20th May 2021

The Secretary of the Expert Committee on the Selection and Use of Essential Medicines,
Department of Essential Medicines and Health Products,
World Health Organization,
20 Avenue Appia, CH-1211, Geneva 27, Switzerland

Subject: Statement of support for adding a 300mg rifapentine scored formulation to the World Health Organization Model List of Essential Medicines

Lupin submits this letter in support of adding a 300 mg scored formulation of rifapentine to the World Health Organization (WHO) Model List of Essential Medicines (EML) for treatment of tuberculosis (TB) infection.

Among the infectious diseases, TB is second only to COVID-19 in terms of mortality and caused 1.4 million deaths in 2019 as per the World TB report. With estimates that up to a quarter of the world population may have Latent TB and is at risk of developing active TB disease during the lifetime, the importance of TB preventive regimens (TPT) cannot be overstated.

Lupin has always been at the forefront of the global fight against TB and we are the largest supplier of first-line anti-TB drugs in the world. Our API and formulation plants operate in compliance with all applicable standards and are approved by the Stringent Regulatory Authorities from across the world including the WHO Pre-qualification programme. Our products are procured by all leading agencies and cater to patients across the globe. We are also the largest supply partners to the governments of high TB burden countries across Africa and Asia, including India.

We note that TPT which combine rifapentine with isoniazid represents the current gold standard of care for prevention of TB disease. Rifapentine is the backbone of new(er) short-course regimens for preventing TB disease, namely the 3HP and 1HP regimens. 3HP requires taking 900 mg of rifapentine and 900 mg of isoniazid once a week for 12 weeks. 1HP consists of taking 600 mg of rifapentine and 300 mg of isoniazid daily for one month. Both 3HP and 1HP regimens are listed as recommended regimens in WHO guidelines and are increasingly included in the national guidelines. We further note that a 300 mg Rifapentine formulation is the optimal dosage strength. Additionally, a functional score supports the use of Rifapentine 300 mg formulation in the current and future regimens by allowing half dosing, if indicated.

We began the development of Rifapentine 300 mg early and have taken the exhibit batches of the formulation by this time. The exhibit batch samples have been charged for stability testing and we expect to have the formulation dossier ready by October'2021. Based on our engagements with various agencies, we have installed sufficient manufacturing capacity to meet the global demand. Moreover, we are also backwardly integrated and produce the Rifapentine API which will enable us to ensure uninterrupted supplies and will support scalability to meet demand surges.

In view of the foregoing, we would request the addition of 300mg Rifapentine scored formulation to the WHO Model List of Essential Medicines to enable us to submit our dossier for review by WHO pre-qualification department. We thank you for the opportunity to submit our letter of support. If you need additional information on our support to this application, please contact Mr. Mukul Jerath (Sr. General Manager – Global Institutional Business at Lupin) at mukuljerath@lupin.com.

Yours sincerely,

Mukul Jerath
Sr. General Manager – GIB

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