Press Release

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Lupin receives U.S. FDA approval for Ethacrynic Acid Tablets USP

Mumbai, Baltimore, September 9, 2019: Pharma major Lupin Limited (Lupin) announced that it has received approval for its Ethacrynic Acid Tablets USP, 25 mg, from the United States Food and Drug Administration (U.S. FDA).

Lupin's Ethacrynic Acid Tablets USP, 25 mg, is the generic version of Edecrin® Tablets, 25 mg, of Bausch Health Americas, Inc. It is indicated for treatment of edema when an agent with greater diuretic potential than those commonly employed is required.

- Treatment of the edema associated with congestive heart failure, cirrhosis of the liver, and renal disease, including the nephrotic syndrome.
- Short-term management of ascites due to malignancy, idiopathic edema, and lymphedema.
- Short-term management of hospitalized pediatric patients, other than infants, with congenital heart disease or the nephrotic syndrome.
- Intravenous ethacrynic acid sodium is indicated when a rapid onset of diuresis is desired, e.g., in acute pulmonary edema, or when gastrointestinal absorption is impaired or oral medication is not practicable.

Ethacrynic Acid Tablets USP (RLD: Edecrin® Tablets) had annual sales of approximately USD 24 million in the US (IQVIA MAT June 2019).

About Lupin Limited

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.

Lupin is the 8th largest generics pharmaceutical company by revenues (31st Mar 2019, Bloomberg LTM) respectively. The Company is the 3rd largest pharmaceutical player in the US by prescriptions (IQVIA MAT Jun 2019); 3rd largest Indian pharmaceutical company by global revenues (31st Mar 2019, Bloomberg LTM); 5th largest generic pharmaceutical player in Japan and 6th largest company in the Indian Pharmaceutical Market (IQVIA MAT Jun 2019).

For the financial year ended 31st March, 2019, Lupin's Consolidated sales and Net profits were at Rs. 163,694 million (USD 2.34 billion) and Rs. 9,466 million (USD 136 million) respectively. Please visit http://www.lupin.com for more information. You could also follow us on Twitter – www.twitter.com/lupinglobal

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