

## **Lupin and Salix Announce Exclusive Distribution Agreement for Canada** ***Zaxine<sup>®</sup>, Relistor<sup>®</sup> and Other Gastroenterology Products***

**September 12, 2014** Lupin Limited (Lupin) and Salix Pharmaceuticals, Inc. (Salix) announced today that they have entered into a definitive distribution agreement under which Salix has granted Lupin the exclusive right to market, distribute and sell certain Salix products in Canada. This includes immediate rights to distribute Zaxine<sup>®</sup> (rifaximin) 550 mg tablets for reduction in risk of overt hepatic encephalopathy (HE) recurrence in patients 18 years of age or older, and Relistor<sup>®</sup> Subcutaneous Injection for the treatment of opioid-induced constipation (OIC) in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Use of RELISTOR beyond 4 months has not been studied. Additionally, the agreement includes future dosage forms, strengths, and indications for such products. Under the agreement, Lupin also has the option to exclusively market, distribute and sell other gastroenterology products in Salix's Canadian pipeline once approved by Health Canada.

Lupin will promote the Salix products through its own sales force in Canada. Lupin is in the process of establishing its Canadian presence and the addition of this significant product portfolio opens up growth opportunities for the future. Zaxine and Relistor are First-in-Class Treatments for their respective disorders and are important treatment options for physicians and their patients, not only in the U.S., but now in Canada.

Under the terms of the Agreement, Salix will receive an upfront payment and distribution fees, and is eligible for additional pre-commercial and sales milestone payments. Salix will supply the products to Lupin under separate supply agreements.

### **About ZAXINE 550 mg**

#### **Indication:**

ZAXINE<sup>®</sup> (rifaximin) 550 mg tablets are indicated for reduction in risk of overt hepatic encephalopathy (HE) recurrence in patients  $\geq$  18 years of age.

#### **Important Safety Information about ZAXINE 550 mg**

ZAXINE<sup>®</sup> (rifaximin) 550 mg tablets are contraindicated in patients with a hypersensitivity to rifaximin, any of the rifamycin antimicrobial agents, or any of the components in ZAXINE. Hypersensitivity reactions have included exfoliative dermatitis, angioneurotic edema, and anaphylaxis.

*Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including ZAXINE, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon which may lead to overgrowth of *C. difficile*. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued.

There is increased systemic exposure in patients with more severe hepatic dysfunction. The clinical trials were limited to patients with MELD scores  $<$  25. Therefore, caution should be exercised when administering ZAXINE to patients with severe hepatic impairment (Child-Pugh C).

Concomitant administration of drugs that are P-glycoprotein (P-gp) inhibitors with ZAXINE can substantially increase the systemic exposure to ZAXINE. Caution should be exercised when concomitant use of ZAXINE and a P-gp inhibitor such as cyclosporine is needed. In patients with hepatic impairment, a potential additive effect of reduced metabolism and concomitant P-gp inhibitors may further increase the systemic exposure to ZAXINE.

Based on animal data, ZAXINE may cause fetal harm. Discontinue in nursing mothers after taking into account the importance of the drug to the mother.

The most common adverse reactions occurring in  $\geq 10\%$  of patients and at a higher incidence than placebo in the clinical study were peripheral edema (15%), nausea (14%), dizziness (13%), fatigue (12%), and ascites (11%).

Xifaxan 550 mg is licensed by Alfa Wassermann S.p.A. to Salix Pharmaceuticals, Inc.

**Please see complete Prescribing Information for ZAXINE.**

### **Important Safety Information about RELISTOR**

RELISTOR<sup>®</sup> (methylnaltrexone bromide) Subcutaneous Injection is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Cases of gastrointestinal (GI) perforation have been reported in adult patients with opioid-induced constipation and advanced illness with conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the GI tract (i.e., cancer, peptic ulcer, Ogilvie's syndrome). Perforations have involved varying regions of the GI tract (e.g., stomach, duodenum, or colon). Use RELISTOR with caution in patients with known or suspected lesions of the GI tract. Advise patients to discontinue therapy with RELISTOR and promptly notify their physician if they develop severe, persistent, or worsening abdominal symptoms.

