BAUSCH Health

Court of Appeals for the Federal Circuit Issues Ruling in Norwich Case that Prevents FDA Approval of Norwich's Abbreviated New Drug Application Until 2029

April 11, 2024

LAVAL, Quebec, April 11, 2024 – Bausch Health Companies Inc. (NYSE/TSX: BHC), and its gastroenterology business Salix Pharmaceuticals, today announced that the U.S. Court of Appeals for the Federal Circuit in the matter of *Salix Pharmaceuticals, LTD. et al v. Norwich Pharmaceuticals, Inc.,* affirmed the May 17, 2023 decision of the U.S. District Court for the District of Delaware that had denied Norwich Pharmaceuticals, Inc.'s motion for modification of the court's final order preventing the U.S. Food and Drug Administration (FDA) from approving its abbreviated new drug application (ANDA) for XIFAXAN (rifaximin) 550 mg before Oct. 2, 2029. The Court of Appeals also affirmed the August 10, 2022 decision of the District Court that invalidated certain U.S. Patents protecting the composition and use of XIFAXAN® for treating IBS-D. As a result of the Federal Circuit's decision, Norwich's abbreviated new drug application for XIFAXAN (rifaximin) 550 mg remains barred from approval by the U.S. Food and Drug Administration until Oct. 2, 2029.

"We are pleased that the Federal Circuit maintained the judgment preventing the approval of Norwich's abbreviated new drug application for XIFAXAN (rifaximin) 550 mg by the U.S. Food and Drug Administration until October 2029," said Thomas J. Appio, Chief Executive Officer. "While we are disappointed that the Federal Circuit affirmed the invalidity of certain XIFAXAN IBS-D patents and disagree with this aspect of the Court's decision, we will continue to vigorously defend our intellectual property. We remain committed to advocating for the safety of patients who have benefited from continued access to XIFAXAN, and we look forward to continuing to serve those patients."

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.

About Salix

Salix Pharmaceuticals is one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases. For more than 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. For more information about Salix, visit www.Salix.com
and connect with us on Twitter and LinkedIn.

About Bausch Health

Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global diversified pharmaceutical company enriching lives through our relentless drive to deliver better health outcomes. We develop, manufacture and market a range of products, primarily in gastroenterology, hepatology, neurology, dermatology, medical aesthetic devices, international pharmaceuticals, and eye health, through our controlling interest in Bausch + Lomb. Our ambition is to be a globally integrated healthcare company, trusted and valued by patients, HCPs, employees and investors. For more information, visit
www.bauschhealth.com
and connect with us on
Twitter
and
LinkedIn.

Forward-looking Statements

This news release may contain forward-looking statements about the future performance of Bausch Health, which may generally be identified by the use of the words "anticipates," "hopes," "expects," "intends," "plans," "should," "could," "would," "may," "believes," "subject to" and variations or similar expressions, including statements about the Company's appeal with respect to, and actions to vigorously defend, its intellectual property. 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. In particular, Bausch Health can offer no assurance as to the timing of any approval by the FDA of any ANDA or amended ANDA and as to the outcome of any appeal. Actual results are subject to other risks and uncertainties that relate more broadly to Bausch Health's overall business, including those more fully described 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.

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