BAUSCH Health

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

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Phase 2 Study Published in Cornea: The Journal of Cornea and External Disease; Study Met Primary Endpoint in Patients with Highly Symptomatic Evaporative Dry Eye Disease Associated with Meibomian Gland Dysfunction

LAVAL, QC and HEIDELBERG, Germany, Jan. 19, 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 pharmaceutical company focusing on first- and best-in-class ocular therapeutics, today announced the first of two Phase 3 studies evaluating NOV03 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) has been completely enrolled with a total of 599 participants.

Additionally, a Phase 2 clinical study (SEECASE) evaluating the efficacy, safety, and tolerability of NOV03 (perfluorohexyloctane) ophthalmic solution in patients with DED associated with MGD has been published in *Cornea: The Journal of Cornea and External Disease*. In the study, NOV03 met its primary efficacy endpoint of statistically significant improvement of total corneal fluorescein staining over control at eight weeks. NOV03 also 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.[1]

"We are committed to addressing the unmet needs of patients, and believe NOV03, if approved, may be a first-in-class treatment option for the millions of patients who suffer from Dry eye disease associated with Meibomian gland dysfunction," said Joseph C. Papa, chairman and CEO, Bausch Health. "This continued progress in our Phase 3 program and the published results of the SEECASE study are both exciting milestones in our development journey for NOV03."

"Dry eye disease is one of the most common ocular surface disorders causing discomfort for millions of Americans," said Joseph Tauber, M.D., founder of Tauber Eye Center in Kansas City, Mo., and lead author of the publication. "Given the key role Meibomian gland dysfunction plays in the pathogenesis of this disease, we are very encouraged by the findings in the SEECASE study, which demonstrate the potential for NOV03 as a possible treatment for those with highly symptomatic DED associated with MGD, and look forward to the results of the Phase 3 studies."

Summary of Phase 2 SEECASE Study Results

The prospective, multicenter, randomized, double-masked, saline-controlled clinical study evaluated NOV03 at two dosing regimens. The data published was based on results from 336 patients age 18 years or older who were randomized to one of four treatment groups: NOV03 four times daily (QID), NOV03 twice daily (BID), saline BID or saline QID (a 2:2:1:1 ratio). The study met its primary efficacy endpoint of statistically significant improvement of total corneal fluorescein staining (tCFS) over control at eight weeks. Data showed a change from baseline of tCFS over control, for both dosing regimens (QID and BID, $P < 0.001$ and $P = 0.009$, respectively). Effects on tCFS and symptoms started at two weeks after start of treatment and

were maintained over the study duration. The effects were dosing schedule dependent. NOV03 was well tolerated with instillation site reactions below 3% in both treatment regimens.[1]

The SEECASE study was conducted at 12 ophthalmology practices in the United States with patients who had a history of DED in both eyes and if one eye (the same eye) met the inclusion criteria at screening and at randomization time. Several symptom assessments such as Eye Dryness Score measured using visual analog scale (VAS), VAS for other symptoms such as burning/stinging, itching, blurred vision, and sensitivity to light, and Ocular Surface Disease Index (OSDI) were evaluated to assess the effect of NOV03 on DED symptomatology.[1]

Patients treated with NOV03 also experienced statistically significant improvement of certain DED symptoms over the entire duration of the Phase 2 study. Changes from baseline were statistically significant compared with those of the control group at week eight [$P < 0.001$ (QID) and $P = 0.002$ (BID)]. Other symptoms evaluated included burning/stinging, sticky feeling, foreign body sensation, itching, blurred vision, sensitivity to light and pain. The following treatment emergent adverse events (TEAEs) reported by more than 2% of subjects were blurred vision in the NOV03 QID group, eye irritation in the NOV03 BID group and eye pain in the saline group. Overall the number of patients reporting at least one TEAE was similar between the treatment groups.[1]

"The results demonstrated in the SEECASE study support NOV03 as a potential new treatment option for patients with DED associated with MGD, and we look forward to learning the results from both of the Phase 3 studies," said Christian Roesky, Ph.D., CEO, Novaliq GmbH.

About NOV03 (perfluorohexyloctane) Ophthalmic Solution
NOV03 is an investigational, proprietary, water-free and preservative-free solution, based on patented EyeSol® technology from Novaliq GmbH.[2] In 2019, Bausch Health and Bausch + Lomb acquired an exclusive license for the commercialization and development of NOV03 in the United States and Canada, and together, they announced in November 2020 that they have initiated the second of two Phase 3 studies to evaluate NOV03.

About Novaliq
Novaliq is a pharmaceutical 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 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. 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. More information can be found at
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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 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

1. 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.
2. 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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