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Within a year the volume of biosimilar versions have grown almost 16 times

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Biocon Ltd, Asia's premier biopharmaceuticals company, has launched KRABEVA, a biosimilar Bevacizumab forthe 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. In an interaction with BioSpectrum, Suresh Subramanian, Sr Vice President & Head Branded Formulations, Biocon talks about how KRABEVA will add revenue to the branded formulations business of Biocon and help tackle the rising cancer burden in India.

How can KRABEVA help tackle the rising cancer burden in India?

With KRABEVA we aim to expand access to a world class, high quality biosimilar Bevacizumab for cancer patients in India. Bevacizumab can be prescribed for the treatment of patients with metastatic colorectal cancer and several other types of lung, kidney, cervical, ovarian and brain cancers. The launch of KRABEVA 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. The market size for Bevacizumab, both innovator product and biosimilars, in India is estimated at Rs 177 crore ($ 27 million), according to IPSOS June MAT 2017 data.

At what price point will Biocon sell KRABEVA in the Indian market?

KRABEVA is the second key oncologic biosimilar product from Biocon's global biosimilars portfolio to be launched in India, and is being offered to patients at prices that make it a high quality affordable alternative to the innovator brand. The 100 mg/4 mL vial of KRABEVA has an MRP of Rs 24,000 and the 400 mg/16 mL vial has an MRP of Rs 39,990, which is substantially lower than the MRP of the 400 mg presentation of the innovator product currently available and lower than some of the other biosimilars versions in the market.

Can you give details of your Oncology portfolio in India and how it has made an impact?

As one of the leading oncology companies in India, we are committed to bring safe, efficacious and affordable medicines for cancer to cater to the needs of patients, caregivers and medical practitioners in the country. Thousands of cancer patients have so far benefited from our oncology portfolio, which is a mix of innovator, biosimilar and generic products. BIOMAb EGFR, CANMAb, EVERTOR, Fosaport, Genxtor from our Oncotherapeutics portfolio featured among the Top 3 brands in their respective categories in Q2FY18. CANMAb, our biosimilar Trastuzumab brand, has helped treat several thousand HER2-positive metastatic breast cancer patients in India since its launch in 2014. It ranks as the No. 2 brand*(Source: IMS)* of Trastuzumab in the country, and garnered a volume market share of over 30% in Q2FY18. BIOMAb EGFR, an affordable, novel MAb therapy targeted at head and neck cancer is considered the best available treatment in its class of drugs given its efficacy and superior safety profile in terms of minimal skin toxicity. The No 1 brand in its category (Source: IMS), BIOMAb EGFR witnessed more than 1000 new enrolments in FY17.

Can you describe the clinical development process for KRABEVA?

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). The Phase III clinical study involving 146 patients of metastatic colorectal cancer (mCRC), has been conducted after obtaining regulatory approvals in India. During the study KRABEVA was found to be equivalent in terms of safety, efficacy and immunogenicity to the reference biologic. The extrapolation to other indications has been approved by the DCGI. Having undergone extensive development at Biocon's Research Centre, KRABEVA is being manufactured at our world class Biologics manufacturing facility at Biocon Park in Bengaluru.

How much has Biocon spent on R&D, including clinical trials, for developing Bevacizumab?

We cannot share molecule wise specific expense details but would like to share that the cost of developing any biosimilar for global markets is estimated to be around $75-150 million in comparison to $2-5 million required to develop a generic. This is because biosimilars are large and complex target-specific molecules, placed at the high end of the pharma value chain. In addition, the investment required for setting up a biologics manufacturing facility ranges from tens to hundreds of millions of dollars. For example, it would take $200-500 million to build a large-scale biologics manufacturing facility versus $30-100 million to build a small molecule manufacturing facility.

How has the entry of biosimilar versions of Bevacizumab helped expand the market for this key cancer drug?

With the advent of some of the brands of biosimilar Bevacizumab last year, the market has clearly expanded. If you compare the volumes of Bevacizumab sold in India, it has gone up by over 1.5 times since 2015, from nearly 50,000 units to over 83,000 in 2017 (IMS MAT June 2017). Interestingly, over 45% of this volume sale can be attributed to biosimilars, in fact within a year the volume of biosimilar versions have grown almost 16 times. This indicates the growing acceptance of biosimilars and augurs well for patients.

How does the 'Qual Check' feature of KRABEVA differentiate it from others?

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. 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 with 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.

With KRABEVA we intend to provide a high quality, world-class biosimilar Bevacizumab as an affordable therapy option for patients of various types of cancers including mCRC, ovarian cancer, advanced non-small-cell lung cancer, recurrent glioblastoma, cervical cancer and renal cancer.

How much do you expect KRABEVA to add to your Branded Formulations India business revenue?

The Branded Formulations business in Q2FY18 had reported a YoY revenue growth of 29% at Rs 176 crore. Good traction in major verticals such as Metabolics, Oncology, Comprehensive Care and the Institutional business drove the robust performance last quarter.

As KRABEVA is being launched in mid-Q3, we expect our Oncology portfolio to benefit from it even though the full revenue impact from KRABEVA launch will fully reflect only in Q4.