Bausch Health Reports Promising R&D Trial Updates on Amiselimod and Scientific Data Presented at International Healthcare Conferences

June 14, 2024

LAVAL, Quebec, June 14, 2024 – Bausch Health Companies Inc. (NYSE/TSX: BHC), a global diversified pharmaceutical company enriching lives through a relentless drive to deliver better health outcomes, recently presented at two global healthcare conferences. Bausch Health's gastroenterology (GI) business, Salix Pharmaceuticals presented data from its Amiselimod clinical trials at Digestive Disease Week (DDW) 2024 during the IMIBD Late Breakers and Innovations in IBD session on May 19, 2024, in Washington, D.C., and post hoc pooled data analysis of Rifaximin at the International Liver Congress 2024™ (ILC 2024): Annual Meeting of the European Association for the Study of the Liver (EASL) on June 8, 2024 in Milan, Italy.

Amiselimod at DDW

Bausch Health shared
positive late-breaking data
from a global Phase 2 study evaluating Amiselimod for the treatment of patients with active, mild to moderate ulcerative colitis (UC) at Digestive Disease Week® (DDW) 2024. The data were presented by Dr. Steven Hanauer and Clifford Joseph Barborka, Professor of Medicine at Northwestern University. The randomized, double-blind, placebocontrolled trial investigated the efficacy and safety of Amiselimod over a 12-week treatment period. The results demonstrated that Amiselimod was well-tolerated and showed promise as a potential treatment for inducing remission in UC patients.

Specifically:

- In the primary endpoint measure – both doses of Amiselimod (0.2mg and 0.4mg daily) led to a significantly greater improvement in Modified Mayo Score (MMS) compared to a placebo group on Day 85. This score reflects disease activity, with a lower score indicating better outcomes. Patients taking Amiselimod experienced an average improvement of -2.3 points, compared to -1.6 points in the placebo group (p-score <0.01)
- In the secondary measures, endoscopic improvement and clinical remission, after 12 weeks, a significantly higher proportion of patients receiving Amiselimod achieved endoscopic improvement (over 42%) compared to placebo (23%) with statistically significant difference (pscore <0.01). Similarly, over 31% of patients on Amiselimod experienced clinical remission compared to 18% in the placebo group (p-score = 0.03).
- In the safety evaluation patients were closely monitored for any adverse events throughout the 12 weeks. The findings concluded that Amiselimod treatment was well-tolerated.

"Our recent trial results are a testament to the dedication and expertise of our research teams," said Dr. Tage Ramakrishna, Chief Medical Officer, President, R&D. "The promising data from this Amiselimod trial brings us closer to offering new, effective treatment to patients suffering from ulcerative colitis (UC). We are excited to advance this therapy to the next stage of development."

Ulcerative colitis is a chronic disease affecting the large intestine, or colon. The condition causes inflammation and ulceration (sores) along the lining of the colon, which can lead to abdominal pain, cramps, bleeding and diarrhea.[1] In ulcerative colitis, the inflammation starts at the rectum and continues through the colon. Symptoms include diarrhea with blood and mucus, pain on the left-hand side of the abdomen, urgency and tenesmus (the feeling of needing to pass stools even if the bowel is empty).[1]

Rifaximin at EASL

At the European Association for the Study of the Liver (EASL) Conference, Bausch Health presented
data comparing Rifaximin monotherapy to lactulose monotherapy in preventing overt hepatic encephalopathy (OHE) recurrence in cirrhosis patients with a history of OHE. This analysis, based on pooled data from two randomized trials (one phase 3 double-blind and one phase 4 open-label), focused on adult patients with cirrhosis and a history of OHE episodes showed that:

- Significantly fewer patients treated with Rifaximin monotherapy experienced an OHE episode compared with lactulose monotherapy (23.2% vs 49.0%, respectively; P<0.0001).
- Rifaximin monotherapy reduced the risk of a breakthrough OHE event by 60% versus lactulose monotherapy during 6 months of treatment.
- Rifaximin monotherapy was well tolerated.

These data suggest Rifaximin monotherapy has the potential to be a viable treatment option for OHE recurrence risk reduction in appropriate patient populations.

About Amiselimod

Amiselimod is a sphingosine-1-phosphate (S1P) receptor functional antagonist and, by inhibiting the receptor function of the lymphocyte sphingosine-1-phosphate (S1P) receptor, retains lymphocytes sequestered in the lymph nodes and prevents them from contributing to autoimmune reactions.[1] Due to this mechanism of action, Amiselimod may potentially be useful for various autoimmune diseases.[2] Affinity to S1P1 and S1P5 receptor subtypes, suggests that Amiselimod could potentially have a more pronounced effect on ulcerative colitis related inflammation than compounds with restricted activity on S1P1 receptor subtype exclusively or combined activity on S1P1 and S1P5.[2]

About XIFAXAN

XIFAXAN® (rifaximin) 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults and for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

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 provide 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
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About Bausch Health

Bausch Health Companies Inc. (NYSE:BHC)(TSX:BHC) is a global diversified pharmaceutical company enriching lives through our relentless drive to deliver better health outcomes. We develop, manufacture and market a range of products, primarily in gastroenterology, hepatology, neurology, dermatology, medical aesthetic devices, international pharmaceuticals, and eye health, through our controlling interest in Bausch + Lomb. Our ambition is to be a globally integrated healthcare company, trusted and valued by patients, HCPs, employees and investors. For more information, visit
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