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Bausch + Lomb Presents Data from First Pivotal Phase 3 Trial of Investigational Treatment NOV03 (Perfluorohexyloctane) at the American Society of Cataract and Refractive Surgery Annual Meeting

April 25, 2022

NOV03 Met Both Primary Endpoints for Signs and Symptoms of Dry Eye Disease

VAUGHAN, ON and LAVAL, QC and HEIDELBERG, Germany, April 25, 2022 /PRNewswire/ -- Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health"), and Novaliq GmbH, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics, today announced that data from the first pivotal Phase 3 trial (GOBI) of NOV03 (perfluorohexyloctane), which is being investigated 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), was presented yesterday as part of a podium presentation on April 24, 2022, at the American Society of Cataract and Refractive Surgery (ASCRS) annual meeting in Washington, D.C.

"The data show that NOV03 met both primary endpoints of total Corneal Fluorescein Staining, a measure that assesses damage to the eye, and visual analogue scale dryness score at day 57," said Joseph Tauber, M.D., founder of Tauber Eye Center in Kansas City, Mo., and leading NOV03 trial investigator. "The fact that NOV03 met both primary endpoints in a single study, which is a rare event in clinical trials in dry eye disease, reinforces its potential as a treatment for addressing both the signs and symptoms of the disease. The unique mechanism of action makes NOV03 an exciting investigational treatment for the signs and symptoms of dry eye."

DED is one of the most common ocular surface disorders, causing discomfort for millions of Americans. MGD is a major cause of the development and progression of evaporative DED, which is caused by a deficient tear film lipid layer that leads to increased tear evaporation.[1,2]

"There is currently no pharmaceutical therapy in the United States approved for the treatment of dry eye disease associated with Meibomian gland dysfunction, and these data support NOV03 as a potential first-in-class option for the treatment of dry eye disease associated with Meibomian gland dysfunction," said Joseph C. Papa, chairman and CEO, Bausch Health. "We intend to submit for approval during the second quarter of 2022."

The data from the Phase 3, multicenter, randomized, hypotonic saline-controlled, double masked GOBI study was based on results from 597 participants ages 18 years and older who were randomized to either receive treatment with NOV03 four times daily or hyptonic saline solution four times daily (n=303 NOV03; n=294 saline). The key points of the study include:

- On day 57, change from baseline in total Corneal Fluorescein Staining (tCFS) was statistically significant in the NOV03 arm compared to the control saline group (-2.0 [2.6] vs. -1.0 [2.7]) (P<0.001) (primary endpoint).
- Additionally on day 57, eye dryness VAS score was statistically significantly improved in the NOV03 arm compared to control group (-27.4 [27.9] vs. -19.7 [26.6]) (P<0.001) (primary endpoint).

- tCFS and eye dryness VAS score was also statistically significant at day 15 (secondary endpoint).

In the study, NOV03 was well tolerated with few subjects experiencing ocular adverse events (AE) (8.3% NOV03 group, 5.1% control group). Blurred vision, mostly mild and transient, was the only AE that occurred in a higher proportion of subjects treated with NOV03 versus control (3.0% vs 0.3%).

"With its novel mode of action, NOV03 is specifically designed to alleviate the signs and symptoms of dry eye disease associated with Meibomian gland dysfunction, and if approved, has the potential to address an unmet medical need," said Christian Roesky, Ph.D., CEO, Novaliq. "We look forward to our continued collaboration with Bausch Health and Bausch + Lomb as we work together to potentially bring this novel treatment option to patients in the United States."

About NOV03 (perfluorohexyloctane) Ophthalmic Solution

NOV03 is an investigational, proprietary, water-free, single-component preservative-free eye drop.[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 GOBI trial,
positive topline data
was announced from the second Phase 3 study (MOJAVE) in September 2021. Additional data from MOJAVE will be shared later this year during a future medical congress and scientific publication.

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
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About Bausch + Lomb

Bausch + Lomb, a leading global eye health business of Bausch Health Companies, Inc., 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
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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, 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 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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- 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.

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