Bausch Health Initiates Second Phase 3 Study For NOV03 Investigational Treatment For Dry Eye Disease Associated With Meibomian Gland Dysfunction

November 24, 2020

LAVAL, Quebec, Nov. 24, 2020 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health" or the "Company") and Bausch + Lomb, its leading global eye health business, announced today that the Company has initiated the second of two Phase 3 studies evaluating the investigational treatment NOV03 (perfluorohexyloctane) as a first-in-class investigational drug with a novel mechanism of action to treat the signs and symptoms of Dry Eye Disease (DED) associated with Meibomian gland dysfunction (MGD). Enrollment of the first Phase 3 study is currently underway and has reached 85% of its enrollment goal.

NOV03 is an investigational, proprietary, water-free and preservative-free solution, based on patented EyeSol® technology from Novaliq GmbH[1]. DED is a chronic and serious disease of the ocular surface[2]. In a Phase 2 study of 336 patients, NOV03 met its primary efficacy endpoint of statistically significant improvement of total corneal fluorescein staining over control at eight weeks. In addition, NOV03 showed statistically significant improvement of certain symptoms, such as severity and frequency of dryness and burning/stinging of the eyes, over the entire duration of the Phase 2 study with no notable safety events.

"Bausch + Lomb, our global eye health business, is focused on researching and bringing forward new options for unmet medical needs, including Dry Eye Disease associated with MGD. It's estimated that more than 16 million Americans suffer from Dry Eye Disease[3], and if approved, NOV03 may be the first pharmaceutical therapy available for U.S. patients who have Dry Eye Disease associated with MGD," said Joseph C. Papa, chairman and CEO of Bausch Health.

About Bausch + Lomb
Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc., is solely focused on helping people see. Its core businesses include over-the-counter products, dietary supplements, eye care products, ophthalmic pharmaceuticals, contact lenses, lens care products, ophthalmic surgical devices and instruments. Bausch + Lomb develops, manufactures and markets one of the most comprehensive product portfolios in the industry, which is available in approximately more than 100 countries. For more information, visit www.bausch.com
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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 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.

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[1] In December 2019, Bausch Health acquired the rights from Novaliq GmbH to pursue development and commercialization of NOV03 for DED and combination products based on NOV03 in additional ophthalmic indications in the United States and Canada.

[2] Lemp et al. Distribution of Aqueous-Deficient and Evaporative Dry Eye in a Clinic-Based Patient Cohort: A Retrospective Study. Cornea. 2012;31:472–478.

[3] Farrand et al. Prevalence of Diagnosed Dry Eye Disease in the United States Among Adults Aged 18 Years and Older. Am J Ophthalmol 2017; 182:90–98.

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