BAUSCH + Health

FDA Approves Bausch + Lomb Alaway® Preservative Free (Ketotifen Fumarate) Ophthalmic Solution, 0.035%

September 25, 2020

LAVAL, QC and DEER PARK, Ill., Sept. 25, 2020 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health"), Bausch + Lomb, a leading global eye health business, and Eton Pharmaceuticals, Inc. (NASDAQ: ETON) today announced that the U.S. Food and Drug Administration (FDA) has approved Alaway® Preservative Free (ketotifen fumarate) ophthalmic solution, 0.035%, antihistamine eye drops (EM-100), as the first over-the-counter (OTC) preservative-free formulation eye drop approved to temporarily relieve itchy eyes due to pollen, ragweed, grass, animal hair and dander, which is one of the eye symptoms that affects approximately 80 percent of people with allergies.[1] Preservatives commonly used in eye drops can cause allergic reactions in some people that can lead to redness, irritation, itching or tearing.[2],[3]



"We're excited to add Alaway Preservative Free – the first and only OTC preservative-free formulation eye drop of its kind – to our existing Bausch + Lomb Consumer Health Care portfolio. Alaway Preservative Free can provide up to 12 hours of relief for people suffering from itchy eyes due to certain eye allergies," said Joe Gordon, U.S. president, Bausch + Lomb. "We expect Alaway Preservative Free will be available for purchase in the Spring of 2021 at major retailers in time for the start of allergy season."

Alaway® Preservative Free is indicated for the temporary relief of itchy eyes due to pollen, ragweed, grass, animal hair and dander in adults and children 3 years of age and older. It is

formulated to relieve eye itch within minutes and can provide up to 12 hours of eye itch relief with one dose.

"We are pleased the FDA has approved Alaway Preservative Free, and we look forward to collaborating with Bausch + Lomb to bring this unique eye drop to patients suffering from itchy eyes associated with eye allergies," said Sean Brynjelsen, CEO, Eton Pharmaceuticals.

An affiliate of Bausch Health acquired the U.S. rights to Alaway Preservative Free from Eton in 2019.

About Eton Pharmaceuticals
Eton Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing, acquiring, and commercializing innovative products. Eton is primarily focused on hospital injectable and pediatric rare disease products. The company's first commercial product, Biorphen, is the only FDA approved ready-to-use formulation of phenylephrine injection and was launched in December 2019. The company's lead pediatric product is the orphan drug Alkindi® Sprinkle, which is currently under review with the FDA. For more information, visit www.etonpharma.com
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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 better. 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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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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[1] The 2018 U.S. Study of Allergies, Multi-sponsor Surveys, Inc. February 2018.
[2] Baudouin C. The Ocular Surface in Glaucoma, Cornea, Volume 28, Number 9, Suppl. 1, October 2009.
[3] Baudouin C. Allergic reaction to topical eye drops. Curr Opin Allergy Clin Immunol. 2005;5:459–63.

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