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ZAXINE® (rifaximin) – Now Indicated in Canada for Patients with Irritable Bowel Syndrome with Diarrhea (IBS-D)^{1,2}

Montreal, Quebec, December 6, 2018 – Lupin Pharma Canada is pleased to announce the approval from Health Canada for ZAXINE® 550 mg (rifaximin) for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults. ZAXINE® for IBS-D is being launched in December of 2018 under a strategic licensing agreement with Salix Pharmaceuticals, Ltd., one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases. The agreement grants Lupin exclusive rights to promote, distribute and market ZAXINE® in Canada. This is in addition to ZAXINE®'s previously approved indication for the reduction in risk of overt hepatic encephalopathy (HE) in adults.¹

Canada has one of the highest rates of IBS worldwide, affecting 13-20% of the population.^{2,3} Of those who do suffer from IBS, about one third have IBS with diarrhea as the primary symptom. Although the exact cause of IBS-D is not known, scientists believe that the microbiota in the gastrointestinal (GI) tract plays an important role in the development of the symptoms associated with IBS-D, such as abdominal pain, bloating, and diarrhea.¹

Speaking on the occasion, **Dr. Sofia Mumtaz, President - Pipeline Management & Legal, Lupin** said, “We are delighted to receive the approval from Health Canada for ZAXINE® (rifaximin, 550 mg tablets) for the treatment of IBS-D. With this new indication approved, the medical fraternity and patients will now have access to an effective medication against one of the most rampantly prevailing issues of IBS-D.”

“There is an unmet treatment need for those who have irritable bowel syndrome with diarrhea, so this is great news for those still grappling to manage their digestive symptoms”, said **Gail Attara, Chief Executive Officer of the Gastrointestinal Society**, a patient group known for its popular website, www.badgut.org.

The safety and efficacy of ZAXINE® 550 mg three times daily for 2 weeks were demonstrated in 3 Phase-III placebo-controlled trials. After treatment, significantly more ZAXINE®-treated patients experienced self-reported relief of IBS symptoms.¹ In addition, a significantly greater proportion of ZAXINE®-treated patients reported relief of abdominal pain and improvement in stool consistency.^{1,4}

“In irritable bowel syndrome, it is not always easy to manage the symptoms effectively,” said **Dr. Guy Aumais, MD, CSPQ, FRCP (C), Gastroenterologist at Maisonneuve-Rosemont and Associate Professor, University of Montreal**. He further added, “ZAXINE® is a short-term, two-week therapy for IBS-D, which will act on symptoms such as diarrhea, bloating and abdominal pain, with lasting relief. With this indication, we now have an interesting new option in the management of IBS-D.”

“An alteration in host-microbiota interactions is a factor in the expression of subsets of IBS patients. ZAXINE® has been shown to improve symptoms in diarrhea predominant IBS-D and its action is likely mediated through attenuation of host microbiota interactions and subsequent symptom generation. This is an important new treatment option for IBS-D patients”, said **Dr. Stephen Collins MBBS, FRCP (UK), FRCP, Professor, Department of Medicine at McMaster University**.

ABOUT ZAXINE® (RIFAXIMIN)

ZAXINE® (rifaximin)'s primary mode of action reduces the bacterial load and bacterial products that can negatively affect the patient, alleviating the most common symptoms of IBS-D including bloating, abdominal pain and diarrhea.¹



As an antibacterial agent that acts locally on the microflora of the gut thereby altering the gut microbiota, ZAXINE® represents an important new therapeutic option in the treatment of IBS-D.

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 13th largest generics pharmaceutical company in terms of market capitalization (30th September 2018, Bloomberg) and the 8th largest generics pharmaceutical company in terms of revenues (30th June 2018, Bloomberg LTM) globally. The Company is the 3rd largest pharmaceutical player in the US by prescriptions for the Total Market (IQVIA MAT September 2018); 3rd largest Indian pharmaceutical company by global revenues (30th June 2018, Bloomberg LTM); 6th largest generic pharmaceutical player in Japan (IQVIA MAT September 2018) and 5th largest company in the Indian Pharmaceutical Market (IQVIA MAT September 2018).

For the financial year ended 31st March 2018, Lupin's Consolidated sales and Net profits before exceptional items were at Rs. 155,598 million (USD 2.41 billion) and Rs. 13,934 million (USD 216 million) respectively. Please visit <http://www.lupin.com> for more information. You could also follow us on Twitter – www.twitter.com/lupinglobal.

CIN: L24100MH1983PLC029442 Registered Office: Lupin Ltd, 3rd Floor, Kalpataru Inspire, Off Western Express Highway, Santacruz (East), Mumbai 400 055.

ZAXINE® (rifaximin) is manufactured by:
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Bridgewater, NJ 08807
USA

In Canada, ZAXINE® (rifaximin) is distributed exclusively by:
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References:

1. ZAXINE® Product Monograph. Salix Pharmaceuticals, Inc., November 30, 2018.
2. <http://cdhf.ca/en/disorders/irritable-bowel-syndrome-ibs/section/resources>
3. <https://www.badgut.org/information-centre/a-z-digestive-topics/ibs/>
4. Pimentel M, Lembo A, Chey WD et al. Rifaximin Therapy for Patients with Irritable Bowel Syndrome without Constipation. N Engl J Med 2011; 364:22-32.