

Bausch Health and Salix to present at the American Association for the Study of Liver Disease (AASLD) the RED-C Phase 3 Study Design for a new investigational product designed to address serious complications of cirrhosis

November 18, 2024

Next generation product may increase gastrointestinal luminal concentration while limiting system exposure

LAVAL, Quebec, November 18, 2024 – Bausch Health Companies Inc. (NYSE/TSX: BHC) and its gastroenterology (GI) business, Salix Pharmaceuticals ("Salix"), today announced the first look at its late-stage RED-C clinical trial program which will be presented at the American Association for the Study of Liver Disease (AASLD), The Liver Meeting® in San Diego, CA. This clinical program was designed to assess the efficacy of a next generation therapeutic, a soluble solid dispersion (SSD) immediate-release rifaximin product, to delay onset of first overt hepatic encephalopathy (OHE) hospitalization. There are no medications globally approved for the primary prophylaxis and delay in decompensation to first episode of OHE in cirrhosis. Another objective of this study is to assess the effects of treatment with this next generation therapeutic on the time to the onset of significant clinical events, including all-cause hospitalization rates, first occurrence of OHE event requiring hospitalization, and all-cause mortality.

The RED-C program is evaluating a next generation therapeutic designed to enhance the gastrointestinal luminal solubility of a unique form of rifaximin in order to preserve epithelial function, limit bacterial translocation to the bloodstream and liver, and reduce proinflammatory cytokine production. The RED-C program includes two global Phase 3, randomized, double-blind, placebo-controlled studies conducted in over 1,000 patients, over 398 study sites, and across 17 countries. Patient enrollment on both trials is now complete with efficacy and safety results to be announced at future congresses.

"The RED-C program underscores our dedication to exploring and identifying new treatments for individuals with cirrhosis," stated Aimee Lenar, Executive Vice President of US Pharma at Bausch Health. "Considering the significant unmet need for cirrhotic patients, the RED-C phase 3 trials have been rigorously designed to assess a potential new option to delay the onset of the first overt hepatic encephalopathy event, and to potentially, delay time to all-cause hospitalization. Enrollment in both trials is now complete, and the trials are progressing at study sites worldwide."

The Salix research to be presented at AASLD 2024 is as follows:

Rifaximin SSD-40IR

- Bajaj, Jasmohan S. et.al. Rifaximin Soluble Solid Dispersion Immediate-Release Tablets for Prevention and Delay of the First Episode of Hepatic Encephalopathy: RED-C Phase 3 Study Design

- o Poster #4198
- o Monday, November 18, 8:00 AM - 5:00 PM PT

About Bausch Health

Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global, diversified pharmaceutical company enriching lives through our relentless drive to deliver better health care outcomes. We develop, manufacture and market a range of products primarily in gastroenterology, hepatology, neurology, dermatology, international pharmaceuticals and eye health, through our controlling interest in Bausch + Lomb Corporation. Our ambition is to be a globally integrated healthcare company, trusted and valued by patients, HCPs, employees and investors. Our gastroenterology business, Salix Pharmaceuticals, is one of the largest specialty pharmaceutical businesses in the world and has licensed, developed and marketed innovative products for the treatment of gastrointestinal diseases for more than 30 years. For more information about Salix, visit www.Salix.com

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