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

May 06, 2020

Salix Will Maintain Market Exclusivity for XIFAXAN®(rifaximin) 550 mg Tablets Until 2028[1]

LAVAL, Quebec, May 6, 2020 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health" or the "Company") along with its wholly owned subsidiary, 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 the outstanding intellectual property litigation with Sandoz Inc., regarding XIFAXAN® (rifaximin) 550 mg tablets. The Salix Parties will grant Sandoz a non-exclusive license effective Jan. 1, 2028 to its intellectual property relating to XIFAXAN 550 mg tablets in the United States.

Sandoz acknowledges the validity of the licensed patents. Final patent expiry on XIFAXAN 550 mg tablets is October 2029.

Under the terms of the agreement, beginning Jan. 1, 2028[1] (or earlier under certain circumstances), Sandoz will have the right to market a royalty-free generic version of XIFAXAN 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 is protected by 23 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.

In September 2018, Bausch Health agreed to resolve earlier outstanding intellectual property litigation with Actavis Laboratories FL, Inc. ("Actavis"), regarding XIFAXAN 550 mg tablets. Under the terms of the agreement, the Salix Parties will grant Actavis a non-exclusive license effective Jan. 1, 2028[2] 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
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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 the Company'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 the Company, 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.

[1] 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. 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.
[2] Actavis 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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