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Bausch + Lomb and Novaliq Announce U.S. FDA Filing Acceptance for Investigational Treatment NOV03 (Perfluorohexyloctane)

PDUFA Action Date is June 28, 2023

VAUGHAN, Ontario, and HEIDELBERG, Germany, Sept. 6, 2022 – Bausch + Lomb Corporation (NYSE/TSX: BLCO) (“Bausch + Lomb”), a leading global eye health company dedicated to helping people see better to live better, and Novaliq GmbH, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) filing for investigational treatment NOV03 (perfluorohexyloctane). A potential first-in-class eye drop with a novel mechanism of action, NOV03 is an investigational therapy to treat the signs and symptoms of dry eye disease (DED) associated with Meibomian gland dysfunction (MGD). NOV03 has been assigned a Prescription Drug User Fee Act (PDUFA) action date of June 28, 2023.

“With the FDA commencing review of the NDA filing, we are one step closer to bringing an important new treatment option to the millions of Americans affected by dry eye disease associated with Meibomian gland dysfunction,” said Joseph C. Papa, CEO, Bausch + Lomb. “NOV03 is distinct from anti-inflammatory and immunomodulatory agents, and, if approved, would be the first prescription eye drop to address excessive tear evaporation. The approval would also mark a significant milestone for Bausch + Lomb, as the company’s first FDA approval for a prescription medicine since becoming a publicly traded company earlier this year.”

DED is one of the most common ocular surface disorders, with MGD as a major cause of development and progression, affecting approximately nine out of 10 people with DED.^{1,2} DED due to MGD is caused by a deficient tear film lipid layer that leads to increased tear evaporation.³ There is currently no approved prescription eye drop in the United States for DED associated with MGD.

“We are thrilled the FDA has accepted our NDA filing for NOV03,” said Christian Roesky, Ph.D., CEO, Novaliq. “With only limited treatment options currently available, NOV03 is a promising potential new therapy, specifically designed to alleviate the signs and symptoms of dry eye disease associated with Meibomian gland dysfunction.”

The clinical development program for NOV03 includes two Phase 3 studies (GOBI and MOJAVE), both of which demonstrated statistically significant improvement vs. control for both primary and key secondary sign and symptom endpoints as early as day 15 and through day 57. NOV03 was well tolerated in both studies.

About NOV03 (perfluorohexyloctane) Ophthalmic Solution

NOV03 (perfluorohexyloctane) is an investigational, proprietary, water-free, non-steroidal, single-component preservative-free eye drop.⁴ In 2019, Bausch + Lomb acquired an exclusive license for the commercialization and development of NOV03 in the United States and Canada. Data from the first pivotal Phase 3 trial (GOBI) were presented at the American Society of Cataract and Refractive Surgery (ASCRS) annual meeting in Washington, D.C. on April 24, 2022. Data from the second pivotal Phase 3 trial (MOJAVE) were presented at the Association for Research in Vision and Ophthalmology (ARVO) annual meeting in Denver on May 2, 2022. Results from the pivotal Phase 2 trial (SEECASE) were published in *Cornea* in September 2021.⁵ The clinical program for NOV03 concluded with the completion of a multi-center, open-label, single-arm, 12-month safety extension trial (KALAHARI).

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.

About Bausch + Lomb

Bausch + Lomb is dedicated to protecting and enhancing the gift of sight for millions of people around the world – from the moment of birth through every phase of life. Its comprehensive portfolio of more than 400 products includes contact lenses, lens care products, eye care products, ophthalmic pharmaceuticals, over-the-counter products and ophthalmic surgical devices and instruments. Founded in 1853, Bausch + Lomb has a significant global research and development, manufacturing and commercial footprint with more than 12,000 employees and a presence in nearly 100 countries. Bausch + Lomb is headquartered in Vaughan, Ontario with corporate offices in Bridgewater, New Jersey. For more information, visit www.bausch.com and connect with us on [Twitter](#), [LinkedIn](#), [Facebook](#) and [Instagram](#).

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 + Lomb’s 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 + Lomb, including but not limited to its project development timelines, launches 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 + Lomb 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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2. Lemp, M. A., Crews, L. A., Bron, A. J., Foulks, G. N., & Sullivan, B. D. (2012). Distribution of aqueous-deficient and evaporative dry eye in a clinic-based patient cohort: a retrospective study. *Cornea*, 31(5), 472–478. <https://doi.org/10.1097/ICO.0b013e318225415a>
3. Geerling G, Baudouin C, Aragona P, et al. (2017). Emerging strategies for the diagnosis and treatment of meibomian gland dysfunction: Proceedings of the OCEAN group meeting. *The Ocular Surface*, 15(2): 179-192. <https://doi.org/10.1016/j.jtos.2017.01.006>
4. In December 2019, Bausch + Lomb 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.
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