BAUSCH Health

Bausch Health Announces Positive Topline Results From Global Phase 2 Study Evaluating Amiselimod (an S1P antagonist) to Treat Ulcerative Colitis

December 21, 2023

Trial Meets Both Primary and Key Secondary Endpoints

LAVAL, Quebec, December 21, 2023 – Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health" or the "Company") today announced positive topline results from the Company's Phase 2 study evaluating Amiselimod, an investigative S1P antagonist, for the treatment of ulcerative colitis (UC).

"We are thrilled with these impressive topline results, and believe that this could offer a much needed improvement in therapy available for patients with ulcerative colitis," said Thomas J. Appio, Chief Executive Officer, Bausch Health.

Amiselimod met the primary and key secondary endpoints including clinical and endoscopic measures in the double-blind period of the study; the open-label extension up to 52 weeks is currently ongoing. Efficacy results were similar for both dose groups (0.2 mg QD and 0.4 mg QD).

The topline results for the key endpoints were as follows:

- The primary endpoint, mean change in modified Mayo Score at Day 85 (-2.3) versus placebo (-1.6), ($p = 0.002$).
- 32.4% of patients on Amiselimod achieved clinical remission, compared to 17.8% on placebo, ($p=0.007$)
- 42.7% of patients on Amiselimod achieved endoscopic improvement (Mayo endoscopy subscore of ≤ 1), compared to 23.4% on placebo, ($p<0.001$).

Amiselimod was well-tolerated, with no unexpected adverse events; coupled with the previous thorough QT study, this indicates that Amiselimod has a favorable safety profile. The full data set from this trial will be available early next year.

Bausch Health's Phase 2 clinical trial was a 12-week, double-blind, placebo-controlled, randomized, dose ranging study to evaluate the efficacy and safety of Amiselimod in 320 patients with mildly-to- moderately active UC.

"Our R&D team will be presenting detailed results at upcoming medical conferences, and we plan to meet with regulatory agencies to advance the program into Phase 3," said Dr. Tage Ramakrishna, Chief Medical Officer, President, R&D, Bausch Health.

About Amiselimod

Amiselimod is a sphingosine-1-phosphate (S1P) receptor functional antagonist and, by inhibiting the receptor function of the lymphocyte sphingosine-1-phosphate (S1P) receptor, retains

lymphocytes sequestered in the lymph nodes and prevents them from contributing to autoimmune reactions.[1] Due to this mechanism of action, Amiselimod may potentially be useful for various autoimmune diseases.[2] Affinity to S1P1, S1P4 and S1P5 receptor subtypes, suggests that Amiselimod could potentially have a more pronounced effect on ulcerative colitis related inflammation than compounds with restricted activity on S1P1 receptor subtype exclusively or combined activity on S1P1 and S1P5. [3]

About Bausch Health

Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global diversified pharmaceutical company whose mission is to improve people's lives with our healthcare products. We develop, manufacture and market a range of products primarily in gastroenterology, hepatology, neurology, dermatology, international pharmaceuticals and eye health, through our controlling ownership interest in Bausch + Lomb Corporation. With our leading durable brands, we are delivering on our commitments as we build an innovative company dedicated to advancing global health. For more information, visit
www.bauschhealth.com
and connect with us on
Twitter (X)
and
LinkedIn.

Forward-looking Statements

This news release contains forward-looking information and statements, within the meaning of applicable securities laws (collectively, "forward-looking statements"), including, but not limited to, statements relating to the Company's ongoing research and development efforts. Forward-looking statements may generally be identified by the use of the words "anticipates," "hopes," "expects," "intends," "plans," "should," "could," "would," "may," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions, and phrases or statements that certain actions, events or results may, could, should or will be achieved, received or taken, or will occur or result, and similar such expressions also identify forward-looking information. These forward-looking 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 these 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 and quarterly reports and detailed from time to time in the Company's other filings with the U.S. Securities and Exchange Commission and the Canadian Securities Administrators, which risks and uncertainties are incorporated herein by reference. Additional information regarding certain of these material factors and assumptions may be found in the Company's filings described above. The Company believes that the material factors and assumptions reflected in these forward-looking statements are reasonable in the circumstances, 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. The Company 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.

REFERENCES

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

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