NEWS RELEASE

LYNPARZA® (olaparib) Reduced the Risk of Invasive Disease Recurrence or Death by 42% Versus Placebo in Adjuvant Treatment of Patients With Germline BRCA Mutations and High-Risk HER2-Negative Early Breast Cancer in Phase 3 OlympiA Trial

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First Medicine Specifically Targeting BRCA Mutations to Demonstrate Statistically Significant Improvement in Invasive Disease-Free Survival in Adjuvant Setting Following Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy

KENILWORTH, N.J.--(BUSINESS WIRE)-- AstraZeneca and Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced the first presentation of data from the Phase 3 OlympiA trial, in which LYNPARZA demonstrated a statistically significant improvement in its primary endpoint of invasive disease-free survival (iDFS) versus placebo in the adjuvant treatment of patients with germline BRCA1/2 mutations and high-risk human epidermal growth factor receptor 2 (HER2)-negative early breast cancer following definitive local treatment and neoadjuvant or adjuvant chemotherapy. Results will be presented during the Plenary Session at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting on June 6 (Abstract LBA#1). Results were also published today in the New England Journal of Medicine.

An estimated 2.3 million people were diagnosed with breast cancer worldwide in 2020, and germline BRCA mutations are found in approximately 5% of patients with breast cancer.

OlympiA is a Phase 3, multicenter, randomized, double-blind, placebo-controlled trial. In the overall trial population

of 1,836 patients, results showed LYNPARZA (n=921) reduced the risk of invasive breast cancer recurrences, second cancers or death by 42% (HR=0.58 [99.5% CI, 0.41-0.82]; p<0.0001) versus placebo (n=915) based on a pre-specified event-driven interim analysis with a median follow-up of 2.5 years. At three years following trial initiation, 85.9% of patients treated with LYNPARZA were alive and free of invasive breast cancer and second cancers versus 77.1% of patients treated with placebo (difference: 8.8% [95% CI, 4.5-13.0]).

Results also showed an improvement in the key secondary endpoint of distant disease-free survival (DDFS) in the overall trial population. LYNPARZA reduced the risk of distant disease recurrence or death by 43% (HR=0.57 [99.5% CI, 0.39-0.83]; p<0.0001). At the time of data cut-off, overall survival (OS) data, while directionally encouraging, did not reach statistical significance and were not mature. The trial will continue to assess OS as a secondary endpoint.

The safety and tolerability profile of LYNPARZA in this trial was in line with that observed in prior clinical trials. The most common adverse events (AEs) (≥20%) were nausea (57%), fatigue (40%), anemia (23%) and vomiting (23%). Grade ≥3 AEs were anemia (9%), neutropenia (5%), leukopenia (3%), fatigue (2%) and nausea (1%). Approximately 10% of patients treated with LYNPARZA discontinued treatment due to AEs.

Andrew Tutt, chair of the OlympiA trial steering committee and professor of oncology, The Institute of Cancer Research, London, and Kings College London, said, “We are thrilled that our global academic and industry partnership in OlympiA has been able to help identify a possible new treatment option for patients with early-stage breast cancer and who have inherited mutations in their BRCA1 or BRCA2 genes. Patients with early-stage breast cancer who have inherited BRCA mutations are typically diagnosed at a younger age compared to those without such a mutation. Olaparib has the potential to be used as a follow-on to all the standard initial breast cancer treatments to reduce the rate of life-threatening recurrence and cancer spread for many patients identified through genetic testing to have mutations in these genes.”

Dave Fredrickson, executive vice president, oncology business unit, AstraZeneca, said, “By providing a treatment which significantly reduces the risk of breast cancer returning in these high-risk patients, we hope LYNPARZAwill set a new benchmark. We are working with regulatory authorities to bring LYNPARZAto these patients as quickly as possible.”

Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories, said, “Results of the OlympiA trial represent a potential step forward for patients with high-risk early breast cancer. These new data support the importance of testing at diagnosisfor BRCA1/2 mutations, which are actionable biomarkers that can help identify patients with early breast cancer who may be eligible for adjuvant treatment with LYNPARZA. Testing for BRCA mutations, in addition to hormone receptor status and the expression of the HER2 protein, will allow clinicians to better inform potential treatment plans for their patients.”

