NEWS RELEASE

LYNPARZA Receives Additional and Broad Approval in the U.S. for Ovarian Cancer

8/17/2017

LYNPARZA's New Tablet Formulation Approved as Maintenance Treatment for Women With Platinum-Sensitive Recurrent Ovarian Cancer Regardless of BRCA-Mutation Status

LYNPARZA Tablets Also Indicated in BRCA-Mutated Ovarian Cancer Beyond the Third-Line Setting

Newly-Approved Tablet Formulation Means Improved Patient Convenience

AstraZeneca and Merck & Co., Inc. (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has granted approval for the PARP inhibitor, LYNPARZA (olaparib), as follows:

- New use of LYNPARZA as a maintenance treatment for recurrent, epithelial ovarian, fallopian tube or primary peritoneal adult cancer who are in response to platinum-based chemotherapy, regardless of BRCA status;
- New use of LYNPARZA tablets (2 tablets twice daily) as opposed to capsules (8 capsules twice daily);
- LYNPARZA tablets also now indicated (conversion from the current accelerated approval) for the use in patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer, who have been treated with three or more prior lines of chemotherapy.

Sean Bohen, executive vice president, global medicines development and chief medical officer of AstraZeneca, said: "Physicians have almost three years of clinical experience with LYNPARZA on the market and we are now pleased to bring this important medicine, in a new tablet formulation, to a broader group of women. Today's approvals validate more than 10 years of dedicated research behind LYNPARZA, the world's first PARP inhibitor, which now

provides oncologists with the greater flexibility for use in terms of treatment settings. It builds on our recently-announced collaboration with Merck, which aims to further increase the number of treatment options available to patients."

Eric Pujade-Lauraine, head of the women cancers and clinical research department at Hôpitaux Universitaires Paris Centre, site Hôtel-Dieu, AP-HP and principal investigator of the SOLO-2 trial, one of the trials supporting the approval, said: "Today's approval is welcome news for U.S. patients with ovarian cancer, who are now able to benefit from treatment with olaparib irrespective of their BRCA-mutation status. This latest regulatory milestone underscores the breadth and depth of clinical data on olaparib, and not only demonstrates its efficacy as maintenance therapy, but adds to the data presented earlier this year showing sustained quality of life for patients undergoing treatment for this serious disease."

Roger M. Perlmutter, president of Merck Research Laboratories, said: "We congratulate AstraZeneca on the approval of these new indications and the new dosage form and schedule for LYNPARZA, an important therapeutic advance for many patients with ovarian cancer. This is a significant first regulatory event in our collaboration with AstraZeneca. We look forward to working with AstraZeneca in our global collaboration to bring this medicine with its new indications to patients."

Two randomized trials supported the new approvals and the conversion of accelerated approval to full approval which was originally based on a single-arm trial:

- SOLO-2 (n=295) confirmed the benefit of LYNPARZA in germline BRCA-mutated (gBRCAm) patients, demonstrating a 70% reduced risk of disease progression or death (HR 0.30 [95% CI, 0.22-0.41], P<0.0001) and improved progression-free survival (PFS) to 19.1 vs 5.5 months for placebo by investigator-assessed analysis.
- Study 19 (n=265) showed that LYNPARZA reduced the risk of disease progression or death by 65% and improved PFS compared with placebo in patients of any BRCA status (HR 0.35 [95% CI, 0.25-0.49], P<0.0001; median PFS of 8.4 months vs 4.8 months for placebo). Additionally, patients in Study 19, treated with LYNPARZA as a maintenance therapy, had a median overall survival (OS) of 29.8 months vs 27.8 months for placebo (HR 0.73 [95% CI, 0.55-0.95]).

Table 1. Summary of key efficacy results from randomized trials:

Analysis		Reduction in the risk of disease progression or death (PFS)	Reduction in the risk of death (OS)
SOLO-2 [gBRCAm]	LYNPARZA	70% (HR 0.30 [95% CI, 0.22-0.41], P<0.0001)	Data not yet mature

Study 19 [PSR OC*]	LYNPARZA	65% (HR 0.35 [95% CI, 0.25-0.49], P<0.0001)	27% (HR 0.73 [95% CI, 0.55-0.95]
	Placebo		

*PSR = Platinum-sensitive recurrent ovarian cancer

The most-common adverse events reported in 20% or more of patients across the SOLO-2 trial in the LYNPARZA arm were anaemia (44%), nausea (76%), vomiting (37%), diarrhoea (33%), fatigue/asthenia (66%), decreased appetite (22%), headache (25%), and dysgeusia (27%). The most-common Grade 3 or 4 adverse events were anaemia (20%), nausea (2.6%), vomiting (2.6%), diarrhoea (1.0%), fatigue/asthenia (4.1%), and headache (0.5%). Discontinuation of LYNPARZA resulting from adverse events was seen in 11% of patients. Dose interruptions of LYNPARZA due to an adverse reaction of any grade was 45%. Dose reductions of LYNPARZA due to an adverse reaction was 25%.

