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European Medicines Agency Validates Marketing Authorization Application For Trodelvy® (sacituzumab govitecan-hziy) For Pre-treated HR+/HER2- Metastatic Breast Cancer

– Application Based on Statistically Significant and Clinically Meaningful Overall Survival and Progression-Free Survival Results from the Phase 3 TROPiCS-02 Study –

– Supplemental Biologics License Application Already Under Priority Review by the U.S. FDA –

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the European Medicines Agency (EMA) has validated a Type II variation Marketing Authorization Application (MAA) for Trodelvy® (sacituzumab govitecan-hziy) for the treatment of adult patients with unresectable 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.

“At Gilead Oncology our ambition is to transform care for people with cancer,” said Bill Grossman, MD, PhD, Senior Vice President, Therapeutic Area Head, Gilead Oncology. “Trodelvy is already moving us towards this ambition and changing the standard of care in second-line metastatic triple-negative breast cancer across the EU. The validation of our Marketing Authorization Application in pre-treated HR+/HER2- metastatic breast cancer marks an important step forward to potentially making Trodelvy available to even more patients with severely limited treatment options.”

This Marketing Authorization Application 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) versus comparator chemotherapies (treatment of physician’s choice (TPC) of chemotherapy). PFS data were published in the *Journal of Clinical Oncology*,and OS data were recently presented at ESMO Congress 2022.

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

In October 2022, the U.S. Food and Drug Administration (FDA) accepted for priority review the supplemental Biologics License Application (sBLA) for Trodelvy for the treatment of adult patients with unresectable locally advanced or metastatic HR+/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 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.

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 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.