Gilead Sciences, Inc. (Nasdaq: GILD) will present additional data from the Phase 3 ASCENT study of Trodelvy® (sacituzumab govitcan-hziy) during the upcoming San Antonio Breast Cancer Symposium (SABCS) being held from December 7-10. These data reinforce the benefits of Trodelvy and the importance of Gilead’s transformative science in cancers with high unmet need. In the United States, Trodelvy is indicated 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.

“Our data at SABCS add to the growing body of evidence supporting the use of Trodelvy for people with metastatic TNBC,” said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. “We continue to advance the treatment of TNBC and are actively exploring the potential of Trodelvy across the breast cancer landscape.”

Highlights at the meeting include an ASCENT analysis examining outcomes for Black patients with metastatic TNBC who were treated with Trodelvy compared to those receiving physician’s choice of chemotherapy. Additional ASCENT analyses will explore health-related quality of life (HRQoL) measures by clinical response and post-progression survival of patients who experienced continued disease progression.

Accepted abstracts are as follows:

- Assessment of Sacituzumab Govitecan in Black Patients from the Phase 3 ASCENT Study in Metastatic Triple-Negative Breast Cancer (Poster #P5-16-07)
- Post-Progression Therapy Outcomes in Patients from the Phase 3 ASCENT Study of Sacituzumab Govitecan in Metastatic Triple-Negative Breast Cancer (Poster # P5-16-15)
- Assessment of Health-Related Quality of Life by Clinical Response from the Phase 3 ASCENT Study in Metastatic Triple-Negative Breast Cancer (Poster #P5-16-01)

The presentations will be made available in-person and on-demand as part of Poster Session 5 beginning Friday, December 10 at 7:00 a.m. CT.

For more information, including a complete list of abstract titles at the meeting, please visit: https://www.sabcs.org/Program/Schedule-at-a-Glance.

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 Triple-Negative Breast Cancer (TNBC)

TNBC is the most aggressive type of breast cancer and accounts for approximately 15% of all breast cancers. TNBC is diagnosed more frequently in younger and premenopausal women and is more prevalent in Black and Hispanic women. TNBC cells do not have estrogen and progesterone receptors and have limited human epidermal growth factor receptor 2 (HER2). Due to the nature of TNBC, effective treatment options are extremely limited compared with other breast cancer types. TNBC has a higher chance of recurrence and metastases than other breast cancer types. The average time to metastatic recurrence for TNBC is approximately 2.6 years compared with 5 years for other breast cancers, and the relative five-year survival rate is much lower. Among women with metastatic TNBC, the five-year survival rate is 12%, compared with 28% for those with other types of metastatic breast cancer.

About Trodelvy

Trodelvy is a first-in-class antibody and topoisomerase inhibitor conjugate directed to the Trop-2 receptor, a protein overexpressed in multiple types of epithelial tumors, including metastatic TNBC and metastatic urothelial cancer (UC), where high expression is associated with poor survival and relapse. Trodelvy is approved for adults with metastatic TNBC in the United States, the European Union, Australia, Canada, Great Britain and Switzerland. Trodelvy is also under multiple regulatory reviews worldwide, including in Singapore and China through our partner Everest Medicines. Trodelvy continues to be developed for potential use in other TNBC and metastatic UC populations and is also being developed as an investigational treatment for hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) metastatic breast cancer and metastatic non-small cell lung cancer. Additional evaluation across multiple solid tumors is also underway.

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.

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 anaphylactoid 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 male patients with female partners 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 bacteraemia (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 trials involving Trodelvy; Gilead’s ability to receive additional regulatory approvals of Trodelvy in a timely manner or at all, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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. 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](http://www.gilead.com).

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

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