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Mylan, Biocon receive positive CHMP opinion for Semglee

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The CHMP positive opinion will be considered by the European Commission.

Mylan and Biocon Ltd. have announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending approval of Semglee, insulin glargine, a long-acting insulin analog used in the treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.

The CHMP positive opinion will be considered by the European Commission. The European Commission decision on the approval is expected in April.

Mylan President Rajiv Malik commented, "We are pleased with CHMP's decision to recommend approval of Mylan and Biocon's biosimilar insulin glargine. With approximately 60 million people living with diabetes in the European Region and prevalence on the rise, we have an important role to play to help increase access to high-quality, more affordable treatment options for patients. Mylan is a global leader in the development and manufacturing of complex products, and we are proud of our regulatory, clinical and scientific capabilities that have allowed us to reach this important milestone."

Arun Chandavarkar**,** CEO and Joint Managing Director, Biocon said, "CHMP's decision to recommend approval of Biocon and Mylan's biosimilar insulin glargine brings us a step closer to offer high quality, affordable options for people with diabetes in the EU. This is an outcome of our commitment to be a credible, global insulins player on the back of significant investments together with our partner Mylan in global scale manufacturing and R&D after having previously obtained approvals for our insulin glargine in Japan and key emerging markets."

Data submitted as part of the Marketing Authorization Application included analytical similarity data, metabolic assays, euglycemic clamp data in type 1 diabetes patients for demonstration of similar PD and PK response, as well as robust clinical endpoint studies in patients with Type 1 and Type 2 Diabetes comparing Semglee with the reference product, insulin glargine to demonstrate similar safety, efficacy and immunogenicity up to 52 weeks.

In addition to the European submission, marketing applications for Semglee have been submitted in Australia, Canada, and the U.S. and are planned for key Emerging Markets.

Biocon and Mylan are exclusive partners on a broad portfolio of biosimilars and insulin analogs. Glargine is one of the three insulin analogs being co-developed by Mylan and Biocon for the global marketplace. Mylan has exclusive commercialization rights for insulin glargine in the U.S., 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 commercialization rights with Mylan in the rest of the world.