NEWS RELEASE

SOLO-1 Phase 3 Trial Demonstrates LYNPARZA® (olaparib) Maintenance Therapy Cut the Risk of Disease Progression or Death by 70 Percent in Patients with Newly-Diagnosed, Advanced BRCA-Mutated Ovarian Cancer

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60 Percent of Patients Receiving LYNPARZA Remained Progression-Free at Three Years Compared to 27 Percent on Placebo Following Platinum-Based Chemotherapy

LYNPARZA Is the Only PARP Inhibitor to Demonstrate an Improvement in Progression-Free Survival in First-Line Maintenance Treatment for Newly-Diagnosed, Advanced Ovarian Cancer

KENILWORTH, N.J.--(**BUSINESS WIRE**)--AstraZeneca and Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced detailed results from the Phase 3 SOLO-1 trial testing LYNPARZA 300 mg tablets twice daily as a maintenance treatment for patients with newly-diagnosed advanced BRCA-mutated (BRCAm) ovarian cancer who were in complete or partial response following first-line standard platinum-based chemotherapy.

Results of the trial confirm the statistically-significant and clinically-meaningful improvement in progression-free survival (PFS) for LYNPARZA as compared to placebo, reducing the risk of disease progression or death by 70 percent (HR=0.30 [95% CI, 0.23-0.41]; p<0.001). At 41 months of follow-up, the median PFS for patients treated with LYNPARZA was not reached compared to 13.8 months for patients treated with placebo. Of those receiving LYNPARZA, 60.4 percent remained progression-free at 36 months, compared to 26.9 percent of women in the

placebo arm. The data were presented at the Presidential Symposium of the ESMO 2018 Congress in Munich, Germany and published simultaneously online in the New England Journal of Medicine (NEJM).

Summary of PFS as Assessed by Investigators 1,2

	LYNPARZA (n=260)	Placebo (n=131)
Number of patients with event (%)3	102 (39.2)	96 (73.3)
Median (in months)	Not reached	13.8
Hazard ratio (95% CI)	0.30 (0.23-0.41)	
P-value	p<0.001	

1 Investigator-assessed
2 Median (interquartile range) duration of follow-up 40.7 months (34.9–42.9) for LYNPARZA and 41.2 months (32.2–41.6) for placebo
3 Analysis was done at 50.6 percent maturity

Sean Bohen, executive vice president, Global Medicines Development and chief medical officer at AstraZeneca, said, “There is currently a significant unmet need in the treatment of advanced ovarian cancer because 70 percent of women relapse within the first three years after their initial treatment. The remarkable results of the SOLO-1 trial, which showed that 60 percent of women with newly-diagnosed, advanced BRCA-mutated ovarian cancer remained progression-free at three years, highlight the potential of LYNPARZA as a first-line maintenance therapy in this setting.”

Dr. Roy Baynes, senior vice president and head of Global Clinical Development, chief medical officer, Merck Research Laboratories, said, “Our collective goal in oncology research is to improve long-term outcomes for people living with cancer. Based on the SOLO-1 trial results, LYNPARZA is the only PARP inhibitor to have demonstrated a significant and clinically-meaningful improvement in reducing the risk of progression or death for newly-diagnosed patients with advanced BRCA-mutated ovarian cancer following platinum-based chemotherapy. We are working with regulatory authorities as quickly as possible to seek approval of LYNPARZA for these patients.”

Kathleen Moore, co-principal investigator of the SOLO-1 trial and associate director, Stephenson Cancer Center at The University of Oklahoma, Oklahoma City, Oklahoma, said, “Women with ovarian cancer are often diagnosed with advanced disease, which unfortunately is associated with poor long-term survival rates. The newly-diagnosed setting is our best opportunity to achieve a sustained remission, since once a patient’s ovarian cancer recurs, it is

typically incurable. The SOLO-1 results demonstrate the potential of LYNPARZA maintenance therapy earlier in the treatment pathway and reinforce the importance of identifying a patient's BRCA mutation status at the time of diagnosis – these results could change the way we treat women with advanced BRCA-mutated ovarian cancer."

The SOLO-1 safety profile was in line with that observed in prior clinical trials. The most common adverse events (AEs) ≥ 20 percent were nausea (77%), fatigue (64%), vomiting (40%), anemia (39%) and diarrhea (34%). The most common ≥ Grade 3 AEs were anemia (22%) and neutropenia (8%). Seventy-one percent of patients on LYNPARZA remained on the recommended starting dose. Additionally, 88 percent of patients on LYNPARZA continued treatment without an AE-related discontinuation. Further, 48 percent of patients on LYNPARZA did not have a dose interruption as a result of an AE.

Per SOLO-1 protocol guidelines, patients who demonstrated a complete response (no radiological evidence of disease) at two years stopped treatment with LYNPARZA; patients who demonstrated a partial response and, who in the opinion of the treating physician can derive further benefit from continuous treatment, were treated beyond two years.

AstraZeneca and Merck are exploring additional trials in ovarian cancer, including the ongoing GINECO/ENGOTov25 Phase 3 trial, PAOLA-1. This trial is testing the effect of LYNPARZA in combination with bevacizumab as a maintenance treatment for patients with newly-diagnosed advanced ovarian cancer regardless of their BRCA status. Results are expected during the second half of 2019.

