

## **Alkem Laboratories launches Cetuxa**

### **World's first biosimilar of Cetuximab for Head and Neck Cancer**

**Mumbai, 29<sup>th</sup> May 2023:** Alkem Oncology has announced the launch of Cetuxa, the world's first biosimilar of Cetuximab used for the treatment of head and neck cancer. This is in line with the company's endeavour to ensure affordability, accessibility, and availability while saving the lives of critically ill Cancer patients. Cetuxa has been researched and manufactured indigenously by Enzene Biosciences Limited, the biological arm of Alkem Laboratories.

Head and neck cancers (HNCs) are one of the most common cancers worldwide and in India too. According to the Global Cancer Observatory (GLOBOCAN) estimates, there were 19.3 million incident cancer cases worldwide in 2020 and India ranked third after China and the United States of America. Overall, 57.5% of global head and neck cancer cases occur in Asia and India accounts for 30% of these cases. Annually, in India, the prevalence of head and neck cancer is approximately 5,00,000 cases with over 1,25,000 deaths.

Cetuxa aims to increase the accessibility and affordability of a novel cancer drug for head and neck cancer patients. It is a biosimilar of cetuximab, a monoclonal antibody, and received DCGI approval on 16th January 2023 for this indication. Cetuximab binds to the extracellular domain of the epidermal growth factor receptor (EGFR), which is overexpressed in many human cancers, including head and neck cancer and colorectal cancer. This process prevents EGFR from binding with its endogenous ligand, blocking the receptor-dependent transduction pathway and providing many anti-tumour effects.

Cetuxa is administered as an intravenous infusion and is available as 100 mg (2 mg/mL) in a single-dose vial. Initial dose is 400 mg/m<sup>2</sup>, follow-up of 250 mg/m<sup>2</sup> per week. Cetuximab has a proven record in terms of better progression-free survival (PFS) and overall survival (OS) compared to chemotherapy alone for the management of head and neck cancer.

*"In India more than 76,000 patients are eligible for the use of cetuximab for the management of head and neck cancer. Currently, only 1,611\* patients are managed by this therapy i.e., around 2% of eligible patients. Its reach in India is limited partly due to its high cost. To address this issue, we have launched an affordable biosimilar which is backed by indigenous research and production. We aim to ensure its availability in all parts of the country making it easily accessible to the Indian population," said **Sandeep Singh, Managing Director at Alkem Laboratories***

*"We are glad to announce Cetuxa drug as it will be a historic breakthrough in terms of saving the lives of cancer patients. We have developed Cetuxa as a goal to make cancer therapy more accessible and affordable to millions of patients suffering from head and neck cancer", said **Dr. Himanshu Gadgil, CEO, at Enzene Biosciences Ltd** (biological arm of Alkem Laboratories ).*

Head and neck cancer is one of the most prevalent cancers in India which is primarily caused by the consumption of tobacco. Furthermore, as most patients are from low to middle socio-economic backgrounds, the launch of Cetuxa will help in making the treatment affordable and accessible to all patients.

Alkem is a leading Indian global pharmaceutical company that manufactures and markets biosimilars and pharmaceutical formulations in India and across the globe.

**For further information**

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**About Alkem Laboratories:** Alkem Laboratories Ltd is an Indian pharmaceutical company engaged in the development, manufacture, and sale of pharmaceutical and nutraceutical products. The company produces branded generics, generic drugs, active pharmaceutical ingredients (APIs) and nutraceuticals in acute and chronic therapeutic areas, such as anti-infective, pain and analgesics, vitamins/minerals/nutrients, cardiac and Diabetology, Gynecology, neuro/central nervous system, dermatology, anti-diabetes, anti-osteoporosis, cardiovascular, and muscle relaxants, which are marketed in Indian and International markets. It operates through the pharmaceutical business segment. Read more at <https://www.alkemlabs.com/index.php>

**About Enzene Biosciences Ltd:** Enzene is an innovation-driven biotech company a subsidiary of Alkem Laboratories Ltd. (which is one of the top five pharmaceutical companies in India), located in Pune, India. Enzene's focus lies in producing biosimilars, novel biologics, synthetic peptides, and phytopharmaceuticals. Enzene also offers a range of CDMO and CMO services in biologics. For more information on Enzene Biosciences Ltd, read more at <http://www.enze.com/>

*(\*As per Ipsos Data 2022)*