CONTACT:

Jacquie Ross, Investors
investor_relations@gilead.com
+1 (650) 358-1054

Dior Sarr, Public Affairs
PublicAffairsCanada@gilead.com
+ 1 (416) 951-4210

HEALTH CANADA ISSUES NOTICE OF COMPLIANCE FOR TRODELVY®, A NEW TREATMENT OPTION FOR AN AGGRESSIVE TYPE OF METASTATIC BREAST CANCER

– TRODELVY Significantly Reduced the Risk of Death by 49% Compared with Single-Agent Chemotherapy in the Phase 3 ASCENT Study[i] –

Mississauga, ON, November 25, 2021 – Gilead Sciences Canada, Inc. (Gilead Canada) today announced that Health Canada has granted Notice of Compliance to Trodelvy® (sacituzumab govitecan) for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior therapies, at least one of them for metastatic disease.[ii]

"mTNBC is particularly challenging to treat, and these women traditionally face a poor prognosis," said Christine Brezden-Masley, Medical Oncologist, Mount Sinai Hospital. "The market authorization for TRODELVY is an important step in their fight against this devastating disease as it's the first and only targeted antibody-drug conjugate treatment in Canada to improve progression-free survival and overall survival in second-line mTNBC versus chemotherapy."

The market authorization is supported by results from the Phase 3 ASCENT study, where TRODELVY showed a statistically significant and clinically meaningful 57% reduction in the risk of disease worsening or death and improved median progression-free survival (PFS) to 4.8 months from 1.7 months seen with physician's choice of chemotherapy alone among all randomized patients, which included those with and without brain metastases (HR: 0.43; 95% CI: 0.35-0.54; p<0.0001).[iii] TRODELVY also reduced the risk of death by 49% and improved median overall survival to 11.8 months vs. 6.9 months with physician's choice of chemotherapy (HR: 0.51; 95% CI: 0.41-0.62; p<0.0001).[iv]

"We are proud to bring TRODELVY to Canada, providing women with mTNBC with a new treatment option for this devastating disease that has proven survival benefits," said Melissa Koomey, Vice President and General Manager, Gilead Canada.

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 mTNBC, where high expression is associated with poor survival and relapse.[v]

"mTNBC is an aggressive and challenging-to-treat disease which primarily affects young women in the prime of their lives," said Cathy Ammendolea, Board Chair, Canadian Breast Cancer Network. "Providing access to such effective therapies represents important progress in offering targeted treatment options to women battling this devastating disease."

"We've learned over the years of working with young women with metastatic breast cancer that they want to live as well as they can for as long as they can and the highest unmet need we hear is for more time – to see children grow, share experiences and contribute to the community. For far too long, people with mTNBC had very few treatment options and now they have an opportunity for what matters to them most – to gain more time," said MJ DeCoteau, Founder and Executive Director, Rethink Breast Cancer.

About Triple-Negative Breast Cancer (TNBC)

TNBC is an aggressive type of breast cancer, accounting for approximately 15% of all breast cancers.[vi] The disease is diagnosed more frequently in younger and premenopausal women and is more prevalent in African American and Hispanic women.[vii ,viii] TNBC cells do not have estrogen and progesterone receptors and have limited HER-2 expression. Medicines targeting these receptors therefore are not typically effective in treating TNBC.

TNBC also 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 5-year survival rate is much lower.[ix] Among women with mTNBC, the 5-year survival rate is 12%, compared with 28% for those with other types of metastatic breast cancer. [x,xi]

Based on previous rates of diagnosis, in Canada, it is estimated that approximately 4,110 new cases of TNBC were diagnosed in 2020.[xii,xiii]

About the ASCENT Study[xiv]

The ASCENT study is a global, open-label, randomized Phase 3 study that enrolled more than 500 patients across 230 study locations. The study evaluated the efficacy and safety of sacituzumab govitecan compared with a single-agent chemotherapy of the physician's choice in patients with unresectable, locally advanced or mTNBC who had received at least two prior systemic treatments. Patients were randomized to receive either sacituzumab govitecan or a chemotherapy chosen by the patient's treating physician. The primary endpoint was progression-free survival (PFS, as determined by blinded independent central review) in patients without brain metastases. Secondary endpoints included: PFS for full study population or intention-to-treat (ITT) population, overall survival in both the ITT population and in the subgroup without brain metastasis, independently determined objective response rate, duration of response, time to onset of response according to Response Evaluation Criteria in Solid Tumors (RECIST 1.1), quality of life and safety.

