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DCGI approves AstraZeneca's eosinophilic asthma drug

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Fasenra™ is an add-on maintenance treatment for patients with severe eosinophilic asthma.

AstraZeneca India, a leading science-led biopharmaceutical company, has received marketing authorisation from Drugs Controller General of India (DCGI) for - use of the original research medicine, Fasenra™ (Benralizumab solution for injection in a single dose prefilled syringe30 mg/ml subcutaneous administration only) in patients with severe asthma (eosinophilic asthma). Benralizumab (Fasenra™) is indicated as an add-on maintenance treatment for severe asthma with an eosinophilic phenotype in adult patients.

Fasenra™ is an add-on maintenance treatment for patients with severe eosinophilic asthma. It is designed to target cells in the body called eosinophils, which are a key cause of the eosinophilic subtype of asthma. Fasenra™is not an inhaler or a steroid and is administered once in 8 weeks under the skin via injection as maintenance therapy.

Gagandeep Singh Bedi, Managing Director, AstraZeneca India, said "The regulatory approval of Fasenra™ in India will provide better medicine for the management of eosinophilic asthma and support patients to attain a better quality of life".

Dr Anil Kukreja, Vice President – Medical Affairs & Regulatory, AstraZeneca India said, "The marketing authorisation for Fasenra™ in India is based on the evidence collated over years, 6 phase III trials conducted globally on more than 11,000 patients, and patient exposure of more than 56000 patient years."