NEWS RELEASE

LYNPARZA Reduced Risk of Death by 31% vs. Enzalutamide or Abiraterone for Men with BRCA1/2 or ATM-Mutated Metastatic Castration Resistant Prostate Cancer Who Progressed Following Enzalutamide or Abiraterone in Phase 3 PROfound Trial

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LYNPARZA is the Only PARP Inhibitor to Demonstrate Improved Overall Survival in Metastatic Castration-Resistant Prostate Cancer

KENILWORTH, N.J.--(BUSINESS WIRE)-- AstraZeneca and Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced final results from the Phase 3 PROfound trial which showed LYNPARZA demonstrated a statistically significant and clinically meaningful improvement in overall survival (OS) versus enzalutamide or abiraterone in men with metastatic castration-resistant prostate cancer (mCRPC) who have BRCA1/2 or ATM gene mutations. Patients had progressed on prior treatment with enzalutamide and/or abiraterone.

Prostate cancer is the second most common type of cancer in men, with an estimated 1.3 million new patients diagnosed worldwide in 2018. Approximately 20-30% of men with mCRPC have an homologous recombination repair (HRR) gene mutation, of which BRCA1/2 and ATM mutations are a subpopulation. Approximately 10-20% of early stage hormone-sensitive prostate cancer cases will develop into CRPC within approximately five years.

In the key secondary endpoint of OS in men with BRCA1/2 or ATM gene mutations, LYNPARZA reduced the risk of

death by 31% vs. retreatment with enzalutamide or abiraterone (HR 0.69 [95% CI, 0.50, 0.97], p=0.0175). Median OS was 19.1 months for LYNPARZA vs. 14.7 months for enzalutamide or abiraterone, despite 66% of men on these treatments having crossed over to receive treatment with LYNPARZA following disease progression.

An exploratory analysis also showed a non-statistically significant improvement in OS in the overall trial population of men with HRR gene mutations (BRCA1/2, ATM, CDK12 and 11 other HRR-mutated [HRRm] genes), reducing the risk of death by 21% with LYNPARZA vs. enzalutamide or abiraterone (HR 0.79 [95% CI, 0.61, 1.03]. Median OS was 17.3 months vs. 14 months for enzalutamide or abiraterone.

The most common adverse reactions (ARs) ≥15% were anemia (50%), nausea (43%), fatigue/asthenia (42%), decreased appetite (31%), diarrhea (21%), vomiting (20%) and constipation (19%). Grade 3 or above ARs were anemia (23%), nausea (2%), fatigue or asthenia (3%), decreased appetite (2%) and diarrhea (1%). Twenty percent of patients on LYNPARZA discontinued treatment due to ARs and 23% had their dose reduced due to an AR.

Dr. Johann de Bono, one of the principal investigators of the PROfound trial and head of drug development at the Institute for Cancer Research and the Royal Marsden Hospital, said, “LYNPARZA has demonstrated significant clinical benefit across key endpoints in PROfound and the final overall survival results for men with BRCA1/2 or ATM mutations reinforce its potential to change the standard of care for men with metastatic castration-resistant prostate cancer. The PROfound trial shows that LYNPARZA can play an important role in this new era of precision medicine in prostate cancer, bringing targeted therapy at a molecular level to patients with a historically poor prognosis and few treatment options.”

Dr. José Baselga, executive vice president, Oncology R&D, AstraZeneca said, “These results help to transform the treatment landscape in certain men with metastatic castration-resistant prostate cancer, where overall survival has been very difficult to achieve. LYNPARZA is the only PARP inhibitor to demonstrate overall survival versus enzalutamide or abiraterone for men with BRCA or ATM mutations. We look forward to continuing to bring LYNPARZA to these patients around the world.”

Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories, said, “The PROfound trial is the first positive Phase 3 trial using molecular biomarker testing to help identify treatment options for certain men with metastatic castration resistant prostate cancer. These results further underpin the importance of genomic testing for HRR gene mutations to help identify this at-risk patient population and help physicians make treatment decisions. These results demonstrate the potential of LYNPARZA for mCRPC patients with certain HRR mutations.”

