BAUSCH Health

U.S. District Court Grants Summary Judgment in Favor of FDA, Salix, and Teva, and Against Norwich

April 17, 2025

LAVAL, Quebec, April 17, 2025 – Bausch Health Companies Inc. (NYSE:BHC)(TSX:BHC) (the "Company" or "Bausch Health"), and its gastroenterology business Salix Pharmaceuticals, Inc., today announced the U.S. District Court for the District of Columbia in the matter of Norwich Pharmaceuticals, Inc. v. Kennedy, et al. (Case No. 25-cv- 00091), denied Norwich's motion for a preliminary injunction treated as a motion for summary judgment in its lawsuit against the U.S. Food and Drug Administration (FDA).

Norwich had asked the District Court for a judgment declaring the FDA's decision to issue tentative approval for Norwich's Abbreviated New Drug Application (ANDA) for XIFAXAN® (rifaximin) 550 mg and failure to determine Teva Pharmaceuticals USA, Inc. (Teva) had forfeited its 180-day exclusivity were arbitrary, capricious, and contrary to law. Norwich sought an injunction directing the FDA to immediately grant Final Approval to Norwich's ANDA for XIFAXAN® (rifaximin) 550 mg. Norwich argued that if upheld, FDA's determination will prohibit Norwich from marketing those products until at least June 29, 2028, assuming Teva launches its rifaximin product in January 2028.

Today, the District Court denied Norwich's motion and granted summary judgment in favor of the FDA, Salix, and Teva, and closed the case.

"We are pleased with the ruling issued today by the U.S. District Court. We will persist in advocating for the well-being of patients who have greatly benefited from sustained access to XIFAXAN," said Thomas J. Appio, CEO of Bausch Health.

Management will release first quarter financial results after market close on Wednesday, April 30, 2025, followed by a conference call and live webcast at 5:00 p.m. U.S. EDT to discuss results and provide a business update.

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 Bausch Health

Bausch Health Companies Inc. (NYSE:BHC)(TSX:BHC), is a global, diversified pharmaceutical company enriching lives through our relentless drive to deliver better health care outcomes. We develop, manufacture and market a range of products primarily in gastroenterology, hepatology, neurology, dermatology, dentistry, aesthetics, international pharmaceuticals and eye health, through our controlling interest in Bausch + Lomb Corporation. Our ambition is to be a globally integrated healthcare company, trusted and valued by patients, HCPs, employees and investors. For more information about Bausch Health, visit

www.bauschhealth.com
and connect with us on
LinkedIn
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Forward-Looking Statements

This news release may contain forward-looking statements within the meaning of applicable securities laws, including the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements may generally be identified by the use of the words "will," "anticipates," "hopes," "expects," "intends," "plans," "should," "could," "would," "may," "believes," "subject to" and variations or similar expressions. These statements are neither historical facts nor assurances of future performance, 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. 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 and quarterly reports 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. 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. The Company undertakes no obligation to update any of these forward-looking statements to reflect events, information or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

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