BAUSCH Health

Salix And Alfasigma Will Initiate Late-Stage Program To Study Rifaximin In Patients With Postoperative Crohn's Disease

October 29, 2018

Companies Announce Resolution of Outstanding Arbitration

BRIDGEWATER, N.J., Oct. 29, 2018 /PRNewswire/ -- Salix Pharmaceuticals, Inc. ("Salix"), one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases and a wholly owned subsidiary of Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health"), announced it has entered into an amendment to its existing license agreement with Alfasigma S.p.A. ("Alfasigma") to initiate a late-stage clinical program to study an investigational formulation of rifaximin in patients with postoperative Crohn's disease, an area of unmet medical need. Additionally, the companies have agreed to resolve the outstanding arbitration regarding another development project for a formulation of rifaximin.

According to the Crohn's & Colitis Foundation, more than 750,000 Americans have Crohn's disease, and of those, up to 75 percent will eventually require surgery. Surgery in Crohn's disease is not curative, and postoperative recurrence frequently occurs.[1]

"Today, there are no approved treatments in the United States for the prevention of postoperative Crohn's disease recurrence. Based on existing clinical data, we believe rifaximin may be a potential treatment solution to help postoperative patients manage their Crohn's disease," said Mark McKenna, president of Salix Pharmaceuticals. "The amended agreement with Alfasigma allows us to start working together on a clinical research program that could lead to a new option in the treatment paradigm for postoperative Crohn's disease patients."

The new formulation of rifaximin, called Extended Intestinal Release (EIR), will be used in the late-stage clinical research program. In 2012, a European clinical Phase 2 study in 402 patients with moderately active Crohn's disease was performed to assess the efficacy and safety of multiple doses of rifaximin-EIR. The Phase 2 trial demonstrated that administration of rifaximin-EIR twice daily for 12 weeks induced remission with few adverse events in patients with moderately active Crohn's disease.[2]

"I am very happy regarding this agreement with Salix as it re-energizes our long-term partnership, one that has played a critical role in the success of XIFAXAN® (rifaximin) in the United States," commented Anton Giorgio Failla, executive director of Corporate Development, Alfasigma. "We look forward to dedicating our efforts to develop a new generation of rifaximin that may improve patients' lives and address a significant unmet medical need."

Resolution of the Arbitration

The companies have agreed to resolve the outstanding arbitration regarding performance under an Amended and Restated License Agreement between Alfasigma and Salix concerning another development project for a new formulation of rifaximin. As a result of the resolution, all claims related to the arbitration will be released.

About XIFAXAN
XIFAXAN® (rifaximin) 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults and for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

IMPORTANT SAFETY INFORMATION

- XIFAXAN is contraindicated in patients with a hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components in XIFAXAN. 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 XIFAXAN, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued.
- There is an increased systemic exposure in patients with severe (Child-Pugh Class C) hepatic impairment. Caution should be exercised when administering XIFAXAN to these patients.
- Caution should be exercised when concomitant use of XIFAXAN and P-glycoprotein (Pgp) and/or OATPs inhibitors is needed. Concomitant administration of cyclosporine, an inhibitor of P-gp and OATPs, significantly increased the systemic exposure of rifaximin. In patients with hepatic impairment, a potential additive effect of reduced metabolism and concomitant P-gp inhibitors may further increase the systemic exposure to rifaximin.
- In clinical studies, the most common adverse reactions for XIFAXAN were: o HE (≥10%): Peripheral edema (15%), nausea (14%), dizziness (13%), fatigue (12%), and ascites(11%) o IBS-D (≥2%): Nausea (3%), ALT increased (2%).
- INR changes have been reported in patients receiving rifaximin and warfarin concomitantly. Monitor INR and prothrombin time. Dose adjustment of warfarin may be required. • XIFAXAN may cause fetal harm. Advise pregnant women of the potential risk to a fetus.

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit
www.fda.gov/medwatch
, or call 1-800-FDA-1088.

Please click
here
for full Prescribing Information.

About Alfasigma
Alfasigma, is an Italy-based integrated multinational pharmaceutical company with 2017 revenues in excess of €1 billion and 2,800 employees globally. Outside of its core Italian market, Alfasigma has 16 subsidiaries in Europe, Asia, North and Central America and Africa, and has authorised distributors in more than 70 countries. More than 44% of Alfasigma turnover comes from internally developed proprietary products, one of which is XIFAXAN.

About Salix
Salix is one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases. For almost 30 years, Salix has licensed, developed, and marketed innovative products to improve patients' lives and arm health care providers with life-changing solutions for many chronic and debilitating conditions. Salix currently markets its product line to U.S. health care providers through an expanded sales force that focuses on gastroenterology, hepatology, pain specialists, and primary care. Salix is headquartered in Bridgewater, New Jersey.

About Bausch Health

Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global company whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of pharmaceutical, medical device and over-the-counter products, primarily in the therapeutic areas of eye health, gastroenterology and dermatology. We are delivering on our commitments as we build an innovative company dedicated to advancing global health. More information can be found at www.bauschhealth.com .

Forward-looking Statements

This news release may contain forward-looking statements, which may generally be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, risks and uncertainties discussed in the Bausch Health's most recent annual or quarterly report and detailed from time to time in Bausch Health's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. In addition, certain material factors and assumptions have been applied in making these forward-looking statements, including that the risks and uncertainties outlined above will not cause actual results or events to differ materially from those described in these forward-looking statements. Bausch Health believes that the material factors and assumptions reflected in these forward-looking statements are reasonable, but readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. Bausch Health and Salix undertake no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

References

- Crohn's & Colitis Foundation (2014) The Facts About Inflammatory Bowel Diseases. http://www.crohnscolitisfoundation.org/assets/pdfs/updatedibdfactbook.pdf . Accessed October 24, 2018.
- Gastroenterology (2011) Rifaximin-Extended Intestinal Release Induces Remission in Patients With Moderately Active Crohn's Disease. https://www.gastrojournal.org/article/S0016-5085(11)01628-3/fulltext Accessed October 24, 2018.

XIF.0196.USA.18

Investor Contact:	**Media Contacts:**
Arthur Shannon	Lainie Keller
arthur.shannon@bauschhealth.com	lainie.keller@bauschhealth.com
(514) 856-3855	(908) 927-0617

(877) 281-6642 (toll free)

Karen Paff

Karen.Paff@salix.com

(908) 927-1190

View original content to download multimedia:
http://www.prnewswire.com/news-releases/salix-and-alfasigma-will-initiate-late-stage-program-to-study-rifaximin-in-patients-with-postoperative-crohns-disease-300739039.html

SOURCE Bausch Health Companies Inc.

Investor Inquiries
ir@bauschhealth.com
877-281-6642
514-856-3855 (Canada)

Media inquiries
Corporate.communications@bauschhealth.com
908-569-3692