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TMH team presents Biocon's Nimotuzumab study results at ASCO 2018

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Biocon's Novel Biologic Nimotuzumab combined with chemo-radiotherapy shows superior efficacy & safety over Standard of Care in a study on Head and Neck cancer patients in India.

Biocon Ltd., Asia's premier biopharmaceuticals company, recently announced that a Tata Memorial Hospital (TMH), Mumbai team led by Dr Kumar Prabhash, Head, Solid Unit, Medical Oncology presented the results of a study with Biocon's novel biologic molecule Nimotuzumab at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting held in Chicago from June 1-5. This 536- patient study was conducted by Dr. Vanita Noronha, Dr. Amit Joshi, Dr. Vijay Patil, Dr. A. K. D'cruz, Dr. Sarbani Lasker, Dr. J. P. Agarwal with Dr. Kumar Prabash as the lead investigator, over a period of 6 years. The study successfully met the primary endpoint of median progression free survival which was three times than that of standard of care.

The investigator-initiated study, one of the largest randomized clinical studies on head and neck cancer patients in India, evaluated the efficacy and safety of administering Nimotuzumab during concurrent chemo-radiation in locally advanced head and neck squamous cell carcinoma (LAHNSCC). Adult patients of LAHNSCC were randomized 1:1 into either radical radiotherapy with weekly cisplatin (CRT arm) or the same schedule of chemo-radiation with weekly Nimotuzumab (NCRT arm). The primary endpoint of the study was 'progression free survival', while other key secondary endpoints were 'disease free survival', 'duration of loco-regional control' and overall survival. The study successfully met the primary endpoint Median progression free survival of 60.3 months in NCRT arm as compared to 21 months in CRT arm which was statistically significant.

We believe Nimotuzumab, will benefit a large number of head and neck cancer patients in India. Nimotuzumab with chemo-radiotherapy will provide an alternate therapeutic option in the armamentarium against locally advanced head and neck cancer," said Principal investigator, Dr Kumar Prabhash, Head, Solid Unit, Medical Oncology, TMH.

"*As the first company in India to successfully introduce a novel targeted anti-EGFR biologic, for the treatment of head and neck cancers in India, the positive results from this large randomized study are a significant milestone in Biocon's 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 that ASCO has recognized the superior efficacy and safety profile of Nimotuzamab and the difference it can make in improving clinical outcomes of head and neck cancer patients by its addition to the standard of care,"* said Suresh Subramanian, Senior Vice President & Head, Branded Formulations-India, Biocon.

Nimotuzumab is the first indigenously produced novel biologic developed by Biocon and introduced in India as BIOMAb EGFR® for head and neck cancer in 2006.

Head and neck cancer is one of the leading cancers in India. Over 16 new patients are diagnosed with this specific cancer every hour in India, and 12 deaths recorded every hour*.

Dr Kumar Prabhash and his team has conducted this large patient study over a period of 6 years to establish the superior profile of Nimotuzumab and the difference it can make to patients. The results also showed that the addition of Nimotuzumab to chemo-radiotherapy improved the locoregional control rate, disease free survival and had a trend towards improvement in overall survival.