Final OS results from the PROfound trial were presented on Sunday, Sept. 20, 2020, during the Presidential Symposium at the European Society for Medical Oncology (ESMO) Virtual Congress 2020 and published

simultaneously in The New England Journal of Medicine.

Summary of OS results

OS data cut-off date was March 20, 2020.

	Men with BRCA1/2 and ATM mutations (Cohort A) Secondary Endpoint		Overall population of men with HRR mutations (Cohorts A+B) Exploratory Endpoint	
	LYNPARZA n=162	Control n=83	LYNPARZA n=256	Control n=131
Median, months	19.1	14.7	17.3	14.0
Hazard ratio (95% CI)	0.69 (0.50, 0.97)		0.79 (0.61, 1.03)	
P-value	0.0175		N/A	

The Phase 3 PROfound trial had met its primary endpoint in August 2019, showing significantly improved radiographic progression-free survival (rPFS) in men with mutations in BRCA1/2 or ATM genes, and had met a key secondary endpoint of rPFS in the overall HRRm population, which formed the basis of the U.S. Food and Drug Administration approval in May 2020. Regulatory reviews are ongoing in the EU and other regions.

AstraZeneca and Merck are exploring additional trials in metastatic prostate cancer including the ongoing Phase 3 PROpel trial, with first data expected in 2021, evaluating LYNPARZA as a first-line medicine for patients with mCRPC in combination with abiraterone acetate versus abiraterone acetate alone.

About PROfound

PROfound is a prospective, multi-center, randomized, open-label, Phase 3 trial evaluating the efficacy and safety of LYNPARZA versus enzalutamide or abiraterone in patients with mCRPC who have progressed on prior treatment with abiraterone or enzalutamide and have a qualifying HRR tumor mutation (BRCA1/2, ATM, CDK12, BARD1, BRIP2, CHEK1, CHEK2, PALB2, PPP2R2A, RAD51B, RAD51D, RAD54L).

The trial was designed to analyze patients with HRRm genes in two cohorts: the primary endpoint was rPFS in those with mutations in BRCA1/2 or ATM genes and then, if LYNPARZA showed clinical benefit, a formal analysis was performed of the overall trial population of patients with HRRm genes (BRCA1/2, ATM, CDK12 and 11 other HRR mutated genes; a key secondary endpoint).

In the U.S., patients are selected for treatment with LYNPARZA based on the following FDA-approved companion

diagnostics:

- FoundationOne CDX: to identify patients with HRR gene alterations in prostate tumor tissue. FoundationOne is a registered trademark of Foundation Medicine, Inc.
- BRACAnalysis CDX: a germline test to identify patients with BRCA1 and BRCA2 gene mutations. Myriad Genetics, Inc. owns and commercializes BRACAnalysis CDX.

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.

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

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 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 Metastatic Castration-Resistant Prostate Cancer (mCRPC)

Prostate cancer is the second-most common cancer in men, with an estimated 1.3 million new cases diagnosed worldwide in 2018, and is associated with a significant mortality rate. Development of prostate cancer is often driven by male sex hormones called androgens, including testosterone. In patients with mCRPC, their prostate cancer grows and spreads to other parts of the body despite the use of androgen-deprivation therapy to block the action of male sex hormones. Approximately 10-20% of men with advanced prostate cancer will develop CRPC within five years, and at least 84% of these men will have metastases at the time of CRPC diagnosis. Of men with no metastases at CRPC diagnosis, 33% are likely to develop metastases within two years. Despite advances in treatment for men with mCRPC, five-year survival is low and extending survival remains a key goal for treating these men.

About Homologous Recombination Repair (HRR) Mutations

HRR mutations occur in approximately 20-30% of patients with mCRPC. HRR genes allow for accurate repair of damaged DNA in normal cells. HRR deficiency (HRD) means the DNA damage cannot be repaired, and can result in normal cell death. This is different in cancer cells, where a mutation in HRR pathways leads to abnormal cell growth and therefore cancer. HRD is a well-documented target for PARP inhibitors, such as LYNPARZA. PARP inhibitors block a rescue DNA damage repair mechanism by trapping PARP bound to DNA single-strand breaks which leads to replication fork stalling causing their collapse and the generation of DNA double-strand breaks, which in turn lead to cancer cell death.

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 more than 125 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 2019 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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