BioSpect
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

# AstraZeneca receives marketing permission for cancer drug in India

17 August 2018 | News

**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.**




AstraZeneca Pharma India Limited (AZPIL) recently 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. 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. *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. 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. It is projected that 56,276 and 1,79,790 Indian patients will be suffering from ovarian cancer and breast cancer respectively in 2020. In India, 5-year survival rate for patients with breast cancer is 66·1% during the period of 2010-14. 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.*