



GILEAD TO ACQUIRE REMAINING WORLDWIDE RIGHTS OF TRODELVY®

- Gilead will Assume Responsibility for Clinical Development and Commercialization in Greater China and South Korea, among Other Asian Markets -

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced an agreement with Everest Medicines to transfer all development and commercialization rights to Gilead for Trodelvy® (sacituzumab govitecan) in Greater China, South Korea, Singapore, Indonesia, Philippines, Vietnam, Thailand, Malaysia and Mongolia.

In China mainland and Singapore, Trodelvy is approved 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. Gilead continues to work closely with regulatory bodies in Hong Kong, South Korea and Taiwan, where New Drug Applications, filed by Everest Medicines for metastatic TNBC, are currently under review.

“Trodelvy is approved for second-line metastatic TNBC in over 35 countries/regions. We thank Everest Medicines for their partnership and important contributions in the development of Trodelvy in Asia. Their collaboration has brought us closer to bringing Trodelvy to patients who need alternative options,” said Bill Grossman, MD, PhD, Senior Vice President, Oncology Clinical Research, Gilead Sciences. “Trodelvy is the cornerstone of our solid tumor portfolio, and we are committed to bringing this transformative therapy to as many patients as possible. We look forward to rapidly advancing our development program in Asia and to realizing the clinical potential of Trodelvy across diverse tumor types.”

In April 2019, Everest Medicines and Immunomedics entered into an agreement granting Everest Medicines an exclusive license to develop and commercialize Trodelvy in Greater China, South Korea, Singapore, Indonesia, Philippines, Vietnam, Thailand, Malaysia and Mongolia, excluding Japan. Gilead subsequently acquired Immunomedics in October 2020 and created an extensive global clinical development program, including investigating Trodelvy as a monotherapy and in

novel combinations, across multiple disease areas including non-small cell lung cancer, metastatic urothelial cancer and gastrointestinal cancers.

“We welcome the opportunity to restructure our partnership with Gilead, which has been built on a shared vision of providing innovative oncology solutions for patients in need. With capital resources and a track record of successful therapeutic development and commercialization for Trodelvy in the U.S., Gilead is an ideal partner to further develop and commercialize Trodelvy in Asia Pacific regions to maximize patient access,” said Kerry Blanchard, MD, PhD, Chief Executive Officer of Everest Medicines. “I am exceedingly proud of what Everest has accomplished in advancing Trodelvy in China and other Asia territories, and we will continue to bring more transformational therapies to patients in China and worldwide with our extensive pipeline of clinical and pre-clinical stage assets.”

Under the terms of the agreement, Gilead will make a \$280 million upfront payment to Everest. In addition, Everest is eligible to receive up to \$175 million in potential additional payments upon achievement of certain regulatory and commercial milestones. Gilead will also have the opportunity to recruit Everest employees working directly on the Trodelvy program. The transaction is expected to close later this year, and will be subject to customary closing conditions, including approval by Everest’s shareholders.

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 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 over 35 countries/regions, 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. Indications 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/mm³ 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 $1500/\text{mm}^3$ on Day 1 of any cycle or neutrophil count below $1000/\text{mm}^3$ 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 \leq 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 \leq 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 $\geq 25\%$) 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 $\geq 25\%$) in the ASCENT study were reduced neutrophils, leukocytes, and lymphocytes.

In the TROPHY study (IMMU-132-06), the most common adverse reactions (incidence $\geq 25\%$) were diarrhea, fatigue, neutropenia, nausea, any infection, alopecia, anemia, decreased appetite, constipation, vomiting, abdominal pain, and rash. The most frequent serious adverse reactions (SAR) ($\geq 5\%$) 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 $\geq 25\%$) 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 the possibility that various closing conditions for the transaction may not be satisfied or waived; the risk that Gilead may not realize the potential benefits of this transaction; Gilead's ability to initiate, progress or complete clinical trials within currently anticipated timelines or at all, and the possibility of unfavorable results from ongoing or additional clinical trials, including those involving Trodelvy; uncertainties relating to regulatory applications for Trodelvy and related filing and approval timelines, including for the treatment of metastatic TNBC, mUC, HR+/HER2- breast cancer, NSCLC, SCLC, head and neck cancer, and endometrial cancer, in the currently anticipated timelines or at all; Gilead's ability to receive regulatory approvals for such indications in a timely manner or at all, including regulatory approvals in Hong Kong, South Korea and Taiwan for metastatic TNBC, 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 such indications and as a result, Trodelvy may never be commercialized for these indications; the risk that physicians may not see the benefits of prescribing Trodelvy; 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 June 30, 2022, 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.

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

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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.