

August 16, 2018

The Manager- Listing

BSE Limited

Corporate Relationship Dept., 5th Floor, New Trading Ring
Rotunda Building, P J Towers, Dalal Street, Fort,
Mumbai - 400001

The Manager- Listing

National Stock Exchange of India Limited

Exchange plaza, 5th Floor, Plot No. C/1, G Block
Bandra –Kurla Complex, Bandra (E),
Mumbai - 400051

Dear Sir(s),

Sub: AstraZeneca Pharma India Limited receives Import and Market Permission in Form 45 (Marketing Authorization) from Drugs Controller General of India (DCGI) for Olaparib Film-coated Tablets 100 mg and 150 mg.

This is to inform that AstraZeneca Pharma India Limited has received Import and Market permission in Form 45 (Marketing Authorization) from the Drugs Controller General of India for Olaparib Tablets 100 mg and 150 mg (Lynparza®).

Olaparib Tablet (Lynparza®) is indicated for:

Ovarian Cancer:

1. for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy
2. for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy

Breast Cancer:

1. in patients with deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have previously 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 treatment

The receipt of this Import and Market permission paves way for the launch of Olaparib Tablets 100 mg and 150 mg (Lynparza®) in India, subject to the receipt of other related statutory approvals and licenses.

Olaparib (Lynparza®) is a product of the AstraZeneca Group.



CORPORATE & REGD. OFFICE
AstraZeneca Pharma India Ltd.
P. B. No. 4525, Block N1, 12th Floor,
Manyata Embassy Business Park,
Rachenahalli, Outer Ring Road,
Bangalore - 560 045, INDIA

TEL : +91 80 6774 8000
FAX : +91 80 6774 8857
CIN : L24231KA1979PLC003563
WEB : www.astrazeneca.com/india

FACTORY
12th Mile on Bellary Road
Venkata, Kattigenahalli Village
Yelahanka
Bangalore - 560 063
INDIA

TEL : +91 80 6774 9000
FAX : +91 80 2846 2208
+91 80 6774 9628

Please find attached a copy of the Press-Release dated August 16, 2018 being issued by the Company in connection with the above.

Kindly take the same on record.

Thanking you,

For AstraZeneca Pharma India Limited



Pratap Rudra
Company Secretary & Legal Counsel



Encl: As above

Business Press Release

AstraZeneca receives marketing permission for Olaparib (Lynparza®) tablet for treatment of ovarian and breast cancer in India

Olaparib is the first FDA-approved oral poly ADP-ribose polymerase (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

Bengaluru, 16 August 2018: AstraZeneca Pharma India Limited (AZPIL) today announced that it has received Import & Market permission for olaparib (Lynparza®) 100 mg and 150 mg tablets in India by the Drug Controller General of India (DCGI). The receipt of this permission paves way for the launch of olaparib (Lynparza®) in India, subject to the receipt of further related statutory approvals and licenses.

For ovarian cancer, olaparib is indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. It is also indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.

For breast cancer, olaparib is indicated for patients with deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have previously 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 treatment

Olaparib (Lynparza®) is a patented product of the AstraZeneca group.

Gagan Singh, Managing Director, AstraZeneca Pharma India Limited said, "The import and market permission for olaparib is a significant milestone for women in India living with platinum-sensitive relapsed ovarian cancer and BRCA-mutated HER-2 negative metastatic breast cancer, which has historically been difficulty-to-treat diseases. Today's approval will bring this innovative, targeted option that may help to delay disease progression for these patients."

Breast and ovarian cancers are the leading causes of cancer-related deaths in women of India. As per three-year report of population based cancer registries-2012-2014 in India, ovarian cancer is the third leading site of cancer among women, trailing behind breast and cervical cancer. The age-adjusted incidence rates of ovarian cancer vary between 1.7 and 15.2 per 100,000 population in different parts of the country [1]. Ovarian cancer has the worst prognosis among all gynaecological malignancies. The overall 5-year survival rate was 46% in USA in 2017 while it was 15.6% during the period of 2010-14 in India, primarily due to the late stage of the disease at diagnosis [3,4]. *As there is no cure for relapsed ovarian cancer, the primary aim of treatment is to slow progression of the disease for as long as possible and improve or maintain the patient's quality of life.*

Breast cancer has been ranked number one cancer among Indian females with age adjusted rate ranging from 4.4 to 41.0 per 100,000 women [2]. Mortality-to-incidence ratio was for breast cancer was found to be as high as 0.66 in rural registries whereas as low as 0.08 in urban registries [2]. It is projected that 56,276 and 1,79,790 Indian patients will be suffering from ovarian cancer and breast cancer respectively in 2020 [1]. In India, 5-year survival rate for patients with breast cancer is 66.1% during the period of 2010-14 [4]. Most of the Indian studies have showed an inverse relationship of stage-of disease with survival. Patients diagnosed with BRCA-related metastatic breast cancer are often younger than other breast cancer patients, and their disease is often much more aggressive and difficult to treat. *While there is currently no cure for metastatic breast cancer, olaparib now offers a new, targeted option that may help to delay disease progression for these patients.*

NOTE TO EDITORS:

About Olaparib (Lynparza®)

Olaparib is a first-in-class poly ADP-ribose polymerase (PARP) inhibitor and the first targeted treatment to potentially exploit tumour DDR-pathway dependencies to preferentially kill cancer cells. Specifically, in vitro studies have shown that olaparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes, resulting in DNA damage and cancer-cell death.

Olaparib is being investigated in a range of DDR-dependent tumour types and is the foundation of AstraZeneca's industry-leading portfolio of compounds targeting DDR mechanisms in cancer cells.

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 cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. 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

About AstraZeneca Pharma India Limited (AZPIL)

AZPIL was established in 1979 and is headquartered at Bengaluru, Karnataka. AZPIL has a workforce of over 1200 employees across the country that is committed to deliver great medicines to patients through innovative science and global excellence in development and commercialization. For more information, please visit: www.astrazeneca.com/india

Contact:

Varsha Das

Corporate Affairs, AstraZeneca Pharma India Limited

Varsha.das1@astrazeneca.com

+91.9008777884

Source:

- [1] National Cancer Registry Programme. Three-Year Report of Population Based Cancer Registries 2012-2014. Bengaluru, India.: Indian Council of Medical Research; 2016 Mar.
- [2] Malvia S, Bagadi SA, Dubey US, Saxena S. Epidemiology of breast cancer in Indian women. Asia-Pac J Clin Oncol. 2017 Aug 1;13(4):289–95.
- [3] Siegel RL, Miller KD, Jemal A. Cancer Statistics, 2017. CA Cancer J Clin. 2017 Jan;67(1):7–30.
- [4] Allemani C, Matsuda T, Carlo VD, Harewood R, Matz M, Nikšić M, et al. Global surveillance of trends in cancer survival 2000–14 (CONCORD-3): analysis of individual records for 37 513 025 patients diagnosed with one of 18 cancers from 322 population-based registries in 71 countries. The Lancet. 2018 Mar 17;391(10125):1023–75.