

## LYNPARZA® (olaparib) RECEIVES ADDITIONAL FDA APPROVAL IN THE US FOR OVARIAN CANCER

***LYNPARZA's new tablet formulation approved as maintenance treatment for women with recurrent ovarian cancer regardless of BRCA-mutation status***

***LYNPARZA tablets also approved for BRCA-mutated ovarian cancer beyond the third-line setting***

***Newly-approved tablet formulation means reduced pill count compared to capsules***

**(WILMINGTON, Del., August 17, 2017)** – AstraZeneca and Merck & Co., Inc., (Merck: known as MSD outside the U.S. and Canada) today announced that the US Food and Drug Administration (FDA) has granted approval for the PARP inhibitor, LYNPARZA® (olaparib), as follows:

- New use of LYNPARZA tablets as a maintenance treatment of adult patients with ovarian cancer, fallopian tube cancer, or primary peritoneal cancer, when the cancer has come back. LYNPARZA is used after the cancer has responded to treatment with platinum-based chemotherapy.<sup>1</sup>
- New use of LYNPARZA tablets (2 tablets twice daily) as opposed to capsules (8 capsules twice daily)<sup>1,2</sup>
- LYNPARZA tablets also now indicated (conversion from the current [accelerated approval](#)<sup>3</sup>) for the treatment of adults who have a certain type of abnormal inherited *BRCA* gene advanced ovarian cancer and have received treatment with 3 or more prior types of chemotherapy medicines. Your health care provider will perform a test to make sure that LYNPARZA is right for you.<sup>1</sup>

Sean Bohan, Executive Vice President, Global Medicines Development and Chief Medical Officer, 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.”

Richard Penson, MD, Clinical Director of Medical Gynecologic Oncology at Massachusetts General Hospital Cancer Center, Associate Professor of Medicine at Harvard Medical School, and the primary investigator in the SOLO-2 trial, said: “Today’s approval demonstrates that olaparib is an effective option for maintenance therapy for certain ovarian cancer patients, regardless of *BRCA* status. We welcome this news in the ovarian cancer community as more options are important to help us ensure that patients can find a treatment that is right for them.”

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

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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.”

The FDA approval of LYNPARZA is based on data from two studies:

- LYNPARZA was studied in 295 women with an inherited *BRCA* mutation and recurrent ovarian cancer who were sensitive to platinum-based chemotherapy. 196 women were given 2 LYNPARZA tablets (150 mg each) 2 times a day and 99 women were given placebo 2 times a day.<sup>1</sup> A placebo is a pill that doesn't contain any active medication.<sup>4</sup> The primary results of the study showed that in women who were given LYNPARZA, their disease progression was delayed by a median of more than 1.5 years (19.1 months). In women who were given placebo, their disease progression was delayed by a median of 5.5 months.<sup>1</sup>
- LYNPARZA was studied in 265 women with platinum-sensitive recurrent ovarian cancer—regardless of whether or not they had a *BRCA* mutation.<sup>1,5</sup> 136 women were given 8 LYNPARZA capsules (50 mg each) 2 times a day and 129 women were given placebo 2 times a day. The primary results of the study showed that in women who were given LYNPARZA, their disease progression was delayed by a median of 8.4 months. In women who were given placebo, their disease progression was delayed by a median of 4.8 months.<sup>1</sup>

For more information on these trials, please visit [www.lynparza.com](http://www.lynparza.com). The full data from the SOLO-2 trial can be found in the July 25, 2017 publication of *The Lancet Oncology*.<sup>6</sup>

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.<sup>3</sup> The Accelerated Approval Program allows for earlier approval of drugs that treat serious conditions.<sup>7</sup> Since then, more than 3,000 advanced ovarian cancer patients have been treated with LYNPARZA capsules.<sup>8</sup> **LYNPARZA capsules are not indicated for maintenance therapy.**<sup>1</sup>

### IMPORTANT SAFETY INFORMATION

**LYNPARZA may cause serious side effects, including:**

**Bone marrow problems called Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML).** Some people who have ovarian cancer and who have received previous treatment with chemotherapy, radiotherapy, or certain other medicines for their cancer have developed MDS or AML during treatment with LYNPARZA. MDS or AML may lead to death. If you develop MDS or AML, your health care provider will stop treatment with LYNPARZA.

