Salix Pharmaceuticals Announces a Phase 2 Investigator-Initiated Study of RELISTOR® (methylnaltrexone bromide: MNTX) in Patients with Resectable Head and Neck Squamous Cell Carcinoma

March 06, 2024

LAVAL, Quebec, March 6, 2024 –– Bausch Health Companies Inc. (NYSE/TSX: BHC) and its gastroenterology business, Salix Pharmaceuticals, today announced that it is supporting a Phase 2 investigator-initiated study (IIS) of RELISTOR® (methylnaltrexone bromide: MNTX) in patients with resectable head and neck squamous cell carcinoma. An IIS is a study that is proposed, developed, and conducted by a qualified sponsor external to Bausch Health/Salix who assumes full responsibility for the study.

The clinical study is being led by Juan P. Cata, M.D. at The University of Texas MD Anderson Cancer Center. The trial is designed to evaluate the potential of treating oral cavity squamous cell carcinoma patients with MNTX. It is a prospective, nonrandomized pilot "proof of concept" study where patients receive subcutaneous MNTX two weeks preoperatively and two weeks postoperatively.

"The preclinical data and clinical suggestions point to potential activity against cancer," Robert Israel, M.D., Senior Vice President, Clinical and Medical Affairs, said. "Having Dr. Cata study this drug in head and neck cancer will shed light on how and if this agent could be further developed as a potential treatment option in neoplastic disease."

Upon completion of the study, participants will be monitored every 3 months during the first two years. The primary endpoint is the successful administration of MNTX for two weeks preoperatively and postoperatively without interruption due to adverse events. Secondary endpoints include tumor viability, proliferation and apoptosis index, objective response rate, survival rates, and patient-reported outcomes.
https://clinicaltrials.gov/
Identifier: NCT06162377.

About RELISTOR

RELISTOR® (methylnaltrexone bromide) is an opioid antagonist. RELISTOR tablets and RELISTOR injection are indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

RELISTOR injection is also indicated for the treatment of OIC in adults with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care.

IMPORTANT SAFETY INFORMATION

RELISTOR tablets and injection are contraindicated in patients with known or suspected mechanical gastrointestinal obstruction and patients at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation.

Cases of gastrointestinal perforation have been reported in adult patients with opioid-induced constipation and advanced illness with conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the gastrointestinal tract (e.g., peptic ulcer disease, Ogilvie's syndrome, diverticular disease, infiltrative gastrointestinal tract malignancies or peritoneal metastases). Take into account the overall risk-benefit profile when using RELISTOR in patients with these conditions or other conditions which might result in impaired integrity of the gastrointestinal tract wall (e.g., Crohn's disease). Monitor for the development of severe, persistent, or worsening abdominal pain; discontinue RELISTOR in patients who develop this symptom.

If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their health care provider.

Symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, diarrhea, abdominal pain, anxiety, and yawning have occurred in patients treated with RELISTOR. Patients having disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal and/or reduced analgesia and should be monitored for adequacy of analgesia and symptoms of opioid withdrawal.

Avoid concomitant use of RELISTOR with other opioid antagonists because of the potential for additive effects of opioid receptor antagonism and increased risk of opioid withdrawal.

The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the immature fetal blood-brain barrier and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Because of the potential for serious adverse reactions, including opioid withdrawal, in breastfed infants, advise women that breastfeeding is not recommended during treatment with RELISTOR. In nursing mothers, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

A dosage reduction of RELISTOR tablets and RELISTOR injection is recommended in patients with moderate and severe renal impairment (creatinine clearance less than 60 mL/minute as estimated by Cockcroft-Gault). No dosage adjustment of RELISTOR tablets or RELISTOR injection is needed in patients with mild renal impairment.

A dosage reduction of RELISTOR tablets is recommended in patients with moderate (Child-Pugh Class B) or severe (Child- Pugh Class C) hepatic impairment. No dosage adjustment of RELISTOR tablets is needed in patients with mild hepatic impairment (Child-Pugh Class A). No dosage adjustment of RELISTOR injection is needed for patients with mild or moderate hepatic impairment. In patients with severe hepatic impairment, monitor for methylnaltrexone-related adverse reactions and dose adjust per Prescribing Information as may be indicated.

In the clinical studies, the most common adverse reactions were:

OIC in adult patients with chronic non-cancer pain

RELISTOR tablets (≥ 2% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (14%), diarrhea (5%), headache (4%), abdominal distention (4%), vomiting (3%), hyperhidrosis (3%), anxiety (2%), muscle spasms (2%), rhinorrhea (2%), and chills (2%).

RELISTOR injection (≥ 1% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (21%), nausea (9%), diarrhea (6%), hyperhidrosis (6%), hot flush (3%), tremor (1%), and chills (1%).

OIC in adult patients with advanced illness

RELISTOR injection (≥ 5% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (29%) flatulence (13%), nausea (12%), dizziness (7%), and diarrhea (6%).

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576 or FDA at 1-800- FDA-1088 or
www.fda.gov/medwatch

Please click
here
for full Prescribing Information for RELISTOR tablets and RELISTOR injection.

About Salix

Salix Pharmaceuticals is one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases. For more than 30 years, Salix has licensed, developed and marketed innovative products to improve patients' lives and arm health care providers with life-changing solutions for many chronic and debilitating conditions. Salix currently markets its product line to U.S. health care providers through an expanded sales force that focuses on gastroenterology, hepatology, pain specialists and primary care. Salix is headquartered in Bridgewater, New Jersey. For more information about Salix, visit www.Salix.com and connect with us on Twitter and LinkedIn.

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. For more information, visit www.bauschhealth.com and connect with us on Twitter and LinkedIn.

Forward-looking Statements

This news release may contain forward-looking statements, which may generally be identified by the use of the words "anticipates," "hopes," "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 Bausch Health 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.

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