BAUSCH Health

Bausch Health Licenses Novaliq's NOV03 Investigational Treatment For Dry Eye Disease Associated With Meibomian Gland Dysfunction

December 20, 2019

LAVAL, Quebec and HEIDELBERG, Germany, Dec. 20, 2019 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health") and Bausch + Lomb, its leading global eye health business, and Novaliq GmbH, a pharmaceutical company focusing on first- and best-inclass ocular therapeutics, announced today that Bausch Health has acquired an exclusive license for the commercialization and development in the United States and Canada of the investigational treatment NOV03 (perfluorohexyloctane), a first-in-class investigational drug with a novel mechanism of action to treat Dry Eye Disease (DED) associated with Meibomian gland dysfunction (MGD).

NOV03 is a proprietary water-free, preservative-free solution based on Novaliq's patented EyeSol® technology. DED is a chronic and serious disease of the ocular surface that can negatively impact quality of life¹. In a Phase 2 study, NOV03 met its primary sign endpoint of improvement of total corneal fluorescein staining over control at eight weeks with high statistical significance (p<0.001). In addition, NOV03 showed statistically significant and clinically meaningful improvement in a variety of symptoms over the entire duration of the trial. A Phase 3 study is underway for NOV03, and Bausch Health anticipates starting an additional Phase 3 study in 2020.

"Bausch Health remains focused on boosting our core businesses, and the addition of this investigational treatment for Dry Eye Disease will help build upon our strong Bausch + Lomb portfolio of integrated eye health products," said Joseph C. Papa, chairman and CEO of Bausch Health. "It is estimated that more than 16 million patients in the United States are diagnosed with Dry Eye Disease², and if approved, NOV03 will be the first pharmaceutical therapy available for patients in the United States suffering from Dry Eye Disease with Meibomian gland dysfunction."

"We are thrilled to partner with Bausch + Lomb who is a leader in the ophthalmic space with a strong commercial footprint in the United States and is also very committed to developing innovative new eye health products," said Christian Roesky, Ph.D., CEO of Novaliq. "As part of Bausch + Lomb's portfolio, we believe that NOV03 will help address the unmet medical need of millions of patients suffering from Dry Eye Disease."

Under the terms of the licensing agreement, Novaliq is eligible to receive upfront and milestone payments based on regulatory and commercialization milestones, and sales royalties based on annual net sales of NOV03 in the United States and Canada.

Bausch Health has the right 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. Novaliq will be eligible to receive additional undisclosed milestone payments plus royalties for any resulting combination products.

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 eye drop technology. Novaliq offers an industry-leading portfolio addressing today's unmet medical needs of millions of patients with eye diseases. Novaliq is headquartered in Heidelberg, Germany and 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 Bausch Health Companies Inc. company, is a leading global eye health organization that 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 www.bausch.com

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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

www.bauschhealth.com

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Bausch Health's Cautionary Note Regarding 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. Where applicable, these statements are based upon the current expectations and beliefs of Bausch Health 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, risks and uncertainties discussed in the Bausch Health's most recent annual or quarterly report and detailed from time to time in the Bausch Health's other filings with the SEC and the Canadian Securities Administrators, which factors are incorporated herein by reference. In addition, certain material factors and assumptions have been applied in making these forward-looking statements, including that the risks and uncertainties outlined above will not cause actual results or events to differ materially from those described in these forward-looking statements. Bausch Health believes that the material factors and assumptions reflected in these forward-looking statements are reasonable, but 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.

¹ Lemp et al. Distribution of Aqueous-Deficient and Evaporative Dry Eye in a Clinic-Based Patient Cohort: A Retrospective Study. Cornea. 2012;31:472–478..

² Farrand et al. Prevalence of Diagnosed Dry Eye Disease in the United States Among Adults Aged 18 Years and Older. Am J Ophthalmol 2017; 182:90–98.

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