

# Bausch Health And Alfasigma Announce Resolution Of XIFAXAN® Intellectual Property Litigation

September 22, 2020

## **Salix Will Maintain Market Exclusivity for XIFAXAN® (rifaximin) 200 mg and 550 mg Tablets Until 2028<sup>1</sup>**

LAVAL, QC, Sept. 22, 2020 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health" or the "Company") along with its gastroenterology business, Salix Pharmaceuticals ("Salix"), which is one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases, together with Salix's licensor Alfasigma SpA (collectively the "Salix Parties"), have agreed to resolve outstanding intellectual property disputes with Sun Pharmaceutical Industries Ltd. ("Sun") regarding XIFAXAN® (rifaximin) 200 mg and 550 mg tablets. The Salix Parties will grant Sun a non-exclusive license effective Jan. 1, 2028 to its intellectual property relating to XIFAXAN 200 mg and 550 mg tablets in the United States.

In April 2019, Bausch Health filed a lawsuit against Sun following receipt of a Notice of Paragraph IV Certification relating to XIFAXAN 200 mg tablets. Additionally, Bausch Health received a Notice of Paragraph IV Certification from Sun relating to XIFAXAN 550 mg tablets on Aug. 10, 2020.

"Resolving these matters with Sun is another testament to the strength of the XIFAXAN intellectual property," said Joseph C. Papa, chairman and CEO, Bausch Health. "We will continue to defend our intellectual property protecting XIFAXAN, and we will continue to invest in the research and development of new indications and formulations for rifaximin that can potentially benefit more patients."

"Alfasigma is satisfied with the resolution," said Pier Vincenzo Colli, CEO of Alfasigma. "In the interest of patients and customers, our company is committed to using any efforts to protect its intellectual property covering XIFAXAN."

Sun acknowledges the validity of the licensed patents with respect to the two XIFAXAN products. Final patent expiry on XIFAXAN 200 mg and 550 mg tablets are July and October 2029, respectively.

Under the terms of the agreement, beginning Jan. 1, 2028<sup>1</sup> (or earlier under certain circumstances), Sun will have the right to market royalty-free generic versions of XIFAXAN 200 mg and 550 mg tablets, should it receive approval from the U.S. Food and Drug Administration (FDA) on its Abbreviated New Drug Application.

Litigation between the parties related to XIFAXAN will be dismissed, and all intellectual Property protecting XIFAXAN remains intact. Bausch Health and Alfasigma remain confident in the strength of the XIFAXAN patents, and they will continue to vigorously defend their intellectual property. XIFAXAN 200 mg and 550 mg tablets are collectively protected by 26 patents covering the

composition of matter and the use of XIFAXAN listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book.

Bausch Health agreed to resolve outstanding intellectual property litigation with Actavis Laboratories FL, Inc. ("Actavis") and Sandoz Inc. ("Sandoz") regarding XIFAXAN 550 mg tablets in September 2018 and in May 2020, respectively. Under the terms of the agreements, the Salix Parties will grant Actavis and Sandoz non-exclusive licenses effective Jan. 1, 2028<sup>2</sup> to the Salix Parties' intellectual property relating to XIFAXAN 550 mg tablets in the United States.

### **About Alfasigma**

Alfasigma, one of the leading Italian pharmaceutical companies, is present in over 90 countries, through distributors and subsidiaries and has a workforce of around 3,000 people, R&D laboratories, and 5 production plants. In Italy, Alfasigma is a leader in the market for prescription products where, in addition to the strong focus on gastrointestinal, it is present in many primary care therapeutic areas. Alfasigma also produces and markets self-medication products, nutraceuticals and food supplements. More information is available at the Alfasigma website at: <http://www.alfasigma.com/en>

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### **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](http://www.bauschhealth.com)

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### **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," "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, the risks and uncertainties discussed in Bausch Health's most recent annual report on Form 10-K and detailed from time to time in Bausch Health's other filings with the U.S. Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. They also include, but are not limited to, risks and uncertainties caused by or relating to the evolving COVID-19 pandemic, and the fear of that pandemic and its potential effects, the severity, duration and future impact of which are highly uncertain and cannot be predicted, and which may have a material adverse impact on Bausch Health, including but not limited to its project development timelines, and costs (which may increase). 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 undertakes 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.

<sup>1</sup> Sun will be able to begin marketing the medicine earlier if another generic rifaximin product is granted approval and starts selling or distributing such generic rifaximin product before Jan. 1, 2028. On Feb. 17, 2020, the Salix Parties received a Notice of Paragraph IV Certification from Norwich Pharmaceuticals, Inc. relating to XIFAXAN tablets, 550 mg; and filed suit against Norwich on March 26, 2020, which remains pending.

<sup>2</sup> Actavis and Sandoz will be able to begin marketing the medicine earlier if another generic rifaximin product is granted approval and starts selling or distributing such generic rifaximin product before Jan. 1, 2028.

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