Lynparza Granted BTD in US for Prostate Cancer

LYNPARZA™ (Olaparib) granted Breakthrough Therapy Designation by US FDA for treatment of BRCA1/2 or ATM gene mutated metastatic Castration Resistant Prostate Cancer

AstraZeneca today announced that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy designation (BTD) for the oral poly ADP-ribose polymerase (PARP) inhibitor Lynparza™ (olaparib), for the monotherapy treatment of BRCA1/2 or ATM gene mutated metastatic Castration Resistant Prostate Cancer (mCRPC) in patients who have received a prior taxane-based chemotherapy and at least one newer hormonal agent (abiraterone or enzalutamide).

The FDA criteria for BTD require preliminary clinical evidence that demonstrates a drug may have substantial improvement on at least one clinically significant endpoint over available therapy. The decision to assign a BTD for Lynparza is based on the results of the TOPARP-A Phase II trial, which found that Lynparza (olaparib) monotherapy in mCPRPC may offer substantial improvement over available therapies for the treatment of the biomarker-selected population with this serious and life-threatening condition. The TOPARP-A Phase II trial was presented at AACR 2015 and published in the New England Journal of Medicine in October 2015[i]. It showed that men with prostate cancer with defective DNA damage repair mechanisms responded to Lynparza (olaparib).

The Breakthrough Therapy designation for Lynparza in this patient population means the FDA will expedite review of submission data within 60 days of receipt.

Antoine Yver, Head of Oncology, Global Medicines Development at AstraZeneca, said: "More than 27,000 men died of prostate cancer last year in the US alone. The Breakthrough Therapy designation for Lynparza is encouraging news for patients, and their families, as there are currently very limited treatment options for metastatic Castration Resistant Prostate Cancer. We will work closely with the FDA to introduce Lynparza as a new treatment option as soon as possible."

Once prostate cancer has progressed to mCPRPC, treatment focuses on extending life, delaying disease progression, and improving symptoms and quality of life. Overall survival time for patients treated with chemotherapy and newer hormonal agents is 10 months[ii]. There are also no approved therapies for third line and above (3L+) mCRPC patients, and no targeted therapies are available for mCRPC patients with somatic or germline mutations in BRCA1, BRCA2 or ATM.

Lynparza (olaparib) is an innovative, first-in-class oral poly ADP-ribose polymerase (PARP) inhibitor that exploits tumour DNA repair pathway deficiencies to preferentially kill cancer cells. This mode of action gives olaparib the potential for activity in a range of tumour types with DNA repair deficiencies.

Lynparza has been approved by regulatory authorities in 40 countries for the maintenance treatment of women with BRCA-mutated ovarian cancer. AstraZeneca is investigating the potential of olaparib in other PARP dependent tumours. Phase III studies in gastric cancer, pancreatic cancer and adjuvant and metastatic BRCAm breast cancers are underway, with further studies planned.

NOTES TO EDITORS

About prostate cancer

In 2015, 27,540 US men died of prostate cancer[iii]. Based on the Global Burden of Disease Cancer Collaboration, there were 1.4 million incidents of prostate cancer and 293,000 deaths worldwide for the year 2013. Prostate cancer caused 4.8 million disability-adjusted life-years globally in 2013, with 57% occurring in developed countries and 43% occurring in developing countries[iv].

About AstraZeneca in Oncology

Oncology is a therapy area in which AstraZeneca has deep-rooted heritage. It will be potentially transformational for the company's future, becoming the sixth growth platform. Our vision is to help patients by redefining the cancer treatment paradigm and one day eliminate cancer as a cause of death. By 2020, we are aiming to bring at least six new cancer medicines to patients.

Our broad pipeline of next-generation medicines is focused on four main disease areas - lung, ovarian, breast and haematological cancers. These are being targeted through four key platforms - immuno-oncology, the genetic drivers of cancer and resistance, DNA damage repair and antibody drug conjugates - with a strong focus on combinations. Our recently announced investment in Acerta Pharma also adds the potentially transformational BTK inhibitor class of treatments to our portfolio, subject to closure in the first quarter of 2016, strengthening further our focus on targeted therapies.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. 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

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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease,

ING - Infection, Neuroscience and Gastrointestinal

28 January 2016

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[i]Mateo J, et al. DNA-Repair Defects and Olaparib in Metastatic Prostate Cancerhttp://www.nejm.org/doi/full/10.1056/NEJMoa1506859?af=R&rss=currentIssue&

[ii] Smith MR, DeBono JS, Sternberg CN, Le Moulec S, Oudard S, De Giorgi U et al. Final analysis of COMET-1: Cabozantinib (Cabo) versus prednisone (Pred) in metastatic castration-resistant prostate cancer (mCRPC) patients (pts) previously treated with docetaxel (D) and abiraterone (A) and/or enzalutamide (E).ASCO GU 2015. J Clin Oncol 2015;33(7):abstr 139.

[iii] National Cancer Institute 2015. http://www.cancer.gov/types/common-cancers accessed September 2015

[iv]Global Burden of Cancer Coalition. The Global Burden of Cancer 2013. *JAMA Oncol*. 2015;1(4):505-527. doi:10.1001/jamaoncol.2015.0735. http://oncology.jamanetwork.com/article.aspx?articleid=2294966#ArticleInformation