# Bausch Health Licenses Eyenovia's Investigational Treatment For The Reduction Of Pediatric Myopia Progression In Children Ages 3-12

October 12, 2020

LAVAL, QC and NEW YORK, Oct. 12, 2020 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health"), Bausch + Lomb, its leading global eye health business, and Eyenovia, Inc., (NASDAQ: EYEN) ("Eyenovia"), a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP™) therapeutics, today announced that an affiliate of Bausch Health has acquired an exclusive license in the United States and Canada for the development and commercialization of an investigational microdose formulation of atropine ophthalmic solution, which is being investigated for the reduction of pediatric myopia progression, also known as nearsightedness, in children ages 3-12. This investigational formulation of atropine is delivered with Eyenovia's proprietary Optejet® dispenser technology.

Myopia is among the most common ocular disorders worldwide and is a leading cause of visual impairment in children. In the United States, myopia is estimated to affect approximately 25 million children, with up to 3 million considered to be at risk for high myopia. 2,3

"Progressive myopia is a serious eye disease that disproportionately affects children," said Joseph C. Papa, chairman and CEO, Bausch Health. "If approved, this product could potentially change the treatment paradigm for the reduction of myopia progression in children ages 3-12, thus helping to fulfill a significant unmet medical need."

"This agreement with Bausch + Lomb, one of the premier eye health businesses in the world, is a significant milestone for our company and validation of the potential of Eyenovia's proprietary Optejet technology to enable microdosing," said Dr. Sean Ianchulev, CEO and chief medical officer, Eyenovia. "We believe that Bausch + Lomb has the resources and commercialization excellence to advance our technology and make it available to the millions of myopic children in the United States, if approved. Eyenovia continues to develop the Optejet platform for use with other compounds to enable delivery of treatments for other indications."

Under the terms of the licensing agreement, Bausch Health will make an upfront \$10 million payment to Eyenovia upon signing and will assume oversight and costs related to the ongoing Phase 3 CHAPERONE clinical trial. Eyenovia is eligible to receive up to \$35 million in additional payments based on approval- and launch-based milestones, as well as royalties ranging from mid-single digit to mid-teen percentages of gross profit on sales in the United States and Canada.

## **About Atropine Ophthalmic Solution**

Atropine ophthalmic solution is Eyenovia's investigational, potentially first-in-class topical treatment for the reduction of pediatric myopia progression, also known as nearsightedness, in children ages 3-12. It has been developed for comfort and ease-of-use in children, and its microdose administration is designed to potentially result in low systemic and ocular drug exposure.

## **About Eyenovia, Inc.**

Eyenovia, Inc. (NASDAQ: EYEN) is a clinical stage ophthalmic biopharmaceutical company

developing a pipeline of microdose array print (MAP™) therapeutics. Eyenovia's pipeline is currently focused on the late-stage development of microdosed medications for presbyopia, myopia progression and mydriasis. For more information, please visit <a href="https://www.eyenovia.com">www.eyenovia.com</a>

**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 <a href="https://www.bausch.com">www.bausch.com</a>

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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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# **Eyenovia Forward-looking Statements**

Except for historical information, all of the statements, expectations and assumptions contained in this press release are forward-looking statements. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions, including estimated market opportunities for our product candidates and any potential revenue from licensing transactions. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and are likely to, differ materially from what is expressed or forecasted in the forwardlooking statements due to numerous factors discussed from time to time in documents which we file with the U.S. Securities and Exchange Commission. In addition, such statements could be affected by risks and uncertainties related to, among other things, our estimates regarding the potential market opportunity for our product candidates and potential revenue from licensing transactions; reliance on third parties, including Bausch Health to develop and commercialize our product candidates; impacts of and uncertainty related to COVID-19; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our product candidates; risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment (which could still be adversely impacted by COVID-19 and resulting social distancing), timing, progress and results of such trials; the timing and our ability to submit applications for, obtain and maintain regulatory approvals for our product candidates; the potential impacts of COVID-19 on our supply chain; the potential advantages of our product candidates; the rate and degree of market acceptance and clinical utility of our product candidates; fluctuations in our financial results, particularly given market conditions and the potential economic impact of COVID-19; our need to raise additional money to fund our operations for at least the next 12 months as a going concern; intellectual property risks; our ability to attract and retain key personnel; changes in legal, regulatory and legislative environments in the markets in which we operate and the impact of these changes on

our ability to obtain regulatory approval for our products; and our competitive position. Any forward-looking statements speak only as of the date on which they are made, and except as may be required under applicable securities laws, Eyenovia does not undertake any obligation to update any forward-looking statements.

# **Bausch Health 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.

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<sup>&</sup>lt;sup>1</sup> Mehta N, Wen A. Myopia: A Global Epidemic. Retina Today. September 2019.

<sup>&</sup>lt;sup>2</sup> Theophanous C. Myopia Prevalence and Risk Factors in Children. Clinical Ophthalmology. December 2018.

<sup>&</sup>lt;sup>3</sup> U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplement, 2019.

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