In February 2021, the Independent Data Monitoring Committee (IDMC) recommended for the OlympiA trial to move to early primary analysis and reporting. Based on the planned interim analysis, the IDMC concluded that the trial crossed the superiority boundary for its primary endpoint of iDFS.

Summary of OlympiA Results

	LYNPARZA (n=921)	Placebo (n=915)
iDFS (primary endpoint)		
HR (99.5% CI)	0.58 (0.41, 0.82)	
p-value	p<0.0001	
Events	106	178
iDFS ratesiii		
One year	93.3%	88.4%
Two years	89.2%	81.5%
Three years	85.9%	77.1%
DDFS (secondary endpoint)		
HR (99.5% CI)	0.57 (0.39, 0.83)	
p-value	p<0.0001	
Events	89	152
DDFS ratesiii		
One year	94.3%	90.2%
Two years	90.0%	83.9%
Three years	87.5%	80.4%
OS at interim (secondary endpoint) ii		
HR (99% CI)	0.68 (0.44, 1.05)	
p-value	p=0.024	
Events	59	86
OS ratesiii		
One year	98.1%	96.9%
Two years	94.8%	92.3%
Three years	92.0%	88.3%

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i The data cut-off date for the interim analysis was March 27, 2020.
ii Statistical significance was not reached based on the interim analysis plan for alpha conservation for future survival analyses.
iii The study was not designed to assess a statistical difference between treatment groups at these timepoints.

OlympiA is a global, collaborative, Phase 3 trial coordinated by the Breast International Group (BIG) worldwide, in partnership with NRG Oncology, the U.S. National Cancer Institute (NCI), Frontier Science & Technology Research Foundation (FSTRF), AstraZeneca and Merck. The trial is sponsored by NRG Oncology in the U.S. and by AstraZeneca outside the U.S.

LYNPARZA is approved in the U.S., Japan and a number of other countries for germline BRCA-mutated, HER2-negative metastatic breast cancer previously treated with chemotherapy and, if hormone receptor-positive, endocrine therapy if appropriate. In the EU, this includes locally advanced breast cancer.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

There are no contraindications for LYNPARZA.

WARNINGS AND PRECAUTIONS

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): Occurred in approximately 1.5% of patients exposed to LYNPARZA monotherapy, and the majority of events had a fatal outcome. The median duration of therapy in patients who developed MDS/AML was 2 years (range: <6 months to >10 years). All of these patients had previous chemotherapy with platinum agents and/or other DNA-damaging agents, including radiotherapy.

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 0.8% of patients exposed to LYNPARZA monotherapy, 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.

Venous Thromboembolic Events: Including pulmonary embolism, occurred in 7% of patients with metastatic castration-resistant prostate cancer who received LYNPARZA plus androgen deprivation therapy (ADT) compared to 3.1% of patients receiving enzalutamide or abiraterone plus ADT in the PROfound study. Patients receiving LYNPARZA and ADT had a 6% incidence of pulmonary embolism compared to 0.8% of patients treated with ADT plus either enzalutamide or abiraterone. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism, and treat as medically appropriate, which may include long-term anticoagulation as clinically indicated.

ADVERSE REACTIONS—First-Line Maintenance BRCAm Advanced Ovarian Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of patients in clinical trials of LYNPARZA in the first-line maintenance setting for SOLO-1 were: nausea (77%), fatigue (67%), abdominal pain (45%), vomiting (40%), anemia (38%), diarrhea (37%), constipation (28%), upper respiratory tract infection/influenza/ nasopharyngitis/bronchitis (28%), dysgeusia (26%), decreased appetite (20%), dizziness (20%), neutropenia (17%), dyspepsia (17%), dyspnea (15%), leukopenia (13%), UTI (13%), thrombocytopenia (11%), and stomatitis (11%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients in clinical trials of LYNPARZA in the first-line maintenance setting for SOLO-1 were: decrease in hemoglobin (87%), increase in mean corpuscular volume (87%), decrease in leukocytes (70%), decrease in lymphocytes (67%), decrease in absolute neutrophil count (51%), decrease in platelets (35%), and increase in serum creatinine (34%).