The most-common adverse events reported in 20% or more of patients across the Study 19 trial in the LYNPARZA arm were anaemia (23%), nausea (71%), vomiting (35%), diarrhoea (27%), fatigue (including asthenia) (63%), decreased appetite (21%), and headache (21%). The most-common Grade 3 or 4 adverse events were anaemia (7.4%), nausea (2.2%), vomiting (2.2%), diarrhoea (2.2%), and fatigue (including asthenia) (8.8%). Discontinuation of LYNPARZA resulting from adverse events was seen in 4% of patients. Dose interruptions of LYNPARZA due to an adverse reaction of any grade was 25%. Dose reductions of LYNPARZA due to an adverse reaction was 15%.

The full data from the SOLO-2 trial can be found in the July 25, 2017 publication of The Lancet Oncology.

LYNPARZA was first approved under the FDA's Accelerated Approval program in December 2014, as a capsule formulation, making it the first poly ADP-ribose polymerase (PARP) inhibitor approved. Since then, more than 3,000 advanced ovarian cancer patients have been treated with LYNPARZA capsules in its approved indication.

About SOLO-2

SOLO-2 was a Phase III, randomized, double-blinded, multicenter trial designed to determine the efficacy of LYNPARZA tablets as a maintenance monotherapy compared with placebo, in patients with platinum-sensitive, relapsed or recurrent gBRCA-mutated ovarian, fallopian tube and primary peritoneal cancer. The trial, conducted in collaboration with the European Network for Gynaecological Oncological Trial Groups (ENGOT) and Groupe d'Investigateurs National pour l'Etude des Cancers de l'Ovaire et du sein (GINECO), randomised 295 patients with documented germline BRCA1 or BRCA2 mutations who had received at least 2 prior lines of platinum-based chemotherapy and were in complete or partial response. Eligible patients were randomized to receive 300mg LYNPARZA tablets twice daily or placebo tablets twice daily.

About Study 19

Study 19 was a Phase II, randomized, double-blinded, placebo-controlled, multicenter trial, which evaluated the efficacy and safety of LYNPARZA compared with placebo in relapsed, high-grade serous ovarian cancer patients, involving 82 sites across 16 countries. Patients received LYNPARZA maintenance monotherapy, at a dose of 400mg per day or matching placebo. Treatment continued until disease progression if toxicities were manageable.

About LYNPARZA

LYNPARZA is an innovative, first-in-class oral poly ADP-ribose polymerase (PARP) inhibitor that may exploit tumor DNA damage response (DDR) pathway deficiencies to preferentially kill cancer cells. It is approved by regulatory authorities in the EU and US for the treatment of women with BRCAm ovarian cancer. LYNPARZA tablets are currently being tested in combinations in a range of tumor types including breast, prostate, and pancreatic cancers.

About the AstraZeneca and Merck Strategic Oncology Collaboration

On July 27, 2017, AstraZeneca and Merck & Co., Inc. announced a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's LYNPARZA, the world's first and leading PARP inhibitor, and potential new medicine selumetinib, a MEK inhibitor, for multiple cancer types. The collaboration is based on increasing evidence that PARP and MEK inhibitors can be combined with PDL-1/PD-1 inhibitors for a range of tumor types. Working together, the companies will jointly develop LYNPARZA and selumetinib in combination with other potential new medicines and as a monotherapy. 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, helping people fight cancer is our passion and supporting accessibility to our cancer medicines is our commitment. Our focus is on pursuing research in immuno-oncology and we are accelerating every step in the journey – from lab to clinic – to potentially bring new hope to people with cancer.

As part of our focus on cancer, Merck is committed to exploring the potential of immuno-oncology with one of the fastest-growing development programs in the industry. We are currently executing an expansive research program that includes more than 500 clinical trials evaluating our anti-PD-1 therapy across more than 30 tumor types. We also continue to strengthen our immuno-oncology portfolio through strategic acquisitions and are prioritizing the development of several promising immunotherapeutic 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 2016 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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