

## LYNPARZA PHASE III SOLO-2 TRIAL SHOWS SIGNIFICANT PROGRESSION-FREE SURVIVAL BENEFIT

*Trial studied Lynparza as maintenance treatment for women with BRCA-mutated metastatic ovarian cancer*

*Initial findings show safety profile with Lynparza tablets was consistent with previous studies*

26 October 2016

AstraZeneca today announced positive results from the Phase III SOLO-2 trial designed to determine the efficacy of *Lynparza* (olaparib) tablets (300mg twice daily) as a monotherapy for the maintenance treatment of platinum-sensitive relapsed, BRCA-mutated ovarian cancer. Results from the trial demonstrate a clinically-meaningful and statistically-significant improvement of progression-free survival (PFS) among patients treated with *Lynparza* compared to placebo and provide additional evidence to support the potential use of *Lynparza* in this patient population.

Importantly, the median PFS in the *Lynparza* arm of SOLO-2 substantially exceeded that observed in the Phase II maintenance study in patients with platinum-sensitive relapsed ovarian cancer (Study 19).<sup>1</sup>

Sean Bohan, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "We are pleased with the robust improvement in progression-free survival demonstrated by *Lynparza* in the SOLO-2 trial. We will work with regulatory authorities to make *Lynparza* tablets available as quickly as possible to patients with ovarian cancer. We remain committed to investigating the full potential of *Lynparza*, both as monotherapy and in combinations, and to identifying all patients who may benefit from this important medicine."

Initial findings demonstrate that safety profile with *Lynparza* tablets was consistent with previous studies. Full results of SOLO-2 will be presented at a forthcoming medical meeting.

Today's positive results follow the Fast Track Designation for *Lynparza* by the US FDA earlier this year, in patients with a BRCA mutation who have platinum-sensitive, relapsed ovarian cancer.

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### NOTES TO EDITORS

#### About SOLO-2

SOLO-2 was a Phase III, multicentre trial designed to determine the efficacy of *Lynparza* tablets as a maintenance monotherapy compared with placebo, in patients with platinum-sensitive relapsed or recurrent BRCA-mutated (BRCAm) ovarian cancer. In SOLO-2, patients with either germline or somatic BRCAm status were eligible for enrolment, although

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due to the lack of widespread availability of tumour BRCA testing, most patients were enrolled on blood-based germline testing. Those few patients who were enrolled based on a tumour test were also found to have a germline BRCA mutation. Patients were randomised to receive either *Lynparza* tablets (300mg twice daily) or placebo until disease progression.<sup>1</sup>

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.

### **About AstraZeneca in ovarian cancer**

Worldwide, ovarian cancer is the 7<sup>th</sup> most commonly diagnosed cancer<sup>2</sup> and the 8<sup>th</sup> most common cause of cancer death in women.<sup>3</sup> The risk of developing ovarian cancer is increased in women with specific inherited genetic abnormalities, including BRCA mutations. AstraZeneca is committed to the continued development of our R&D portfolio for ovarian cancer, with a focus on improved care for all patients, including the development of targeted therapies for patients with specific gene mutations such as BRCA.

### **About Lynparza**

*Lynparza* (olaparib) is an innovative, first-in-class oral poly ADP-ribose polymerase (PARP) inhibitor that may exploit tumour 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* is the foundation of AstraZeneca's industry-leading portfolio of compounds targeting DNA damage response (DDR) mechanisms in cancer cells.

### **About ENGOT**

ENGOT (European Network for Gynaecological Oncological Trial groups) is a research network of the European Society of Gynaecological Oncology (ESGO) and was founded in 2007. Currently, ENGOT consists of 19 cooperative groups from 15 European countries. ENGOT's ultimate goal is to bring the best treatment to gynaecological cancer patients through the best science, and enabling every patient in every European country to access a clinical trial. ENGOT coordinates and promotes multinational clinical trials within Europe on patients with gynaecological cancer. This coordination is particularly relevant for academic clinical trials, translational research, research on rare diseases, and for clinical trials sponsored by the industry.

### **About GINECO**

GINECO (Groupe d'Investigateurs National pour l'Etude des Cancers de l'Ovaire et du sein) is the French Cooperative Group in Oncology labelled by INCA (Institut National du Cancer or French NCI) for developing and conducting gynaecological and advanced breast cancer clinical trials at the national and international level. The network is nationwide with 700 specialized investigators belonging to more than 150 public or private oncology units. The GINECO group was founded in 1993 and is member of international consortia such as ENGOT and GCIG (Gynecologic Cancer InterGroup). GINECO was the ENGOT leading group for SOLO-2 trial.

### **About AstraZeneca in Oncology**

AstraZeneca has a deep-rooted heritage in Oncology and offers a quickly growing portfolio of new medicines that have the potential to transform patients' lives and the Company's future. With at least 6 new medicines to be launched between 2014 and 2020 and a broad pipeline of small molecules and biologics in development, we are committed to advancing New Oncology as one of AstraZeneca's six 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 haematology.

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By harnessing the power of four scientific platforms -- immuno-oncology, the genetic drivers of cancer and resistance, DNA damage response and antibody drug conjugates -- and by championing the development of personalised 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 commercialisation 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.com](http://www.astrazeneca.com) and follow us on Twitter @AstraZeneca.

<sup>1</sup> National Institutes of Health. Olaparib Treatment in BRCA Mutated Ovarian Cancer Patients After Complete or Partial Response to Platinum Chemotherapy. Available at: <http://clinicaltrials.gov/show/NCT01874353>. Last accessed October 2016.

<sup>2</sup> Cancer Research UK. Ovarian cancer incidence statistics. Available at: <http://www.cancerresearchuk.org/cancer-info/cancerstats/types/ovary/incidence/uk-ovarian-cancer-incidence-statistics>. Last accessed June 2016.

<sup>3</sup> Cancer Research UK. Ovarian cancer mortality statistics. Available at: <http://www.cancerresearchuk.org/cancer-info/cancerstats/types/ovary/mortality/> Last accessed June 2016.

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