If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their physician.

Use of RELISTOR beyond four months has not been studied.

Safety and efficacy of RELISTOR have not been established in pediatric patients.

The most common adverse reactions reported with RELISTOR compared with placebo in clinical trials were abdominal pain (28.5%), flatulence (13.3%), nausea (11.5%), dizziness (7.3%), diarrhea (5.5%), and hyperhidrosis (6.7%).

RELISTOR is under license to Salix Pharmaceuticals, Inc. from Progenics Pharmaceuticals, Inc.

**RELISTOR full Prescribing Information for the U.S. is available at [www.RELISTOR.com](http://www.RELISTOR.com).**

### **About Salix Pharmaceuticals, Inc.**

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

Salix trades on the NASDAQ Global Select Market under the ticker symbol “SLXP”.

For more information, please visit our Website at [www.salix.com](http://www.salix.com) or contact Salix at 919-862-1000. Follow us on Twitter (@SalixPharma) and Facebook ([www.facebook.com/SalixPharma](http://www.facebook.com/SalixPharma)). Information on our Twitter feed, Facebook page and web site is not incorporated in our filings with the SEC.

### **About Lupin Limited**

Lupin is an innovation led transnational pharmaceutical company producing and developing a wide range of branded and generic formulations as well as 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 positions in the Anti-TB and Cephalosporin segment.

Lupin is the 5th largest and fastest growing top 5 generics player in the US (5.3% market share by prescriptions, IMS Health) and the 3rd largest Indian pharmaceutical company by sales. The Company is also the fastest growing top 10 generic pharmaceutical players in Japan and South Africa (IMS).

For the financial year ended March 2014, Lupin's Consolidated turnover and Profit after Tax were Rs. 110,866 million (USD 1.83 billion) and Rs. 18,364 million (USD 304 million) respectively. Please visit <http://www.lupinworld.com> or Twitter (@LupinLimited) for more information.

### **For queries, please contact -**

#### **For Lupin:**

Shamsher Gorawara  
Head – Corporate Communications  
Lupin Limited  
Ph: +91 - 9820338555  
email: [shamshergorawara@lupinpharma.com](mailto:shamshergorawara@lupinpharma.com)

Alpesh Dalal  
Head – M & A and Investor Relations  
Lupin Limited  
Ph: +91 98 20 023 511  
email: [alpeshdlal@lupinpharma.com](mailto:alpeshdlal@lupinpharma.com)

#### **For Salix:**

Adam C. Derbyshire  
Executive Vice President  
and Chief Financial Officer  
919-862-1000

G. Michael Freeman  
Associate Vice President, Investor Relations  
and Corporate Communications  
919-862-1000

### **Lupin Safe Harbor Statement**

#### *Salix Disclosure Notice*

*Please Note: The statements provided herein that are not historical facts are or might constitute projections and other forward-looking statements regarding future events. Although we believe the expectations reflected in such forward-looking statements are based on reasonable assumptions, our expectations might not be attained. Forward-looking statements are just predictions and are subject to known and unknown risks and uncertainties that could cause actual events or results to differ materially from expected results. Factors that could cause actual events or results to differ materially from those described herein include, among others: uncertainty that Uceris (budesonide) 2 mg rectal foam will be commercially successful; market acceptance for approved products; generic and other competition in an increasingly global industry; litigation and the possible impairment of, or inability to*

*obtain, intellectual property rights and the costs of obtaining such rights from third parties in an increasingly global industry; the cost, timing and results of clinical trials and other development activities involving pharmaceutical products; post-marketing approval regulation, including the ongoing Department of Justice investigation of Salix's marketing practices; revenue recognition and other critical accounting policies; the need to acquire new products; changes in tax laws or interpretations thereof; general economic and business conditions; and other factors. Readers are cautioned not to place undue reliance on the forward-looking statements included herein, which speak only as of the date hereof. Salix does not undertake to update any of these statements in light of new information or future events, except as required by law. The reader is referred to the documents that Salix files from time to time with the SEC.*