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US FDA approves Lupin's pegfilgrastim biosimilar application

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BLA expands the company's oncology portfolio

Lupin announced that the US FDA has accepted the Biologics License Application (BLA) for its proposed biosimilar to Neulasta (pegfilgrastim) through a filing using the 351(k) pathway. Pegfilgrastim has estimated annual sales of $3.66 billion in the US (IQVIA MAT December 2020).

Commenting on the development, Vinita Gupta, CEO, Lupin said, “FDA’s acceptance of our BLA is a significant achievement and demonstrates our commitment to delivering products which increase access in areas of substantial medical need. This BLA expands our oncology portfolio, an area of increasing focus for Lupin. We look forward to the opportunity to bring affordable biologic options to patients and increasing access to this important treatment.”

Nilesh Gupta, MD, Lupin said, “The pegfilgrastim filing is our first biosimilar filing in the US and is a milestone in our research and innovation journey as we continue to focus on delivering unique and affordable solutions to alleviate disease burden. Biosimilars is a key part of our growth strategy and we are proud of the world-class achievements of our group.’’

The BLA submission is supported by similarity data from analytical, pharmacokinetic, pharmacodynamic and immunogenicity studies.

Dr Cyrus Karkaria, President, Lupin Biotech said, “With significant investment in our biotechnology division over the years, we remain committed to bringing much-needed innovative products to market. This milestone further encourages us to continue advancing our robust Biosimilars pipeline across the globe to provide an effective, affordable alternative for consumers.”