ADVERSE REACTIONS—First-Line Maintenance Advanced Ovarian Cancer in Combination with Bevacizumab

Most common adverse reactions (Grades 1-4) in ≥10% of patients treated with LYNPARZA/bevacizumab compared to a ≥5% frequency for placebo/bevacizumab in the first-line maintenance setting for PAOLA-1 were: nausea (53%), fatigue (including asthenia) (53%), anemia (41%), lymphopenia (24%), vomiting (22%) and leukopenia (18%). In addition, the most common adverse reactions (≥10%) for patients receiving LYNPARZA/bevacizumab irrespective of the frequency compared with the placebo/bevacizumab arm were: diarrhea (18%), neutropenia (18%), urinary tract infection (15%) and headache (14%).

In addition, venous thromboembolic events occurred more commonly in patients receiving LYNPARZA/bevacizumab (5%) than in those receiving placebo/bevacizumab (1.9%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients for LYNPARZA in combination with bevacizumab in the first-line maintenance setting for PAOLA-1 were: decrease in hemoglobin (79%), decrease in lymphocytes (63%), increase in serum creatinine (61%), decrease in leukocytes (59%), decrease in absolute neutrophil count (35%) and decrease in platelets (35%).

ADVERSE REACTIONS—Maintenance Recurrent Ovarian Cancer

Most common adverse reactions (Grades 1-4) in ≥20% of patients in clinical trials of LYNPARZA in the maintenance setting for SOLO-2 were: 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%), decreased appetite (21%) and dyspepsia (20%).

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/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%), mean corpuscular volume elevation (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 Metastatic 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%).

ADVERSE REACTIONS—First-Line Maintenance gBRCAm Metastatic Pancreatic Adenocarcinoma

Most common adverse reactions (Grades 1-4) in ≥10% of patients in clinical trials of LYNPARZA in the first-line maintenance setting for POLO were: fatigue (60%), nausea (45%), abdominal pain (34%), diarrhea (29%), anemia (27%), decreased appetite (25%), constipation (23%), vomiting (20%), back pain (19%), arthralgia (15%), rash (15%), thrombocytopenia (14%), dyspnea (13%), neutropenia (12%), nasopharyngitis (12%), dysgeusia (11%), and stomatitis (10%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients in clinical trials of LYNPARZA in the first-line maintenance setting for POLO were: increase in serum creatinine (99%), decrease in hemoglobin (86%), increase in mean corpuscular volume (71%), decrease in lymphocytes (61%), decrease in platelets (56%), decrease in leukocytes (50%), and decrease in absolute neutrophil count (25%).

ADVERSE REACTIONS—HRR Gene-mutated Metastatic Castration Resistant Prostate Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of patients in clinical trials of LYNPARZA for PROfound were: anemia (46%), fatigue (including asthenia) (41%), nausea (41%), decreased appetite (30%), diarrhea (21%), vomiting (18%), thrombocytopenia (12%), cough (11%), and dyspnea (10%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients in clinical trials of LYNPARZA for PROfound were: decrease in hemoglobin (98%), decrease in lymphocytes (62%), decrease in leukocytes (53%), and decrease in absolute neutrophil count (34%).

DRUG INTERACTIONS

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

CYP3A Inhibitors: Avoid coadministration of strong or moderate CYP3A inhibitors when using LYNPARZA. If a

strong or moderate CYP3A inhibitor must be coadministered, reduce the dose of LYNPARZA. Advise patients to avoid grapefruit, grapefruit juice, Seville oranges, and Seville orange juice during LYNPARZA treatment.

CYP3A Inducers: Avoid coadministration of strong or moderate CYP3A inducers when using 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 or moderate hepatic impairment (Child-Pugh classification A and B). There are no data in patients with severe hepatic impairment (Child-Pugh classification C).

Renal Impairment: No dosage modification is recommended in patients with mild renal impairment (CLcr 51-80 mL/min estimated by Cockcroft-Gault). In patients with moderate renal impairment (CLcr 31-50 mL/min), reduce the dose of LYNPARZA 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 in the United States

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

First-Line Maintenance BRCAm Advanced Ovarian Cancer

For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

First-Line Maintenance HRD-Positive Advanced Ovarian Cancer in Combination with Bevacizumab

In combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based

chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:

- a deleterious or suspected deleterious BRCA mutation and/or
- genomic instability

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

Maintenance Recurrent Ovarian Cancer

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.

