Bausch + Lomb Completes Enrollment Of Second Phase 3 Study For NOV03 (perfluorohexyloctane)

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LAVAL, QC and HEIDELBERG, Germany, July 7, 2021 /PRNewswire/ -- Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health" or the "Company"), and Novaliq GmbH, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics, today announced the second of two Phase 3 (MOJAVE) studies evaluating the investigational drug NOV03 (perfluorohexyloctane) as a first-in-class eye drop with a novel mechanism of action to treat the signs and symptoms of dry eye disease (DED) associated with meibomian gland dysfunction (MGD), has been completely enrolled with a total of 622 participants.

Dry eye disease, one of the most common ocular surface disorders, causes discomfort for millions of Americans, and MGD plays a key role in the development of this disease.[1,2]

"With its novel mechanism of action, NOV03, if approved, may be a first-in-class treatment option to specifically treat the symptoms of dry eye disease associated with MGD," said Joseph C. Papa, chairman and CEO, Bausch Health. "We hope to submit a New Drug Application for NOV03 to the U.S. Food and Drug Administration in 2022."

The Phase 3 program for NOV03 also includes a previous Phase 3, multi-center, randomized, double-masked, saline-controlled trial (GOBI), for which the companies announced statistically significant topline results in April 2021, and an ongoing multi-center, open-label, single-arm 12-month safety extension trial (KALAHARI).

"We are very pleased with the progress of the Phase 3 program for NOV03. We are hopeful the results of the MOJAVE study will be consistent with the results of the GOBI trial and reconfirm all efficacy and safety results from the earlier phases of the development program for NOV03," said Christian Roesky, Ph.D., CEO, Novaliq.

About NOV03 (perfluorohexyloctane) Ophthalmic Solution
NOV03 is an investigational, proprietary, water-free and preservative-free solution, based on patented EyeSol® technology from Novaliq GmbH.[3] In 2019, Bausch Health and Bausch + Lomb acquired an exclusive license for the commercialization and development of NOV03 in the United States and Canada. In addition to the Phase 3 program, in January 2021, the companies

announced the results from a Phase 2 clinical study (SEECASE) evaluating NOV03 were published in
Cornea: The Journal of Cornea and External Disease
.[4]

About Novaliq
Novaliq is a biopharmaceutical company focusing on the development and commercialization of first- and best-in-class ocular therapeutics based on EyeSol®, the worldwide first water-free technology. Novaliq offers an industry-leading portfolio addressing today's unmet medical needs of millions of patients with eye diseases. Novaliq GmbH is headquartered in Heidelberg, Germany and Novaliq Inc. has an office in Cambridge, MA, USA. The long-term shareholder is dievini Hopp BioTech holding GmbH & Co. KG, an active investor in Life and Health Sciences companies. More on
www.novaliq.com
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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 100 countries. More information can be found at
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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. For more information, visit
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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," "hopes," "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 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.

References

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- Sun M, Moreno IY, Dang M, Coulson-Thomas VJ. Meibomian Gland Dysfunction: What Have Animal Models Taught Us? Int J Mol Sci. 2020 Nov 21;21(22):8822. doi: 10.3390/ijms21228822. PMID: 33233466; PMCID: PMC7700490. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7700490/ . Accessed 4/8/21
- 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.
- Tauber J, Wirta DL, Sall K, Majmudar PA, Willen D, Krösser S; SEECASE study group. A Randomized Clinical Study (SEECASE) to Assess Efficacy, Safety, and Tolerability of NOV03 for Treatment of Dry Eye Disease. Cornea. 2020 Dec 22; Publish Ahead of Print.

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