Bausch Health Initiates VIRAZOLE® (Ribavirin for Inhalation Solution, USP) Clinical Study in Patients with COVID-19

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Bausch Health Is Working with Multiple Health Authorities to Make VIRAZOLE Available as a Potential Treatment for COVID-19

LAVAL, Quebec, April 13, 2020 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health" or the "Company") today announced it has initiated a clinical trial program in Canada evaluating an investigational use of VIRAZOLE® (Ribavirin for Inhalation Solution, USP) in combination with standard of care therapy to treat hospitalized adult patients with respiratory distress due to COVID-19. Because ribavirin is a synthetic nucleoside that works to stop viral replication, VIRAZOLE may be effective in reducing the severity of COVID-19 infection.

VIRAZOLE is currently approved in several countries around the world, including the United States and Canada, for the treatment of hospitalized infants and young children with severe lower respiratory tract infections due to respiratory syncytial virus (RSV).

The initial clinical study has been approved by Health Canada and is expected to begin within the next few weeks. The Company is also in discussions with the U.S. Food and Drug Administration and health authorities in multiple countries regarding additional studies to evaluate VIRAZOLE as a treatment for COVID-19 infection. The Bausch Foundation is also continuing to work directly with health authorities in Italy to make VIRAZOLE for inhalation available free of charge in compassionate use in Italian hospitals.

"VIRAZOLE has demonstrated antiviral activity in treating severe pediatric respiratory infections, and we believe it may be a valuable agent in reducing respiratory distress in adults suffering from COVID-19. We are actively pursuing approval of our trial protocol around the world to test the efficacy and safety of VIRAZOLE in this patient population," said Joseph C. Papa, chairman and CEO, Bausch Health. "Bausch Health will remain focused – for as long as necessary – on doing our part to help end this unprecedented global health pandemic, including donating our health care products, conducting research to find new treatment options and supporting patients, health care providers and our employees."

The initial study protocol is an open label, interventional trial that will evaluate the safety and efficacy of VIRAZOLE in hospitalized adult patients, aged 18 or older, who have tested positive for COVID-19, and as a result of their infection, have significant respiratory distress. Two active study arms will compare different dosing regimens of VIRAZOLE in combination with standard of care therapy. More details on the study can be found on the
Health Canada Clinical Trials Database
and on
Health Canada COVID-19 List of Clinical Trials
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About VIRAZOLE®
VIRAZOLE (ribavirin for inhalation solution, USP) aerosol is indicated only for lower respiratory

tract infection due to RSV. Treatment may be initiated while awaiting rapid diagnostic test results. However, treatment should not be continued without documentation of RSV infection.

VIRAZOLE is not approved by Health Canada for use in COVID-19 patients.

Limited clinical data indicate that VIRAZOLE administered as a small particle aerosol may be beneficial in the treatment of severe respiratory syncytial virus infection in neonates and infants when associated with underlying cardiovascular, pulmonary or immune deficiency. Treatment should be confined to hospitalized patients, and administration should be continuous during the period of therapy apart from the time required for ancillary care of the patient. Only severe RSV lower respiratory tract infection is to be treated with VIRAZOLE aerosol.

VIRAZOLE aerosol treatment must be accompanied by and does not replace standard supportive respiratory and fluid management for infants and children with severe respiratory tract infection.

Use of VIRAZOLE aerosol is contraindicated in women or girls who are or may become pregnant during exposure to the drug. VIRAZOLE may cause fetal harm, and respiratory syncytial virus infection is self-limited in this population. VIRAZOLE is not completely cleared from human blood even four weeks after administration. Although there are no pertinent human data, VIRAZOLE has been found to be teratogenic and/or embryolethal in nearly all species in which it has been tested; however, pregnant baboons given up to 120 mg/kg/day of ribavirin over a 4-day period within the 20 days of organogenesis during gestation failed to exhibit any teratogenic effect.

WARNINGS

Close monitoring of patients and respiratory equipment must be guaranteed when VIRAZOLE is used in infants requiring assisted ventilation. Precipitation of VIRAZOLE powder in respiratory equipment may interfere with safe and effective patient ventilation.

Bronchospasm was observed in a tolerance study with ribavirin aerosol in adults with chronic obstructive pulmonary disease and asthma.

