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EMA accepts Biocon's review plea for drug

BENGALURU, DHNS: Biocon, India's largest and fully integrated, biopharmaceutical company, has announced that the European Medicines Agency (EMA) has accepted for review of its partner Mylan's Marketing Authorisation Application for insulin glargine.

Mylan and Biocon, which have co-developed insulin glargine, a long-acting insulin analog used to treat adults with type 2 diabetes and adults and pediatric patients (children 6 years and older) with type 1 diabetes for the control of high blood sugar.

Dr Arun Chandavarkar, CEO and Joint MD, Biocon, said, "This is the first filing in a developed market that incorporates product validated at our state-of-the-art Malaysia facility and takes us a step closer to our mission of improving access to more affordable in-



sulins globally."

Mylan has exclusive commercialisation rights for insulin glargine in the US, Canada, Australia, New Zealand, the European Union and European Free Trade Association countries. Biocon has exclusive rights for Japan and a few emerging markets; and co-exclusive commercialisation rights with Mylan in the rest of the world.

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