LYNPARZA is a first-in-class poly ADP-ribose polymerase (PARP) inhibitor approved in the U.S. since 2014. LYNPARZA has a broad clinical development program and AstraZeneca and Merck are working together to deliver LYNPARZA as quickly as possible to more patients across multiple cancer types.

LYNPARZA is not currently FDA-approved for advanced BRCAm ovarian cancer treatment in the first-line maintenance setting. LYNPARZA is indicated for the maintenance treatment of recurrent ovarian cancer in response to platinum-based chemotherapy regardless of BRCA mutation status, and for the treatment of advanced ovarian cancer patients with a germline BRCA mutation previously treated with three or more lines of chemotherapy. Physicians should select advanced ovarian cancer patients for therapy based on a FDA-approved companion diagnostic. Please see complete indications below.

Important Safety Information

Contraindications

There are no contraindications for LYNPARZA.

Warnings and Precautions

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): Occurred in <1.5% of patients exposed to LYNPARZA monotherapy, and the majority of events had a fatal outcome. The duration of therapy in patients who developed secondary MDS/AML varied from <6 months to >2 years. All of these patients had previous chemotherapy with platinum agents and/or other DNA-damaging agents, including radiotherapy, and some also had a history of more than one primary malignancy or of bone marrow dysplasia.

Do not start LYNPARZA until patients have recovered from hematological toxicity caused by previous chemotherapy (≤Grade 1). Monitor complete blood count for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities, interrupt LYNPARZA and monitor blood count weekly until recovery.

If the levels have not recovered to Grade 1 or less after 4 weeks, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. Discontinue LYNPARZA if MDS/AML is confirmed.

Pneumonitis: Occurred in <1% of patients exposed to LYNPARZA, and some cases were fatal. If patients present with new or worsening respiratory symptoms such as dyspnea, cough, and fever, or a radiological abnormality occurs, interrupt LYNPARZA treatment and initiate prompt investigation. Discontinue LYNPARZA if pneumonitis is confirmed and treat patient appropriately.

Embryo-Fetal Toxicity: Based on its mechanism of action and findings in animals,

LYNPARZA can cause fetal harm. A pregnancy test is recommended for females of

reproductive potential prior to initiating treatment.

Females

Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 6 months following the last dose.

Males

Advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 3 months following the last dose of LYNPARZA and to not donate sperm

during this time.

Adverse Reactions—Maintenance Setting

Most common adverse reactions (Grades 1-4) in ≥20% of patients in clinical trials of LYNPARZA in the maintenance setting for SOLO-2: nausea (76%), fatigue (including asthenia) (66%), anemia (44%), vomiting (37%), nasopharyngitis/upper respiratory tract infection (URI)/influenza (36%), diarrhea (33%), arthralgia/myalgia (30%), dysgeusia (27%), headache (26%), decreased appetite (22%), and stomatitis (20%).

Study 19: nausea (71%), fatigue (including asthenia) (63%), vomiting (35%), diarrhea (28%), anemia (23%), respiratory tract infection (22%), constipation (22%), headache (21%), and decreased appetite (21%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients in clinical trials of LYNPARZA in the maintenance setting (SOLO-2/Study 19) were: increase in mean corpuscular volume (89%/82%), decrease in hemoglobin (83%/82%), decrease in leukocytes (69%/58%), decrease in lymphocytes (67%/52%), decrease in absolute neutrophil count (51%/47%), increase in serum creatinine (44%/45%), and decrease in platelets (42%/36%).

Adverse Reactions—Advanced gBRCAm Ovarian Cancer

Most common adverse reactions (Grades 1-4) in ≥20% of patients in clinical trials of LYNPARZA for advanced gBRCAm ovarian cancer after 3 or more lines of chemotherapy (pooled from 6 studies) were: fatigue (including asthenia) (66%), nausea (64%), vomiting (43%), anemia (34%), diarrhea (31%), nasopharyngitis/upper respiratory tract infection (URI) (26%), dyspepsia (25%), myalgia (22%), decreased appetite (22%), and arthralgia/musculoskeletal pain (21%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients in clinical trials of LYNPARZA for advanced gBRCAm ovarian cancer (pooled from 6 studies) were: decrease in hemoglobin (90%), increase in mean corpuscular volume (57%), decrease in lymphocytes (56%), increase in serum creatinine (30%), decrease in platelets (30%), and decrease in absolute neutrophil count (25%).

Adverse Reactions—gBRCAm, HER2-Negative Breast Cancer

Most common adverse reactions (Grades 1-4) in ≥20% of patients in OlympiAD were: nausea (58%), anemia (40%), fatigue (including asthenia) (37%), vomiting (30%), neutropenia (27%), respiratory tract infection (27%), leukopenia (25%), diarrhea (21%), and headache (20%).