Respiratory function should be carefully monitored during treatment. If initiation of VIRAZOLE aerosol treatment appears to produce sudden deterioration of respiratory function, treatment should be stopped and only reinstituted with caution and continuous monitoring.

Although VIRAZOLE is not indicated in adults, the physician should be aware that it is teratogenic in animals.

VIRAZOLE administered by aerosol produced cardiac lesions in mice and rats after 30 and 36 mg/kg, respectively, for 4 weeks, and after oral administration in monkeys at 120 mg/kg and rats at 154 to 200 mg/kg for 1 to 6 months. VIRAZOLE aerosol administered to developing ferrets at 60 mg/kg for 10 or 30 days resulted in inflammatory and possibly emphysematous changes in the lungs. Proliferative changes were seen at 131 mg/kg for 30 days. The significance of these findings to human administration is unknown.

VIRAZOLE lyophilized in 6 gram vials is intended for use as an aerosol only.

It has been noted that ribavirin has shown some evidence of mutagenesis in some in vitro test systems. Carcinogenicity studies are incomplete and inconclusive. Some evidence for the production of benign tumors has been shown.

PRECAUTIONS

VIRAZOLE has been in use for many years in human beings without any reported adverse effects in human fetuses. However, there are no adequate and well-controlled studies in pregnant women, and there is little published evidence of its safety in the early stages of human

pregnancy. Since VIRAZOLE is delivered in aerosolized form and because of known teratogenic effects in animals, pregnant women should not care for patients receiving VIRAZOLE, although human teratogenic effects have not been proven.

Patients with lower respiratory tract infection due to respiratory syncytial virus require optimum monitoring and attention to respiratory and fluid status.

ADVERSE REACTIONS

The safety data from patients treated with VIRAZOLE aerosol has been carefully evaluated in 26 studies. Bronchospasm was observed in a tolerance study with VIRAZOLE aerosol (20 mg/mL) in adults. One of six adult patients with chronic obstructive pulmonary disease and two of six asthmatic adults became dyspneic during the period of VIRAZOLE aerosol administration. These patients required chronic administration of bronchodilators which were discontinued 24 hours prior to VIRAZOLE treatment. An inhalation of a bronchodilator by puffer produced symptomatic relief and return to baseline conditions.

Several serious adverse events occurred in severely ill infants with life-threatening underlying diseases, many of whom required assisted ventilation. These events include: worsening of respiratory status, bacterial pneumonia and pneumothorax. The role of VIRAZOLE in these events is indeterminate.

There were nineteen deaths during or shortly after treatment with VIRAZOLE aerosol. No death was attributed to ribavirin aerosol by the investigators.

Some subjects requiring assisted ventilation have experienced serious difficulties, which may jeopardize adequate ventilation and gas exchange. Precipitation of drug within the ventilatory apparatus, including the endotracheal tube, has resulted in increased positive end expiratory pressure and increased positive inspiratory pressure. Accumulation of fluid in tubing ("rain out") has also been noted.

Although anemia has not been reported with use of the aerosol, it occurs frequently with oral and intravenous ribavirin, and most infants treated with the aerosol have not been evaluated 1 or 2 weeks post-treatment when anemia is likely to occur. Reticulocytosis has been reported with aerosol use.

Conjunctivitis has been reported in controlled studies with VIRAZOLE aerosol, however, no significant difference was observed between VIRAZOLE treated and control groups.

In Canada, report any SUSPECTED ADVERSE REACTIONS to Bausch Health Companies Inc. at 1-800-321-4576 or Health Canada at 1-866-234-2345 or https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html
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Please click
here
for full Prescribing Information in Canada.

About the Bausch Foundation

The Bausch Foundation was established in 2017 to improve the lives of patients globally by providing access to safe, effective medicines and by financially supporting health care education and causes around the world. Since its inception, the Bausch Foundation has contributed millions of dollars' worth of financial and product donations to global and local charitable health organizations.

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 .

Forward-looking Statements

This news release contains 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 the Company'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 the Company, including but not limited to its supply chain, third party suppliers, project development timelines, and costs (which may increase) and revenue and margins (both of which may decrease). 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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