

Salix Enters Into Exclusive License Agreement With Mitsubishi Tanabe Pharma To Develop And Commercialize Late Stage Investigational S1P Modulator For The Treatment Of Inflammatory Bowel Disease

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Investigational Oral Compound to Strengthen Salix's Expanding Pipeline

BRIDGEWATER, N.J., April 25, 2019 /PRNewswire/ -- Salix Pharmaceuticals ("Salix"), one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases, and a wholly owned subsidiary of Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health"), announced today that its affiliate has entered into an exclusive licensing agreement with Mitsubishi Tanabe Pharma Corporation (MTPC) (TSE: 4508) to develop and commercialize MT-1303 (amiselimod), a late-stage oral compound that targets the sphingosine 1-phosphate (S1P) receptor that plays a role in autoimmune diseases, such as Inflammatory Bowel Disease (IBD) and ulcerative colitis. ^{1,2}

Approximately 1.6 million Americans currently suffer from IBD and as many as 70,000 new cases of IBD are diagnosed in the United States annually.³ Of the 1.6 million Americans with IBD, about 907,000 of them have ulcerative colitis.⁴ Beyond conventional therapies such as mesalamines, steroids and systemic immunosuppressive agents, IBD can also be managed through the use of antibody-based biologics.⁴ While many patients have benefited from these antibody-based therapies, a number of patients do not respond to biologics.⁵

"For patients living with IBD, amiselimod represents an opportunity to develop an oral, non-immunogenic treatment as an alternative to biologics and other available therapies,"¹ said Mark McKenna, president, Salix Pharmaceuticals. "Today's announcement reflects Salix's commitment to serving the unmet needs of gastrointestinal patients and to offering health care providers with new treatment options to consider when they are managing patients who suffer from this chronic, life-long condition."

Under the agreement, MTPC grants Bausch Health exclusive rights to develop and commercialize MT-1303 worldwide, except for Japan and certain other countries in Asia, in all fields, excluding neurology, rheumatology and certain rare dermatology diseases, where MTPC retains the rights. Bausch plans to initiate development of MT-1303 in ulcerative colitis. Under the terms of the license, Bausch Health will pay to MTPC a one-time up-front payment, as well as certain development and regulatory-based milestone payments and sales-based royalties.

About MT-1303(amiselimod)

MT-1303 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, MT-1303 may potentially be useful for various autoimmune diseases. ² Mitsubishi Tanabe Pharma has conducted clinical trials for MT-1303 for multiple

sclerosis, psoriasis, Crohn's disease and systemic lupus erythematosus in Europe and in Japan.^{2,7} Affinity to S1P1, S1P4 and S1P5 receptor subtypes, suggests that MT-1303 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 S1P5.⁸

About Mitsubishi Tanabe Pharma

Mitsubishi Tanabe Pharma, which was founded in 1678, has its headquarters in Doshomachi, Osaka, which is the birthplace of Japan's pharmaceutical industry. With business centered on ethical pharmaceuticals, Mitsubishi Tanabe Pharma is a well-established company and has the longest history of any listed company in Japan. In accordance with the corporate philosophy of "contributing to the healthier lives of people around the world through the creation of pharmaceuticals," the Company formulated the key concept of Open Up the Future under the Medium-Term Management Plan 16-20. Through the discovery of drugs that address unmet medical needs, centered on its priority disease areas — autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines — Mitsubishi Tanabe Pharma will strive to contribute to the health of patients around the world.

For more information, go to
<https://www.mt-pharma.co.jp/>

About Salix

Salix is one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases. For almost 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.

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 may contain forward-looking statements, which may generally be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "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, risks and uncertainties discussed in the Bausch Health's most recent annual or quarterly report and detailed from time to time in Bausch Health's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. In addition, certain material factors and assumptions have been applied in making these forward-looking statements, including that the risks and uncertainties outlined above will not cause actual results or events to differ materially from those described in these forward-looking statements. Bausch Health believes that the material factors and assumptions reflected in these forward-looking statements

are reasonable, but 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 and Salix undertake 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.

References

- Kunio Sugahara, Yasuhiro Maeda. Amiselimod, a novel sphingosine 1-phosphate receptor-1 modulator, has potent therapeutic efficacy for autoimmune diseases, with low bradycardia risk. British Journal of Pharmacology. January 2017.
- Peyrin-Biroulet, Ronald Christopher Modulation of sphingosine-1-phosphate in inflammatory bowel disease. Autoimmunity Reviews. February 2017
- Crohn's Colitis Foundation.
<https://www.crohnscolitisfoundation.org/assets/pdfs/updatedibdfactbook.pdf>. Accessed April 22, 2019.
- Loftus EV, Jr., Shivashankar R, Tremaine WJ, Harmsen WS, Zinsmeister AR. Updated Incidence and Prevalence of Crohn's Disease and Ulcerative Colitis in Olmsted County, Minnesota (1970-2011). ACG 2014 Annual Scientific Meeting. October 2014
- Triantafyllidis J, Merikas E, Georgopoulos F. Current and Emerging Drugs for the Treatment of Inflammatory Bowel Disease. Drug Design, Development and Therapy. April 2011.
- Ben-Horin S, Chowers Y. Review Article: Loss of Response to Anti-TNF Treatments in Crohn's Disease. Alimentary Pharmacology and Therapeutics. March 2011.
- Joshua Chang, Victoria P. Werth, Therapeutic options for cutaneous lupus erythematosus: recent advances and future prospects. Expert Rev Clin Immunol. October 2016.
- [BiseraStepanovska](#),
,
[AndreaHuwiler](#)
. Targeting the S1P receptor signaling pathways as a promising approach for treatment of autoimmune and inflammatory diseases. Pharmacological Research. February 2019.

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