BAUSCH Health

Bausch + Lomb Presents Data from Second Pivotal Phase 3 Trial of Investigational Treatment NOV03 (Perfluorohexyloctane) at the Association for Research in Vision and Ophthalmology Annual Meeting

May 03, 2022

NOV03 Met Primary Endpoints for Signs and Symptoms of Dry Eye Disease Associated with Meibomian Gland Dysfunction in Both Phase 3 Trials

VAUGHAN, ON and LAVAL, QC and HEIDELBERG, Germany, May 3, 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 second pivotal Phase 3 trial (MOJAVE) of investigational treatment NOV03 (perfluorohexyloctane) were presented virtually yesterday at the Association for Research in Vision and Ophthalmology (ARVO) annual meeting. NOV03 is being investigated as a first-in-class treatment with a novel mechanism of action to treat the signs and symptoms of dry eye disease (DED) associated with Meibomian gland dysfunction (MGD).

"The findings show that NOV03 met both efficacy endpoints, which reinforces the results from the first pivotal Phase 3 clinical trial and builds upon the growing body of evidence in support of NOV03 as a potential first-in-class treatment for dry eye disease associated with Meibomian gland dysfunction," said Joseph C. Papa, chairman and CEO, Bausch Health. "If approved, NOV03 would be the first pharmaceutical therapy available in the United States with a novel mechanism of action designed to alleviate both signs and symptoms for those suffering with dry eye disease associated with Meibomian gland dysfunction."

DED is one of the most common ocular surface disorders, causing discomfort for approximately 18 million Americans.[1,2] 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.[3] In one trial, it was found that approximately 86% of patients with DED had MGD involvement.[4]

The data presented from the second Phase 3, multicenter, randomized, hypotonic saline-controlled, double masked trial show NOV03 met both primary efficacy endpoints: total Corneal Fluorescein Staining (tCFS), a measure of assessing damage to the eye, and VAS eye dryness endpoints at day 57.

"We are excited to see consistent data on multiple fronts across both Phase 3 studies of NOV03. In addition to meeting each of the primary sign and symptom efficacy endpoints, NOV03 continues to appear to be well tolerated in this population," said John Sheppard, M.D., professor of Ophthalmology, Eastern Virginia Medical School, Norfolk, Va., EyeCare Partners Mid-Atlantic Medical Director and NOV03 trial investigator. "Treatment options for dry eye disease associated with Meibomian gland dysfunction in the United States are currently limited to mechanical

methods, such as medical devices, warm compresses, lid scrubs and massage. If approved, NOV03 would offer eye care professionals a promising new therapeutic pharmaceutical approach for these patients."[5]

The data was based on results from 620 participants ages 18 years and older who were randomized to either receive treatment with NOV03 four times daily or hypotonic saline solution four times daily (n=311 NOV03; n=309 saline). Key points from the trial 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 (-2.3 [2.8] vs. -1.1 [2.9]) (P<0.001) (primary endpoint).
- Additionally on day 57, VAS eye dryness score was statistically significantly improved in the NOV03 arm compared to control group (-29.5 [28.6] vs. -19.0 [27.2]) (P<0.001) (primary endpoint).
- tCFS and VAS eye dryness score were also statistically significant at day 15 (secondary endpoints).

In the trial, NOV03 was well tolerated with few subjects experiencing ocular adverse events (AE) in the study eye (9.6% NOV03 group, 9.7% control group). Blepharitis, mostly mild, was the only AE that occurred in a >1% higher proportion of subjects treated with NOV03 versus control (1.6% vs 0.3%).

"These results reaffirm the safety and efficacy data of NOV03 as a potential treatment option for patients with dry eye disease associated with Meibomian gland dysfunction," said Christian Roesky, Ph.D., CEO, Novaliq. "In collaboration with Bausch Health and Bausch + Lomb, we look forward to submitting NOV03 for FDA approval during the second quarter of 2022 with the potential to bring a novel drug option for this condition to the United States."

About NOV03 (perfluorohexyloctane) Ophthalmic Solution
NOV03 is an investigational, proprietary, water-free, single-component preservative-free eye drop.[6] 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 data from the MOJAVE trial, data from the first pivotal Phase 3 trial (GOBI) was presented at the American Society of Cataract and Refractive Surgery (ASCRS) annual meeting in Washington, D.C. on April 24, 2022. Results from the pivotal Phase 2 trial (SEECASE) was published in *Cornea: The Journal of Cornea and External Disease* in September 2021.[7] The clinical development program for NOV03 is expected to conclude with an ongoing 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, 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
www.bausch.com
and connect with us on
Twitter
,
LinkedIn
,
Facebook
and
Instagram
.

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
www.bauschhealth.com
and connect with us on
Twitter
and
LinkedIn
.

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.

References

- Leonardi, A., Modugno, R. L., & Salami, E. (2021). Allergy and Dry Eye Disease. *Ocular immunology and inflammation*, *29*(6), 1168–1176. https://doi.org/10.1080/09273948.2020.1841804

.
- 2020 Dry Eye Products Market Report: A global Analysis for 2019 to 2025. Market Scope. Retrieved from https://www.market-scope.com/pages/reports/250/2020-ophthalmic-landscape-report-global-analysis-for-2019-to-2025-april-2021#reports
.
- Findlay, Q., & Reid, K. (2018). Dry eye disease: when to treat and when to refer. *Australian prescriber*, *41*(5), 160–163. https://doi.org/10.18773/austprescr.2018.048
.
- 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. doi.org/10.1097/ICO.0b013e318225415a
.
- Meibomian Gland Dysfunction and Treatment. American Association for Pediatric Opthalmology and Strabismus. Retrieved from https://aapos.org/glossary/meibomian-gland-dysfunction-and-treatment. Accessed 4/21/22
.
- 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. 2021; 40(9):1132-1140.

Novaliq Media Contact:	**Bausch Health Investor Contact:**
Simone Angstmann-Mehr	Arthur Shannon
info@novaliq.com	arthur.shannon@bauschhealth.com
	(514) 856-3855
	(877) 281-6642 (toll free)

	Bausch Health Media Contact:
	Lainie Keller
	lainie.keller@bauschhealth.com

View original content to download multimedia: https://www.prnewswire.com/news-releases/bausch--lomb-presents-data-from-second-pivotal-phase-3-trial-of-investigational-treatment-nov03-perfluorohexyloctane-at-the-association-for-research-in-vision-and-ophthalmology-annual-meeting-301537751.html

SOURCE Bausch Health Companies Inc.

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

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