October 11, 2022

U.S. FDA Accepts for Priority Review the Supplemental Biologics License Application for Gilead's Trodelvy® for Pre-Treated HR+/HER2- Metastatic Breast Cancer

– Supplemental Biologics License Application (sBLA) Based on Statistically Significant and Clinically Meaningful Overall Survival and Progression-Free Survival Results from the Phase 3 TROPiCS-02 Study –

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced the U.S. Food and Drug Administration (FDA) has accepted for priority review the supplemental Biologics License Application (sBLA) for Trodelvy® (sacituzumab govitecan-hziy) for the treatment of adult patients with unresectable locally advanced or metastatic hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative (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 FDA grants priority review for therapies that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. The Prescription Drug User Fee Act (PDUFA) target action date is currently set for February 2023.

"Trodelvy has already changed the treatment landscape in second-line metastatic triple-negative breast cancer and pre-treated metastatic urothelial cancer, and today's news marks our third supplemental application acceptance within the last two years," said Bill Grossman, MD, PhD, Senior Vice President, Therapeutic Area Head, Gilead Oncology. "People with pre-treated HR+/HER2- metastatic breast cancer who have progressed on endocrine-based therapies and chemotherapy have limited treatment options, and we look forward to working with the FDA to potentially make Trodelvy available to patients who need it most."

This sBLA is based on data from the registrational Phase 3 TROPiCS-02 study, which met its primary endpoint of progression-free survival (PFS) and key secondary endpoint of overall survival (OS) over comparator chemotherapy (treatment of physician's choice (TPC) of chemotherapy). PFS data were presented at the 2022 ASCO Annual Meeting and published in the Journal of Clinical Oncology,and OS data

were recently presented at ESMO Congress 2022. In the study, Trodelvy demonstrated a 34% reduction in risk of disease progression or death (median PFS: 5.5 versus 4 months; hazard ratio [HR]: 0.66; 95% CI: 0.53-0.83; p=0.0003) and a 21% decrease in the risk of death compared to TPC (median OS: 14.4 months vs. 11.2 months; HR=0.789; 95% CI: 0.646-0.964; p=0.02).

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.

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

About HR+/HER2- Metastatic Breast Cancer

Hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) breast cancer is the most common type of breast cancer and accounts for approximately 70% of all new cases, or nearly 400,000 diagnoses worldwide each year. Almost one in three cases of early-stage breast cancer eventually become metastatic, and among patients with HR+/HER2- metastatic disease, the five-year relative survival rate is 30%. As patients with HR+/HER2- metastatic breast cancer become resistant to endocrine-based therapy, their primary treatment option is limited to single-agent chemotherapy. In this setting, it is common to receive multiple lines of chemotherapy regimens over the course of treatment, and the prognosis remains poor.

About the TROPiCS-02 Study

The TROPiCS-02 study is a global, multicenter, open-label, Phase 3 study, randomized 1:1 to evaluate Trodelvy versus physicians' choice of chemotherapy (eribulin, capecitabine, gemcitabine, or vinorelbine) in 543 patients with HR+/HER2- metastatic breast cancer who were previously treated with endocrine therapy, CDK4/6 inhibitors and two to four lines of chemotherapy for metastatic disease. The primary endpoint is progression-free survival per Response Evaluation Criteria in Solid Tumors (RECIST 1.1) as assessed by blinded independent central review (BICR) for participants treated with Trodelvy compared to those treated with chemotherapy. Secondary endpoints include overall survival, overall response rate, clinical benefit rate and duration of response, as well as assessment of safety and tolerability and quality of life measures. In the study, HER2 negativity was defined per American Society of Clinical Oncology (ASCO) and the College of American Pathologists (CAP)

criteria as immunohistochemistry (IHC) score of 0, IHC 1+ or IHC 2+ with a negative in-situ hybridization (ISH) test.

More information about TROPiCS-02 is available at https://clinicaltrials.gov/ct2/show/NCT03901339.

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 35 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.