

## Biocon to focus on innovative therapy for Head & Neck cancer in India

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Biocon Ltd., Asia's premier biopharmaceuticals company, organized a scientific session and a panel discussion on Creating a paradigm shift in patient outcomes in cancer treatment through innovative targeted therapies. A panel of leading Oncologists focused on the evolution of cancer care treatment in India and highlighted the role of Biosimilars and Biologics in driving newer standards of testing and care in the country. In particular, the discussion focused on targeted therapies in Head and Neck Cancer, including the usage of Biocon's novel Biologic – BioMab EGFR (Nimotuzumab).

The discussion saw an exchange of views from an august panel of senior specialists: Dr. G K Rath, Head, National Cancer Institute, AIIMS; Dr. Harit Chaturvedi, Director of Surgical Oncology, Max Super Speciality Hospital, Saket; Dr. Kumar Prabash, Professor & Head Solid Unit, Medical Oncology, Tata Memorial Hospital; Dr Shyam Aggarwal, Senior Consultant, Medical Oncology, Sir Ganga Ram Hospital; Dr Vijay Anand Reddy, Senior Consultant - Clinical Oncology & Radiotherapy at Apollo Health City; Dr Sumit Goyal, Senior Consultant, Department of Medical Oncology at RGCI; Dr. Atul Sharma, Professor, Medical Oncology, IRCH, AIIMS.

The panellists agreed that "Developments focused on accuracy and precision have improved quality of life for cancer patients. Dependence on targeted therapies proves that drugs specifically designed to target tumour cells, offer better efficacy, safety and tolerability and may eventually become the standard of care, bringing a paradigm shift in cancer management."

Head and neck cancers are a significant problem in our country constituting approximately one-third of all cancer cases, in contrast to 4-5% in the developed world. Paradoxically, however, management of these cancers is dictated by guidelines emanating from the West, with just a handful of seminal publications from India. Hence, there is a necessity to bring to the fore, novel treatments and interventions that address disease management and cure in the Indian context.

Against this backdrop, Biocon had developed a novel biologic in early 2000's and launched in India, its flagship Oncology Product BioMab EGFR (Nimotuzumab) for Head and Neck Cancer in 2006. The product has made a difference to several thousand patients so far and a new large scale investigator-led randomized clinical study at Tata Memorial Hospital has demonstrated the superior profile of this therapy leading to better patient outcomes for head and neck cancer patients.

Conducted with 536 patients from Tata Memorial Hospital, the results of this study, which were recently presented at the annual conference of the American Society of Clinical Oncologists (ASCO), evaluated the efficacy and safety of administering Nimotuzumab.

Among the largest randomized clinical studies on head and neck cancer, it proved how the introduction of this molecule, to the existing standard of care in patients of Head and Neck cancer, dramatically improved treatment outcomes on factors like progression-free survival, disease-free survival, duration of loco-regional control and overall survival. Till now the main management of Head and Neck Cancer was Chemotherapy + Radiation therapy however this study opens up a new improved way of managing Locally Advanced Head and Neck Cancer as it will now allow clinicians to add Biomab ( Nimotuzumab ) which is a targeted therapy to the current standard of Care (CRT). Biomab has a unique bivalent binding, because of which it binds primarily at the site of cancer cells where there is over expression of the EGFR protein. This is significant since this mechanism of action of Biomab ensures that only the cancerous cells are destroyed, unlike other targeted agents, ensuring that it does not cause additional toxicity.

Key results of the study:

- Improvement in median progression free survival by almost three times: Patients who were administered Biomab along with the usual chemo – radiation therapy, had survived without the disease progressing for almost three times more than patients who were only administered chemo-radiation.
- Reduction in risk of disease progression by 26%
- Reduction in grade 3-5 adverse events (except mucositis): This led to better compliance in the study, with no patient drop off due to severe side effects
- Significant improvement in Loco-regional control and disease free survival: Which means that further growth of tumour may get arrested

In an additional scientific meeting of Oncologists at Chennai, 50% of the oncologists in attendance suggested said that these results are practice changing and they will like to add Nimotuzumab to current standard of Care (CRT) to all their patients of locally advanced Head and Neck Cancer.

Suresh Subramanian, Senior Vice President & Head, Branded Formulations business – India and South Asia, Biocon said “As the first company in India to successfully introduce a novel targeted anti-EGFR biologic, for the treatment of head and neck cancers, the positive results from this large randomized study are a significant milestone in our ongoing efforts to establish Nimotuzumab's ‘best-in-class’ status for the treatment of one of the most common forms of cancer in the country.

We are pleased with the global recognition of the superior efficacy and safety profile of Nimotuzumab and the difference it can make in improving clinical outcomes of head and neck cancer patients by its addition to the standard of care. ”

Biocon has been in the forefront of a long-running crusade against cancer. India's first indigenously manufactured novel biologic Nimotuzumab (BIOMAb EGFR®) was Biocon's first effort at providing an affordable therapy to patients in India. As India's leading Oncology Company, Biocon has already introduced several anti-cancer therapies, ranging from premium generics to biosimilars and novel biologics, for the benefit of patients, caregivers and medical practitioners in the country. Biocon's portfolio of therapies covers a wide range of cancer sites across head and neck, breast, colorectum, ovary, cervix, kidney, brain and lungs, as well as, supportive therapy.

Through its niche portfolio of oncology therapeutics, Biocon has been able to make a significant impact in the area of cancer care in India. In addition to novel biologics, Biocon is addressing a large unmet need for advanced cancer medicines in India through high quality, affordable biosimilars that provide cost-effective alternatives to expensive reference biologics.

Beyond medicines, Biocon has adopted a 360-degree strategy which involves establishing the scientific concept of a therapy through science symposia and advisory boards; generating scientific data through investigator-initiated studies and then publishing the results in reputed journals to build prescriber confidence; creating disease awareness through campaigns, free diagnostic consultations and referral meets; and patient assistance programs involving part therapy assistance and patient counselling helplines. Biocon also conducts 'Converge', an international summit for tumor specific discussions focused on breast and head & neck cancer.

Biocon's CSR arm, Biocon Foundation, implements several technology-based interventions for early detection, prevention and treatment of cancer. We organise screening camps for the underprivileged in rural and semi-urban India, thus facilitating early detection at the doorstep. By empowering frontline health workers to conduct cancer screening in a low resource settings, Biocon Foundation has ensured that these services reach remote pockets in a cost-effective manner. Through its flagship cancer detection program, the Foundation has screened over 53,000 men and women for oral, breast and cervical cancers till date. Patients with potential risk have been supported to undergo further evaluation.

In a developing country like India, innovations enabling cheaper drugs and early diagnosis can work wonders in cancer care. Biocon has carved out its own path keeping in view India's healthcare challenges, and with the realization that without affordability medicines would not reach patients. Our cancer therapies developed on this philosophy – from supportive care and cytotoxic drugs to biosimilar antibodies and novel molecules – have made an enduring impact on the lives of thousands of cancer patients in India.