Symptoms of low blood cell counts are common during treatment with LYNPARZA, but can be a sign of serious bone marrow problems, including MDS or AML. Symptoms may include: weakness, weight loss, fever, frequent infections, blood in urine or stool, shortness of breath, feeling very tired, bruising or bleeding more easily.

Your health care provider will do blood tests to check your blood cell counts:

- Before treatment with LYNPARZA
- Every month during treatment with LYNPARZA

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- Weekly if you have low blood cell counts that last a long time. Your health care provider may stop treatment with LYNPARZA until your blood cell counts improve

**Lung problems (pneumonitis).** Tell your health care provider if you have any new or worsening symptoms of lung problems, including shortness of breath, fever, cough, or wheezing. Your health care provider may do a chest x-ray if you have any of these symptoms. Your health care provider may temporarily stop treatment or completely stop treatment if you develop pneumonitis. Pneumonitis may lead to death.

**Before you take LYNPARZA, tell your health care provider about all your medical conditions, including if you:**

- Have lung or breathing problems
- Have liver problems
- Have kidney problems
- Are pregnant or plan to become pregnant. LYNPARZA can harm your unborn baby and may cause loss of pregnancy (miscarriage)
  - If you are able to become pregnant, your health care provider may do a pregnancy test before you start treatment with LYNPARZA
  - Females who are able to become pregnant should use effective birth control (contraception) during treatment with LYNPARZA and for 6 months after receiving the last dose of LYNPARZA
  - Talk to your health care provider about birth control methods that may be right for you
  - Tell your health care provider right away if you become pregnant
- Are breastfeeding or plan to breastfeed. It is not known if LYNPARZA passes into your breast milk. Do not breastfeed during treatment with LYNPARZA and for 1 month after receiving the last dose of LYNPARZA. Talk to your health care provider about the best way to feed your baby during this time

**Tell your health care provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking LYNPARZA and certain other medicines may affect how LYNPARZA works and may cause side effects.

**How should I take LYNPARZA?**

- Take LYNPARZA tablets exactly as your health care provider tells you
- Your health care provider may temporarily stop treatment with LYNPARZA or change your dose of LYNPARZA if you experience side effects
- LYNPARZA comes as tablets and capsules. LYNPARZA tablets and capsules are **not** the same. If your health care provider prescribes LYNPARZA tablets for you, **do not** take LYNPARZA capsules. **Do not** take more than 4 LYNPARZA tablets in 1 day. If you have any questions about LYNPARZA, talk to your health care provider or pharmacist
- Take LYNPARZA by mouth 2 times a day
- Each dose should be taken about 12 hours apart
- Swallow LYNPARZA tablets whole. Do not chew, crush, dissolve, or divide the tablets
- Take LYNPARZA with or without food
- If you miss a dose of LYNPARZA, take your next dose at your usual scheduled time. Do not take an extra dose to make up for a missed dose
- If you take too much LYNPARZA, call your health care provider or go to the nearest hospital emergency room right away

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## What should I avoid while taking LYNPARZA?

- Avoid grapefruit, grapefruit juice, Seville oranges, and Seville orange juice during treatment with LYNPARZA since they may increase the level of LYNPARZA in your blood

## LYNPARZA may cause serious side effects. The most common side effects of LYNPARZA are:

- Nausea or vomiting. Tell your health care provider if you get nausea or vomiting. Your health care provider may prescribe medicines to treat these symptoms
- Tiredness or weakness
- Diarrhea
- Headache
- Changes in kidney function blood test
- Low number of platelets
- Changes in the way food tastes
- Loss of appetite
- Low number of red or white blood cells
- Mouth sores
- Respiratory infections
- Indigestion or heartburn
- Sore throat or runny nose
- Upper respiratory infection
- Cough
- Pain in the joints, muscles, and back
- Rash
- Pain or discomfort in the stomach area

These are not all the possible side effects of LYNPARZA. Call your health care provider for medical advice about side effects.

