Press Release

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Lupin receives approval for Leflunomide Tablets USP

Mumbai, Baltimore, February 5, 2020: Pharma major Lupin Limited (Lupin) announced that it has received approval for its Leflunomide Tablets USP, 10 mg and 20 mg, from the United States Food and Drug Administration (U.S. FDA), to market a generic equivalent of Arava® Tablets, 10 mg and 20 mg, of Sanofi-Aventis. The product would be manufactured at Lupin's Pithampur (Unit 1) facility, India.

Leflunomide Tablets USP, 10 mg and 20 mg, are indicated for the treatment of adults with active rheumatoid arthritis (RA).

Leflunomide Tablets USP (RLD: Arava® Tablets) had an annual sales of approximately USD 44 million in the U.S. (IQVIA MAT December 2019).

About Lupin Limited

Lupin is an innovation-led transnational pharmaceutical company headquartered in Mumbai, India. The Company develops and commercializes a wide range of branded and generic formulations, biotechnology products and APIs in over 100 markets in the U.S., India, South Africa and across Asia Pacific (APAC), Latin America (LATAM), Europe and Middle-East regions.

The Company enjoys leadership position in the cardiovascular, anti-diabetic, and respiratory segments and has significant presence in the anti-infective, gastro-intestinal (GI), central nervous system (CNS) and women's health areas. Lupin is the third largest pharmaceutical company in the U.S. by prescriptions and in India by global revenues. The Company invests 9.6 % of its revenues on research and development.

Lupin has 15 manufacturing sites, seven research centers, more than 20,000 professionals working globally, and has been consistently recognized as a 'Great Place to Work' in the Biotechnology & Pharmaceuticals sector.

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For further information or queries please contact –

Arvind Bothra Head – Investor Relations and Corporate Communications Email: arvindbothra@lupin.com Tel: +91-22 6640 8237	**Manjira Sharma** General Manager – Corporate Communications Email: manjirasharma@lupin.com Tel: +91-22-6640 2532

Safe Harbor Statement

Arava® is a registered trademark of Sanofi-Aventis Deutschland GmbH (German subsidiary of Sanofi-Aventis)