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Lupin's Pune Biotech facility receives EU GMP clearance

27 March 2019 | News

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Pharma major Lupin Limited has announced that it has received the 'European Good Manufacturing Practice' (EU GMP) certificate for its Mammalian Facility in Pune where Etanercept Biosimilar is intended to be manufactured.

This GMP certification further confirms that Lupin has a robust manufacturing facility that ensures consistent and controlled production as per EU quality standards.

Commenting on this development, Mr. Nilesh Gupta, Managing Director, Lupin Limited stated, "Etanercept is a complex product that requires a sophisticated development facility for production. The EU GMP certificate is a noteworthy achievement by the Biotech manufacturing team. With this timely approval of our biotech facility we are well on track to start

preparing for the manufacture and launch of our Etanercept Biosimilar for Europe. This will enable us to offer a high-quality option that helps reducing healthcare expenses".

"Etanercept is used globally in the fight against a range of severe autoimmune disorders. The successful approval of the facility is testament to our quality and compliance standards and is a major step in achieving our goal for market entry in to Europe post approval of the product," said Dr. Cyrus Karkaria, President, Lupin Biotech. "After significant investment in our biotechnology R&D division over the years, this is the first biosimilar for regulated markets developed and manufactured in-house at Lupin. It is an important achievement for us and sets the tone for future biosimilar development."

Lupin is an innovation led transnational pharmaceutical company developing and delivering a wide range of branded & generic formulations, biotechnology products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership position in the Anti-TB segment.