

Press Release

For Immediate Release

The US FDA Approves First Supplemental Abbreviated New Drug Application (sANDA) for Glenmark Pharmaceuticals' Manufacturing Facility in Monroe, North Carolina

sANDA approval is for manufacturing of Atovaquone and Proguanil Hydrochloride Tablets, 250 MG/100 MG AND 62.5 MG/25 MG at Monroe facility

Mumbai, India; June 19, 2018: Glenmark Pharmaceuticals, a global pharmaceutical company, today announced that the U.S. Food & Drug Administration provided its first supplemental Abbreviated New Drug Application (sANDA) approval for the company's manufacturing facility in Monroe, North Carolina. The approval covers: Atovaquone and Proguanil Hydrochloride Tablets, 250 MG/100 MG and 62.5 MG/25 MG, a generic version of GlaxoSmithKline's Malarone® (atovaquone and proguanil hydrochloride) Tablets¹.

"This approval is an important milestone for our U.S. business, as the Monroe, N.C. site will expand our portfolio by providing the manufacturing foundation for future product approvals," said Robert Matsuk, President, North America & Global API at Glenmark Pharmaceuticals. "Additionally, we are pleased that the investment we've made in our site will continue to create new, high-quality jobs in the Monroe community, where we have a commitment to long-term growth and expansion."

The Monroe, North Carolina facility is Glenmark's first manufacturing site in the U.S., designed to manufacture a variety of fixed dose pharmaceutical formulations. Glenmark has invested more than \$100 million into the facility with plans for further expansion in the coming years. At peak capacity, the site is anticipated to produce 300-400 million tablets and capsules, 20-25 million vials and pre-filled syringes and 25-30 million ampoules for inhaled formulations. Globally, Glenmark has 16 manufacturing facilities in Europe, India and the U.S., operating under Good Manufacturing Practices (GMP) to ensure quality and safety.

About Glenmark Pharmaceuticals Ltd.:

Glenmark Pharmaceuticals Ltd. (GPL) is a global innovative pharmaceutical company with operations in more than 50 countries. Glenmark has a diverse pipeline with several compounds in various stages of clinical development, primarily focused in the areas of oncology, respiratory disease and dermatology. Glenmark has improved the lives of millions of patients by offering safe, affordable medications for nearly 40 years. For more information, visit glenmarkpharma-us.com.

References:

¹ *MALARONE is a registered trademark of the GSK group of companies*

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