FIRST AND ONLY PARP INHIBITOR, LYNPARZA® (OLAPARIB) APPROVED AS A FIRST-LINE MAINTENANCE THERAPY TREATMENT IN *BRCA*-MUTATED ADVANCED OVARIAN CANCER

AstraZeneca and Merck's Lynparza reduced the risk of disease progression or death by 70% compared to placebo following response to platinum-based chemotherapy

MISSISSAUGA, ON, May 8, 2019 /CNW/ - AstraZeneca Canada and Merck Canada today announced the Health Canada approval of Lynparza (olaparib) as a monotherapy maintenance treatment of adult patients with advanced *BRCA*-mutated (*BRCA*m) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) to first-line platinum-based chemotherapy. Patients must have confirmation of *BRCA* mutation (identified by either germline or tumour testing) before treatment is initiated.

This is the first and only regulatory approval for a poly ADP-ribose polymerase (PARP) inhibitor in Canada in the first-line maintenance setting for patients with this disease.

"Until now, women diagnosed with *BRCA*-mutated ovarian cancer have had limited options for first-line treatments. The approval of Lynparza is an exciting milestone as it provides a new first-line treatment option that offers the potential of sustained remission," said Dr. James Bentley, President, The Society of Gynecologic Oncology of Canada. "This new approval reinforces the importance of *BRCA* testing for all patients with an ovarian and fallopian tube cancer. No woman should be left behind."

"This is tremendous and welcome news for women diagnosed with *BRCA*-mutated ovarian cancer," added Elisabeth Baugh, CEO of Ovarian Cancer Canada. "Survival rates for this disease have remained too low for 50 years, and for roughly the last 20 years, there has been significant challenge in arriving at new treatments. Women have run out of treatment options very quickly. Today's announcement brings the hope and possibility of saving more lives through new therapies that allow earlier treatment for ovarian cancer patients."

About the SOLO-1 Trial

The Notice of Compliance was granted based on positive results from the pivotal Phase III SOLO-1 trial, in which Lynparza reduced the risk of disease progression or death by 70% in patients with *BRCA*m advanced ovarian cancer, who were in complete or partial response to platinum-based chemotherapy compared to placebo (HR 0.30 [95% CI 0.23-0.41], p<0.0001).[i] With a median of 41 months follow-up, median progression-free survival (PFS) in the Lynparza arm was not reached versus 13.8 months with placebo.[ii] The SOLO-1 trial also showed 60% of patients receiving Lynparza remained progression-free at 3 years compared to 27% of patients receiving placebo .[iii]

The safety profile of Lynparza was consistent with previous clinical trials.[iv] The most common adverse drug reactions (ADRs) (of >20% any grade) were nausea (77%), fatigue (63%), vomiting

(40%), anemia (39%), diarrhea (34%), constipation (28%), dysgeusia (26%), neutropenia (23%) and headache (23%).[v]

This approval is the third regulatory approval for Lynparza in the first-line maintenance setting for *BRCA*m advanced ovarian cancer, following FDA approval in the US in December 2018 and in Brazil earlier this year.

About Lynparza (olaparib)

Lynparza was the first Health Canada-approved oral (PARP) inhibitor that may exploit tumor DNA damage response (DDR) pathway deficiencies to potentially kill cancer cells.[vi]

AstraZeneca and Merck are conducting multiple Lynparza phase III studies across a variety of indications and tumour types.

Lynparza is a registered trademark of AstraZeneca AB, used under license by AstraZeneca Canada Inc. and Merck Canada Inc.

About Ovarian Cancer in Canada

Ovarian cancer is one of the fifth most common cancers for Canadian women.[vii] An estimated 2,800 Canadians will be diagnosed with the disease this year, and 1,800 women will die from it.[viii] The majority of cases are high-grade epithelial ovarian cancer. Approximately 25 per cent of Canadian women with this type of ovarian cancer have an abnormality in their *BRCA*1/2 genes, which increases their risk of developing ovarian cancer.[ix]

With genetic testing, women who carry the *BRCA* gene can determine whether increased observation and preventive action (e.g. removal of the fallopian tubes and/or ovaries) are viable options. Women already diagnosed with *BRCA*-mutated or high-grade ovarian cancer should speak to their doctor about new treatment options available to them.

About the AstraZeneca and Merck strategic oncology collaboration

In 2017, AstraZeneca and Merck, announced a global strategic oncology collaboration to co-develop and co-commercialize Lynparza, the world's first PARP inhibitor, and potential new medicine selumetinib, a MEK inhibitor, for multiple cancer types. Working together, the companies will develop Lynparza and selumetinib in combination with other potential new medicines and as monotherapies. Independently, the companies will develop Lynparza and selumetinib in combination with their respective PD-L1 and PD-1 medicines.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialization of primary and specialty care medicines that transform lives. Our primary focus is on three important areas of healthcare: Cardiovascular and Metabolic disease; Oncology; and Respiratory, Inflammation and Autoimmunity. AstraZeneca operates in more than 100 countries and its innovative medicines are used by millions of patients worldwide. In Canada, we employ more than 675 employees across the country and our

headquarters are located in Mississauga, Ontario. For more information, please visit the company's website at www.astrazeneca.ca.

About Merck

For over a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola.

Based in Kirkland, Québec, Merck employs approximately 765 people across Canada. Merck is one of the top R&D investors in Canada, with investments totaling $69 million in 2018 and more than $1 billion since 2000. For more information about our operations in Canada, visit www.merck.ca and connect with us on YouTube and Twitter @MerckCanada.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in

the company's 2017 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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[i] AstraZeneca Canada Inc., Lynparza® (olaparib) tablets. Product Monograph. May 2019.
[ii] Ibid.
[iii] Ibid.
[iv] Ibid.
[v] Ibid.
[vi] Ibid.
[vii] Ovarian Cancer Canada. About Ovarian Cancer. Accessed April 10, 2019. Available at: http://www.ovariancanada.org/about-ovarian-cancer
[viii] Canadian Cancer Society. Ovarian Cancer Statistics. Accessed April 10, 2019. Available at: http://www.cancer.ca/en/cancer-information/cancer-type/ovarian/statistics/?region=on
[ix] Ovarian Cancer Canada. About Ovarian Cancer. Disease Basics. Accessed April 10, 2019. Available at: https://ovariancanada.org/About-Ovarian-Cancer/Disease-Basics/What-is-ovarian-cancer