

# LUPIN LICENSES US RIGHTS FOR PROPRIETARY BIOADHESIVE TECHNOLOGY FOR RIFAXIMIN TO SALIX PHARMACEUTICALS

Lupin and Salix to Collaborate in the Development and Commercialization of an Extended Release Rifaximin Product

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Mumbai, Oct 5<sup>th</sup>, 2009 – Pharma Major, Lupin Ltd today announced that it has granted Salix Pharmaceuticals, Ltd. (NASDAQ:SLXP) the exclusive rights for the United States to its bioadhesive drug delivery technology for use with Rifaximin.

Lupin and Salix have entered into an agreement under which the two companies will collaborate in the development and commercialization of an extended release product incorporating Rifaximin and utilizing Lupin's proprietary bioadhesive technology. In connection with this agreement, Lupin and Salix have also entered into an exclusive agreement in the United States for supply of Rifaximin active pharmaceutical ingredient (API). Salix has made a \$5 million up-front payment and will make additional regulatory milestone payments to Lupin. In addition, Salix will pay royalties on net sales of the bioadhesive Rifaximin product to Lupin.

Nilesh Gupta, Group President and Executive Director, Lupin, stated "We are very pleased to enter into this collaboration with Salix. We believe our proprietary bioadhesive drug delivery technology, which combines controlled-release as well as slowed gastrointestinal transit, would provide an extended release formulation of rifaximin that will be an important component of Salix's lifecycle management strategy for rifaximin. This formulation coupled with Salix's commercialization capabilities gives us the opportunity to jointly bring a great product to the marketplace. Importantly, this alliance further validates Lupin's increasing capabilities in the drug delivery space."

Carolyn Logan, President and CEO, Salix, commented, "We are pleased to enter into this strategic collaboration with Lupin. This collaboration to develop and commercialize an extended release formulation of rifaximin is a significant advancement in rifaximin's lifecycle management strategy. With this collaboration Salix embarks on the development of our next generation rifaximin product incorporating Lupin's proprietary drug delivery platform with our proprietary gut-targeted antibiotic. We believe this novel delivery approach, which combines controlled-release as well as slowed gastrointestinal transit of rifaximin, might prove to provide a number of clinical advantages including patient compliance and patient

convenience. The acquisition of these rights to Lupin's proprietary bioadhesive drug delivery technology should serve to further protect this important Company asset."

## About XIFAXAN® (Rifaximin)

Rifaximin is a gut-selective antibiotic with negligible systemic absorption (<0.4%) and broad-spectrum activity in vitro against both gram-positive and gram-negative pathogens. Rifaximin has a similar tolerability profile to that of placebo. XIFAXAN revenue for 2008 was approximately \$80 million.

Rifaximin tablets 200 mg, which Salix markets in the United States under the trade name XIFAXAN® (Rifaximin) tablets 200 mg, currently is approved for the treatment of patients, 12 years of age or older, with travelers' diarrhea (TD) caused by non–invasive strains of Escherichia coli. XIFAXAN (Rifaximin) is a gut–selective antibiotic with negligible systemic absorption (<0.4%) and broad–spectrum activity in vitro against both gram–positive and gram–negative pathogens. Rifaximin has a similar tolerability profile to that of placebo and has activity against the most common TD pathogens. XIFAXAN should not be used in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli. XIFAXAN should be discontinued if diarrhea symptoms get worse or persist more than 24–48 hours and alternative antibiotic therapy should be considered. In clinical trials, XIFAXAN was generally well tolerated. The most common side effects (vs. placebo) were flatulence 11.3% (versus 19.7%), headache 9.7% (versus 9.2%), abdominal pain 7.2% (versus 10.1 %) and rectal tenesmus 7.2% (versus 8.8%).

Rifaximin has been used in Italy for 24 years and is approved in 33 countries. Salix acquired rights to market Rifaximin in North America from Alfa Wassermann S.p.A. in Bologna, Italy. Alfa Wassermann markets Rifaximin in Italy under the trade name Normix®.

### About Lupin

Headquartered in Mumbai, India, Lupin Limited is an innovation led transnational pharmaceutical company producing a wide range of quality, affordable generic and branded formulations and APIs for the developed and developing markets of the world. The Company today has significant market share in key markets in the Cardiovasculars (prils and statins), Diabetology, Asthma, Pediatrics, CNS, GI, Anti-Infectives and NSAIDs therapy segments, not to mention global leadership positions in the Anti-TB and Cephalosporins. The Company's R&D endeavors have resulted in significant progress in its NCE program. The Company's foray into Advanced Drug Delivery Systems has resulted in the development of platform technologies that are being used to develop value-added generic pharmaceuticals.

Our Drugs and products reach over 70 countries in the world. Today, Lupin has the unique distinction of being the fastest growing top 10 Generics players in the two largest pharmaceutical markets of the world – The U.S (ranked 9th by prescriptions & growing at 92 %) and Japan (ranked 7th and growing at 23%). The company is also the fastest growing, top 5 pharmaceutical players in India (ORG IMS - March 2009) and the fastest growing Generic player in South Africa (ranked 6th and growing at over 30 % YoY - IMS)

For the financial year ended March 2009, Lupin's Consolidated Revenues and Profit after Tax were Rs.39,145 million and Rs. 5015 million respectively.

### **About Salix Pharmaceuticals**

Salix Pharmaceuticals, Ltd., headquartered in Raleigh, NC, develops and markets prescription pharmaceutical products for the treatment of gastrointestinal diseases. Salix's strategy is to in-license late-stage or marketed proprietary therapeutic drugs, complete with any required development and regulatory submission of these products, and them through the Company's gastroenterology specialty sales and marketing team.

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