Most common laboratory abnormalities (Grades 1-4) in >25% of patients in OlympiAD were: decrease in

hemoglobin (82%), decrease in lymphocytes (73%), decrease in leukocytes (71%), increase in mean corpuscular volume (71%), decrease in absolute neutrophil count (46%), and decrease in platelets (33%).

Drug Interactions

Anticancer Agents: Clinical studies of LYNPARZA in combination with other myelosuppressive anticancer agents, including DNA-damaging agents, indicate a potentiation and prolongation of myelosuppressive toxicity.

CYP3A Inhibitors: Avoid concomitant use of strong or moderate CYP3A inhibitors. If a strong or moderate CYP3A inhibitor must be co-administered, reduce the dose of LYNPARZA. Advise patients to avoid grapefruit, grapefruit juice, Seville oranges, and Seville orange juice during LYNPARZA treatment.

CYP3A Inducers: Avoid concomitant use of strong or moderate CYP3A inducers when using LYNPARZA. If a moderate inducer cannot be avoided, there is a potential for decreased efficacy of LYNPARZA.

Use In Specific Populations

Lactation: No data are available regarding the presence of olaparib in human milk, its effects on the breastfed infant or on milk production. Because of the potential for serious adverse reactions in the breastfed infant, advise a lactating woman not to breastfeed during treatment with LYNPARZA and for 1 month after receiving the final dose.

Pediatric Use: The safety and efficacy of LYNPARZA have not been established in pediatric patients.

Hepatic Impairment: No adjustment to the starting dose is required in patients with mild hepatic impairment (Child-Pugh classification A). There are no data in patients with moderate or severe hepatic impairment.

Renal Impairment: No adjustment to the starting dose is necessary in patients with mild renal impairment (CLcr=51-80 mL/min). In patients with moderate renal impairment (CLcr=31-50 mL/min), reduce the dose to 200 mg twice daily. There are no data in patients with severe renal impairment or end-stage renal disease (CLcr ≤30 mL/min).

Indications

LYNPARZA is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.

For the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with 3 or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

In patients with deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine treatment. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

Please see complete **Prescribing Information** , including Patient Information (Medication Guide).

About the SOLO-1 Phase 3 Trial

SOLO-1 is a Phase 3, randomized, double-blind, placebo-controlled, multi-center trial to evaluate the efficacy and safety of LYNPARZA tablets (300 mg twice daily) as maintenance monotherapy compared with placebo in newly-diagnosed patients with advanced BRCA-mutated ovarian cancer following platinum-based chemotherapy. The trial randomized 391 patients with a deleterious or suspected deleterious BRCA1 or BRCA2 mutation who were in clinical complete or partial response following platinum-based chemotherapy. Patients were randomized (2:1) to receive LYNPARZA or placebo for up to two years or until disease progression (at the investigator's discretion). The primary endpoint was investigator-assessed progression-free survival and key secondary endpoints include time to second disease progression or death, time to first subsequent treatment and overall survival.

About Ovarian Cancer

Approximately 20,000 women in the U.S. are diagnosed with ovarian cancer (including ovarian, fallopian tube and primary peritoneal cancers) each year. Among women in the U.S., it is the ninth most common cancer and the fifth leading cause of cancer death.

The risk of developing ovarian cancer is increased in women with specific inherited genetic abnormalities, including BRCA mutations.

About BRCA Mutations

BRCA1 and BRCA2 are human genes that produce proteins responsible for repairing damaged DNA and play an important role in maintaining the genetic stability of cells. When either of these genes is mutated, or altered, such

that its protein product either is not made or does not function correctly, DNA damage may not be repaired properly, and cells become unstable. As a result, cells are more likely to develop additional genetic alterations that can lead to cancer.

About LYNPARZA ® (olaparib)

LYNPARZA is the first-in-class PARP inhibitor and the first targeted treatment to potentially exploit DNA damage response (DDR) pathway deficiencies, such as BRCA mutations, to preferentially kill cancer cells. Specifically, in vitro studies have shown that LYNPARZA-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes, resulting in DNA damage and cancer cell death. LYNPARZA is being tested in a range of DDR-deficient tumor types.

LYNPARZA, which is being jointly developed and commercialized by AstraZeneca and Merck, has a broad and advanced clinical trial development program, and AstraZeneca and Merck are working together to deliver it as quickly as possible to more patients across multiple cancer types.

About the AstraZeneca and Merck Strategic Oncology Collaboration

In July 2017, AstraZeneca and Merck, known as MSD outside the United States and Canada, 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.

Merck's Focus on Cancer

Our goal is to translate breakthrough science into innovative oncology medicines to help people with cancer worldwide. At Merck, the potential to bring new hope to people with cancer drives our purpose and supporting accessibility to our cancer medicines is our commitment.

As part of our focus on cancer, Merck is committed to exploring the potential of immuno-oncology with one of the largest development programs in the industry across more than 30 tumor types. We also continue to strengthen our portfolio through strategic acquisitions and are prioritizing the development of several promising oncology candidates with the potential to improve the treatment of advanced cancers.

For more information about our oncology clinical trials, visit **www.merck.com/clinicaltrials**.

About Merck

For more than 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. For more information, visit **www.merck.com** and connect with us on **Twitter**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

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. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. 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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