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Biocon launches KRABEVA to treat cancer

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Biocon Launches KRABEVA, Biosimilar Bevacizumab for Treating Several Types of Cancer in India



Biocon Ltd, Asia's premier biopharmaceuticals company, has launched KRABEVA, a biosimilar Bevacizumab for the treatment of patients with metastatic colorectal cancer and other types of lung, kidney, cervical, ovarian and brain cancers, in India.

KRABEVA, a monoclonal antibody (mAb) developed by Biocon, will help expand access to a world class, high quality biosimilar Bevacizumab for cancer patients in India. It is the world's first and only Bevacizumab with a unique 'Qual-Check' mechanism, which will ensure that patients get a quality-ascertained product right up to infusion.

Bevacizumab is indicated as a first-line treatment of patients with metastatic colorectal cancer (mCRC).It is accepted as a standard treatment option in combination with chemotherapy for patients with non-small-cell lung cancer (NSLC), metastatic renal cell carcinoma and recurrent ovarian cancer.

Dr Arun Chandavarkar, CEO & Joint Managing Director, Biocon said: "With KRABEVA we intend to provide a high quality, world-class biosimilar Bevacizumab as an affordable therapy option for patients of various types of cancer. We believe KRABEVA will be an important addition to our Oncology portfolio of novel biologics as well as biosimilars, which are making a significant impact in the realm of cancer care in India."

KRABEVA is the second key oncologic biosimilar product from Biocon's global biosimilars portfolio to be launched in India, in order to address the unmet patient need for affordable biological therapies. It is being offered to patients at an MRP of Rs 24,000 for 100 mg / 4 ml vials and Rs 39,990 for 400 mg / 16 ml vials, making it a high quality affordable alternative to the innovator brand.

KRABEVA is being launched post successful completion of Phase III clinical trials and approval of Biocon's Marketing Authorization Application by the Drug Controller General of India (DCGI).

Most biologic products require a specific storage condition to maintain the safety, purity and potency of the drug. An efficient and seamless cold chain prevents denaturation of antibodies due to heat.

KRABEVA is being introduced with an innovative temperature-sensitive packaging that includes thermo-chromic stickers, which change colour irreversibly if the cold chain temperature is not maintained.

This first-of-its-kind 'Qual Check' feature ensures quality check of the product up to the point of administration to the patient. This will provide greater confidence to pharmacists, nurses and caregivers about the quality of the product they are dispensing and will enable better patient safety.

Biocon's biosimilar Bevacizumab has been developed for global markets with a clear focus to meet strict quality and regulatory requirements and provide access to a high quality biosimilar to patients.

The Phase III clinical study involving 146 patients of mCRC, has been conducted after obtaining regulatory approvals in India. The extrapolation to other indications has been approved by the DCGI.

The global Phase III trial in non-small-cell lung cancer (NSLC) patients is being conducted at more than 100 sites across multiple countries using an EU and US sourced reference product. Prior to this, a three-way Phase I PK study in healthy volunteers was conducted in Europe.

Bevacizumab is a monoclonal antibody (mAb) targeting Vascular Endothelial Growth Factor- A (VEGF-A), a cell protein that induces growth of blood vessels that feed tumors. By blocking this protein, Bevacizumab cuts the supply of food and oxygen to the tumor, thus starving it.

Bevacizumab is prescribed in the treatment of several cancers including metastatic colorectal cancer, ovarian cancer, advanced non-small-cell lung cancer, recurrent glioblastoma, cervical cancer and renal cancer.

The launch of KRABEVA, biosimilar Bevacizumab, comes at a time when the incidence of cancer is projected to reach alarming numbers, with over 17.3 lakh new cases of cancer and over 8.8 lakh cancer deaths projected in India by 2020 as per the Indian Council of Medical Research (ICMR).

An estimated 64,000 cases of colorectal cancer were diagnosed and 49,000 deaths recorded due to the disease in India, according to GLOBOCAN's 2012 estimates of the worldwide incidence and mortality from cancers.

There were an estimated 1.14 lakh new lung cancer cases in India in 2016 and the number is projected to grow to 1.40 lakh by 2020, according to ICMR. Similarly, new cervical cancer cases are expected to rise from an estimated 1 lakh in 2016 to

about 1.04 lakh by 2020.

Global sales of the innovator product in 2016 were pegged at USD 6.9 billion. The market size for Bevacizumab, both innovator product and biosimilar, in India is estimated at Rs. 177 Crore (USD 27 million), according to IPSOS June MAT 2017 data.