Advanced gBRCAm Ovarian Cancer

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.

gBRCAm HER2-Negative Metastatic Breast Cancer

For the treatment of adult patients with deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer, who have 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 therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

First-Line Maintenance gBRCAm Metastatic Pancreatic Cancer

For the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

HRR Gene-mutated Metastatic Castration Resistant Prostate Cancer

For the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have

progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

Please **click here** for complete Prescribing Information, including Patient Information (Medication Guide).

About Breast Cancer

Breast cancer is the most common cancer among women worldwide, and an estimated 70% of all breast cancer cases are diagnosed at an early stage. Breast cancer is one of the most biologically diverse tumor types with various factors underlying its development and progression. The discovery of biomarkers in the development of breast cancer has greatly impacted the scientific understanding of the disease and the treatment of patients who develop the disease.

About BRCA Mutations

BRCA1 and BRCA2 (breast cancer susceptibility genes 1/2) are human genes that produce proteins responsible for repairing damaged DNA and play an important role 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 OlympiA

OlympiA is a Phase 3, double-blind, parallel-group, placebo-controlled, multicenter trial evaluating the efficacy and safety of LYNPARZAversus placebo as adjuvant treatment in patients with gBRCAm high-risk HER2-negative early breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy. Patients were randomized to LYNPARZA (300 mg twice daily) or placebo. The primary endpoint of the trial is iDFS, which is defined as time from randomization to date of first loco-regional or distant recurrence or new cancer or death from any cause. Key secondary endpoints include OS and DDFS, which is defined as time from randomization until documented evidence of first distant recurrence of breast cancer or death without distant recurrence.

About BIG

The Breast International Group (BIG) is an international not-for-profit organization for academic breast cancer research groups from around the world, based in Brussels, Belgium.

Founded by leading European opinion leaders in 1999, the organization aims to address fragmentation in breast cancer research and now represents a network of over 50 like-minded research groups affiliated with specialized hospitals, research centers and leading experts across approximately 70 countries on six continents.

BIG's research is supported in part by its philanthropy unit, known as BIG against breast cancer, which is used to interact with the general public and donors, and to raise funds for BIG's purely academic breast cancer trials and research programs.

About FSTRF

Frontier Science & Technology Research Foundation (FSTRF) is a non-profit, research organization which supports research networks, pharmaceutical companies and investigators to conduct scientifically meaningful high-quality clinical trials. The OlympiA trial involved research staff in the U.S. and in the Affiliate office in Scotland.

FSTRF works with scientists and technicians in more than 800 laboratories, universities and medical centers around the world to provide a comprehensive range of research services throughout the clinical trial process including design, analysis and reporting.

Through its work, FSTRF aims to advance the application of statistical science and practice and data management techniques in science, healthcare and education.

About NRG Oncology

NRG Oncology is a network group funded by the U.S. National Cancer Institute (NCI), a part of the National Institutes of Health.

NRG Oncology brings together the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Radiation Therapy Oncology Group (RTOG), and the Gynecologic Oncology Group (GOG), with the mission to improve the lives of cancer patients by conducting practice-changing multi-institutional clinical and translational research. NRG Oncology sponsored OlympiA in the U.S. and collaborated with the other adult cancer clinical trials research groups funded by the NCI, Alliance, ECOG/ACRIN and the Southwest Oncology Group. The NCI and AstraZeneca are collaborating under a Cooperative Research and Development Agreement between the parties.

About LYNPARZA® (olaparib)

LYNPARZA is a 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. Inhibition of PARP

with LYNPARZA leads to the trapping of PARP bound to DNA single-strand breaks, stalling of replication forks, their collapse and the generation of DNA double-strand breaks and cancer cell death. LYNPARZA is being tested in a range of tumor types with defects and dependencies in the DDR.

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 understand how it may affect multiple PARP-dependent tumors as a monotherapy and in combination 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 certain oncology products including LYNPARZA, the world's first PARP inhibitor, for multiple cancer types. Working together, the companies will develop these products in combination with other potential new medicines and as monotherapies. Independently, the companies will develop these oncology products 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 130 years, Merck, 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 in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. 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 the global outbreak of novel coronavirus disease (COVID-19); 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 2020 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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