*You are encouraged to report negative side effects of prescription drugs to the FDA.*

*Visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch) or call 1-800-FDA-1088.*

**Please see complete [Prescribing Information](#) for LYNPARZA tablets and complete [Prescribing Information](#) for LYNPARZA capsules, including Patient Information (Medication Guides).**

– ENDS –

## NOTES TO EDITORS

### About Ovarian Cancer Patient Resources

*My LYNPARZA* is an educational support program that can help patients during their treatment with LYNPARZA. Once enrolled in the program, patients will receive information about ovarian cancer and treatment with LYNPARZA, regular e-mails with tips on getting the most out of living with ovarian cancer and a treatment journal to help track their questions and any side effects to share with their health care provider.

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Additionally, AstraZeneca Access 360™ is a reimbursement program designed to streamline access to AstraZeneca medicines by:

- Helping patients identify their coverage specific to their prescribed medicine
- Assisting providers with the reimbursement process
- Connecting patients to affordability programs to help patients gain access to necessary AstraZeneca medications

### About LYNPARZA® (olaparib)

LYNPARZA was the first FDA-approved PARP inhibitor.<sup>1,9-11</sup> Cancer happens when cells grow out of control.<sup>12</sup> Because of this growth, cancer cells have a higher risk of accumulating DNA damage.<sup>13</sup> To help fix this damage and survive, the cancer cells rely on several different methods of repair, including one that involves the PARP enzyme.<sup>14</sup> By helping to stop PARP from working, LYNPARZA can limit a cancer cell's ability to repair DNA damage and that can lead to cancer cell death.<sup>1,14,15</sup> LYNPARZA may also impact other cells and tissues in the body.<sup>1</sup>

LYNPARZA is the foundation of AstraZeneca's industry-leading portfolio of compounds targeting DDR mechanisms in cancer cells.<sup>3,16,17</sup>

LYNPARZA tablets are currently being investigated in combinations in a range of tumor types, including breast, prostate, and pancreatic cancer.<sup>18-21</sup>

LYNPARZA capsules (400mg twice daily) will still be available through a limited specialty pharmacy network, for patients currently being treated for deleterious or suspected deleterious germline *BRCA*-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. LYNPARZA tablets and capsules are not the same.<sup>1</sup>

If you have been prescribed LYNPARZA tablets, do not take the capsules. If you have any questions about LYNPARZA, please talk with your health care provider.<sup>1</sup>

### 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 and is aimed at maximizing the potential of LYNPARZA to become the preferred backbone of combination therapies. 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.

### About AstraZeneca in Ovarian Cancer

Approximately 20,000 women in the United States are diagnosed with ovarian cancer each year. Among women in the United States, it is the ninth most common cancer and the fifth leading cause of cancer death.<sup>22</sup>

The risk of developing ovarian cancer is increased in women with specific inherited genetic abnormalities, including *BRCA* mutations.<sup>23</sup>

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AstraZeneca is committed to the continued development of our R&D portfolio for ovarian cancer, with a focus on improved care for all patients.

## About AstraZeneca in Oncology

AstraZeneca has a deep-rooted heritage in Oncology and offers a quickly growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. With at least six new medicines to be launched between 2014 and 2020 and a broad pipeline of small molecules and biologics in development, we are committed to advance New Oncology as one of AstraZeneca's five Growth Platforms focused on lung, ovarian, breast and blood cancers. In addition to our core capabilities, we actively pursue innovative partnerships and investments that accelerate the delivery of our strategy as illustrated by our investment in Acerta Pharma in hematology.

By harnessing the power of four scientific platforms – Immuno-Oncology, Tumor Drivers and Resistance, DNA Damage Response and Antibody Drug Conjugates – and by championing the development of personalized combinations, AstraZeneca has the vision to redefine cancer treatment and one day eliminate cancer as a cause of death.

## About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three main therapy areas – Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit [www.astrazeneca-us.com](http://www.astrazeneca-us.com) and follow us on Twitter @AstraZenecaUS.

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