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New Data for Trodelvy® Demonstrate Clinical Efficacy Across Trop-2 Expression Levels in HR+/HER2- Metastatic Breast Cancer

– Late-Breaking TROPiCS-02 Analysis Shows that Trodelvy Demonstrates Consistent Efficacy Across Trop-2 Expression Levels –

– Trop-2 is Highly Expressed in 90% of Breast Cancers –

– Trodelvy® is Currently Under Priority Review with the U.S. FDA for Pre-Treated HR+/HER2- Metastatic Breast Cancer –

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced new data from a post-hoc analysis from the Phase 3 TROPiCS-02 study evaluating Trodelvy® (sacituzumab govitecan-hziy; SG) versus comparator chemotherapy (physicians' choice of chemotherapy, TPC) in patients with HR+/HER2- metastatic breast cancer who progressed on endocrine-based therapies and at least two chemotherapies. In the analysis, Trodelvy® improved progression-free survival (PFS), overall survival (OS) and objective response rate (ORR) compared with TPC across Trop-2 expression levels. Details of the late-breaking abstract will be presented today at the 2022 San Antonio Breast Cancer Symposium (SABCS, Abstract #GS1-11).

"Sacituzumab govitecan improved both progression-free survival and overall survival in pre-treated HR+/HER2- metastatic breast cancer in the Phase 3 TROPiCS-02 study compared to standard chemotherapy options. This post-hoc analysis demonstrates that the level of Trop-2 expression on an individual's tumor did not impact sacituzumab govitecan efficacy," said Dr. Hope Rugo, Professor of Medicine and Director, Breast Oncology and Clinical Trials Education at the University of California San Francisco Comprehensive Cancer Center, U.S. "These data can give us confidence in the potential benefit of sacituzumab govitecan for patients with endocrine-resistant metastatic breast cancer who have progressed on available chemotherapies, across Trop-2 expression levels."

Trop-2, a protein found on the surface of cancer cells, is involved in several cellular processes regulating cancer growth and invasion. It is highly expressed in most human solid tumors, including more than 90% of breast cancers. In the TROPiCS-02 study, Trop-2 expression was measured by immunohistochemistry and expressed as a histochemical score (H-score; range, 0-300). Efficacy outcomes were assessed across H-score groups, including those with very low Trop-2 expression. Across each H-score subgroup, Trodelvy® demonstrated improved PFS, OS and ORR compared to TPC, which is consistent with the PFS, OS and ORR in the TROPiCS-02 intention-to-treat population.

“The prognosis for patients with pre-treated HR+/HER2- metastatic breast cancer who have developed resistance to endocrine-based therapies has been poor, and these TROPiCS-02 study results demonstrate clinical efficacy with Trodelvy®, across Trop-2 expression levels,” said Bill Grossman, MD, PhD, Senior Vice President, Therapeutic Area Head, Gilead Oncology. “Our ambition is to continue our impact beyond our current approval in second-line metastatic TNBC, and we look forward to advancing discussions with the U.S. FDA and global health authorities to help bring Trodelvy® to more people living with metastatic breast cancer.”

The safety profile for Trodelvy® in TROPiCS-02 was consistent with prior studies, with no new safety signals identified in this population.

Detailed statistically significant and clinically meaningful PFS and OS results from the Phase 3 TROPiCS-02 study were presented at ASCO 2022 and ESMO 2022, respectively. Based on these data, the U.S. Food and Drug Administration (FDA) accepted for priority review the supplemental Biologics License Application (sBLA) for Trodelvy® in adult patients with unresectable locally advanced or metastatic HR+/HER2- (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting. The Prescription Drug User Fee Act (PDUFA) target action date is currently set for February 2023.

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; pleasesee below for additional Important Safety Information.

Summary of post-hoc analysis results by Trop-2 expression

Trop-2 expression, H-score	n (SG/TPC)	Median PFS (SG vs TPC), months	PFS Hazard Ratio (95%CI)	Median OS (SG vs TPC), months	OS Hazard Ratio (95%CI)
<100	96/96	5.3 vs. 4.0	0.77 (0.54-1.09)	14.6 vs. 11.3	0.75 (0.54-1.04)
≥100	142/128	6.4 vs. 4.1	0.60 (0.44-0.81)	14.4 vs. 11.2	0.83 (0.62-1.11)
≤10	34/45	5.5 vs. 4.3	0.89 (0.51-1.57)	17.6 vs. 12.3	0.61 (0.34-1.08)
>10-<100	62/51	5.0 vs. 3.5	0.67 (0.42-1.07)	13.7 vs. 11.0	0.81 (0.54-1.23)
>10	204/179	5.6 vs. 4.0	0.62 (0.48-0.80)	14.1 vs. 11.1	0.82 (0.65-1.0)

H-score, histochemical score; OS, overall survival; PFS, progression-free survival; SG, sacituzumab govitecan; TPC, treatment of physician's choice.

Additional Abstracts across Gilead's Breast Cancer Franchise at 2022 SABCS:

Gilead is also presenting a number of other abstracts at the congress, including patient-reported outcomes data from TROPiCS-02, and in preclinical research and

trials in progress in metastatic triple-negative breast cancer (TNBC). Accepted abstracts at SABCS 2022 include (all times CDT):

Abstract Disposition	**Abstract Title**
Oral Presentation	
Presentation # GS1-11 Tuesday, Dec. 6 4:30 PM	Sacituzumab Govitecan (SG) vs. Treatment of Physician's Choice (TPC) by Trop-2 Expression in the TROPiCS-02 Study of Patients (Pts) With HR+/HER2- Metastatic Breast Cancer (mBC)
Poster Presentations	
Poster # P3-07-08 Wednesday, Dec. 7 5:00 PM	Exposure-Adjusted Incidence Rates (EAIRs) of Adverse Events (AEs) From the Phase 3 TROPiCS-02 Study of Sacituzumab Govitecan (SG) vs Treatment of Physician's Choice (TPC) in HR+/HER2- Metastatic Breast Cancer
Poster # P4-07-65 Thursday, Dec. 8 7:00 AM	Effect of Sacituzumab Govitecan vs Chemotherapy in HR+/HER2- Metastatic Breast Cancer: Patient-Reported Outcomes From the TROPiCS-02 Trial

Poster # P4-07-12 Thursday, Dec. 8 7:00 AM	Development of Triple-Negative Breast Cancer (TNBC) Syngeneic Models and TROP2-Directed Antibody-Drug Conjugate (ADC) Surrogate to Model Therapeutic Combinations
Poster # OT2-10-01 Wednesday, Dec. 7 5:00 PM	A Phase 2, Randomized Study of Magrolimab Combination Therapy in Adult Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (TiP)

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 40 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 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.

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.