BAUSCH Health

Bausch Health Announces Investigational In Vitro Data Indicating Complete Inactivation Of SARS-CoV-2 With LUMIFY® And BESIVANCE® Eye Drops Preserved With Benzalkonium Chloride

November 16, 2020

LAVAL, Quebec, Nov. 16, 2020 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health") and Bausch + Lomb, its leading global eye health business, today announced the results of new investigational *in vitro* data showing that two benzalkonium chloride (BAK) preserved eye drops, LUMIFY® (brimonidine tartrate ophthalmic solution 0.025%) redness reliever eye drops and BESIVANCE® (besifloxacin ophthalmic suspension) 0.6%, indicated complete inactivation of Severe Acute Respiratory Syndrome-related Coronavirus 2 (SARS-CoV-2 or COVID-19). These data were presented at the 2020 Ocular Microbiology and Immunology Group 54th Annual Meeting that took place virtually on Friday, Nov. 13, 2020.

"Our team presented investigational data that evaluated the *in vitro* antiviral activity of LUMIFY and BESIVANCE against SARS-CoV-2, and the results indicated complete inactivation of the virus," said Joseph C. Papa, chairman and CEO, Bausch Health. "The clinical relevance of this *in vitro* data is not known, and our intention is to further review these data to determine next steps, including potential discussions with regulatory agencies around the world."

In the study, researchers evaluated the *in vitro* antiviral activity of LUMIFY and BESIVANCE against SARS-CoV-2 using a Vero E-6 host-cell system. Both LUMIFY and BESIVANCE contain 0.01% BAK, a quaternary ammonium compound commonly used as a preservative in ophthalmic topical solutions. The activity of BAK against SARS-CoV-2 is not well understood.

Time kill testing of SARS-CoV-2 cultures was conducted by multiple dosing of each formulation at contact times representative of those recommended in the Instructions for Use in both products. All tests were conducted in triplicate and in accordance with ASTM E1052-20, suspension time-kill test for virus standard practices. Following the required contact time, test solutions were neutralized, serially diluted and inoculated onto the Vero E6 host-cell system. Test samples were incubated with the Vero E6 host-cells and after 4-9 days, the presence of residual viable virus was scored.

The results indicated complete inactivation of SARS-CoV-2 virus at all contact times. Log_{10} reductions for LUMIFY were ≥1.80, ≥2.14 and ≥2.02 at 8-hour, 24-hour and 72-hour contact times, respectively, and Log_{10} reductions for BESIVANCE were ≥1.95 and ≥2.56 at the 24-hour and 72-hour contact times, respectively. The clinical relevance of these *in vitro* findings is not known.

Neither LUMIFY nor BESIVANCE have been proven to prevent or treat COVID-19 in humans nor have they been approved for those uses by the U.S. Food and Drug Administration (FDA). Consumers and patients should only use these products in accordance with their directions for use and the directions of their doctor.

About LUMIFY (brimonidine tartrate ophthalmic solution 0.025%) Redness Reliever Eye Drops

LUMIFY is the first and only over-the-counter eye drops developed with low dose brimonidine tartrate 0.025% for the relief of redness of the eye due to minor irritations. Unlike other redness relievers, LUMIFY selectively targets redness, with a reduced risk of certain side effects, including rebound redness and loss of efficacy over time, when used as directed. For more information on LUMIFY, visit
www.lumifydrops.com
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Indication and Important Safety Information for BESIVANCE (besifloxacin ophthalmic suspension) 0.6%

Indication

BESIVANCE (besifloxacin ophthalmic suspension) 0.6% is a quinolone antimicrobial indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria: *Aerococcus viridans**, CDC coryneform group G, *Corynebacterium pseudodiphtheriticum**, *Corynebacterium striatum**, *Haemophilus influenzae*, *Moraxella catarrhalis**, *Moraxella lacunata**, *Pseudomonas aeruginosa**, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus hominis**, *Staphylococcus lugdunensis**, *Staphylococcus warneri**, *Streptococcus mitis* group, *Streptococcus oralis*, *Streptococcus pneumoniae*, *Streptococcus salivarius**

*Efficacy for this organism was studied in fewer than 10 infections.

Important Safety Information

- BESIVANCE is not for injection into the eye.
- As with other anti-infectives, prolonged use of BESIVANCE may result in overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, discontinue use and institute alternative therapy.
- Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with BESIVANCE.
- The most common adverse event reported in approximately 2% of patients treated with BESIVANCE was conjunctival redness. Other adverse events reported in patients receiving BESIVANCE occurring in approximately 1-2% of patients included: blurred vision, eye pain, eye irritation, eye pruritus and headache.
- Safety and effectiveness in infants below one year of age have not been established.

Click
here
for full Prescribing Information for BESIVANCE.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit
www.fda.gov/medwatch
or call **1-800-FDA-1088**.

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
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 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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