Important Safety Information

Most serious warnings and precautions:

- **Severe or life-threatening neutropenia**. Withhold TRODELVY for absolute neutrophil count below 1500/mm3 or neutropenic fever. Complete blood counts should be monitored prior to initiation of TRODELVY and prior to each dose, and as clinically indicated. Based on the severity of neutropenia, TRODELVY may require dose interruption or reduction. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.
- **Severe diarrhea**. Monitor patients with diarrhea and give fluid and electrolytes as needed. At the onset of 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.

The most common adverse reactions (incidence >25%) reported in patients receiving TRODELVY in the ASCENT study were: neutropenia (64.0%), diarrhea (65.1%), nausea (62.4%), fatigue (51.6%), alopecia (46.9%), anemia (39.1%), constipation (37.2%), vomiting (33.3%), and decreased appetite (27.5%).

For all important safety information for TRODELVY, including contraindications, additional warnings and precautions, adverse reactions and drug interactions, please see the Canadian product monograph at www.gilead.ca.

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. Gilead Sciences Canada, Inc. is the Canadian affiliate of Gilead Sciences, Inc., and was established in Mississauga, Ontario, in 2006. For more information on Gilead Sciences, please visit the company's website at www.gilead.com.

Forward-Looking Statement

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 within currently anticipated timelines or at all, including those involving Trodelvy; the possibility of unfavorable results from ongoing or additional trials, including those involving Trodelvy; Gilead's ability to receive regulatory approvals in a timely manner or at all, including additional regulatory approvals of Trodelvy for the treatment of metastatic TNBC, metastatic breast cancer, metastatic UC, metastatic non-small cell lung cancer and other solid tumors, and the risk that physicians may not see the benefits of prescribing Trodelvy; and any such approvals may be subject to significant limitations on use; the risk that physicians 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.

TRODELVY, Gilead and the Gilead logo are trademarks of Gilead Sciences, Inc., or its related companies.

For more information about Gilead, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@Gilead Sciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

---

[i] TRODELVY® Product Monograph, September 24, 2021 (www.gilead.ca)
[ii] Ibid.
[iii] Ibid.
[iv] Ibid.
[v] Ambrogi F, Fornili M, Boracchi P, Trerotola M, Relli V, et al. (2014) Trop-2 Is a Determinant of Breast Cancer Survival. PLoS ONE 2014;9(5): e96993.
[vi] American Cancer Society. Triple-negative breast cancer. Available at: https://www.cancer.org/cancer/breast-cancer/about/types-of-breast-cancer/triple-negative.html Accessed on: October 20, 2021.
[vii] Breastcancer.org. Triple-Negative Breast Cancer. Available at: https://www.breastcancer.org/symptoms/types/triple-negative Accessed on: August 24, 2021.
[viii] Plasilova M, et al. Features of triple-negative breast cancer. *Medicine (Baltimore)*. 2016; 95(35): e4614.
[ix] Dent, R., et al. Triple-Negative Breast Cancer: Clinical Features and Patterns of Recurrence. Clin Cancer Res 2007;4429 13(15) August 1, 2007.
[x] American Cancer Society. Triple-negative breast cancer. Available at: https://www.cancer.org/cancer/breast-cancer/about/types-of-breast-cancer/triple-negative.html Accessed on: August 24, 2021.
[xi] American Cancer Society. Survival rates for breast cancer. Available at: https://www.cancer.org/cancer/breast-cancer/understanding-a-breast-cancer-diagnosis/breast-cancer-survival-rates.html Accessed on August 24, 2021.
[xii] American Cancer Society. Triple-negative Breast Cancer. Available at: https://www.cancer.org/cancer/breast-cancer/understanding-a-breast-cancer-diagnosis/types-of-breast-cancer/triple-negative.html. Last accessed: March 2021.
[xiii] Canadian Cancer Society. Breast Cancer Statistics. Available at: https://www.cancer.ca/en/cancer-information/cancer-type/breast/statistics/?region=on Accessed on: October 20, 2021.
[xiv] TRODELVY® Product Monograph, September 24, 2021 (www.gilead.ca)