



Morphic Announces Initiation of EMERALD-2 Phase 2b Clinical Trial of MORF-057 in Patients with Moderate-to-Severe Ulcerative Colitis

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First patient dosed in global study of oral $\alpha 4\beta 7$ integrin inhibitor

WALTHAM, Mass., Nov. 22, 2022 (GLOBE NEWSWIRE) -- [Morphic Therapeutic](#) (Nasdaq: MORF), a biopharmaceutical company developing a new generation of oral integrin therapies for the treatment of serious chronic diseases, today announced that the EMERALD-2 phase 2b study of MORF-057 in ulcerative colitis (UC) has commenced with the first patient receiving MORF-057.

"MORF-057 offers the possibility of efficacy and tolerability through the proven mechanism of $\alpha 4\beta 7$ inhibition, together with the ease and convenience of oral dosing for patients suffering from IBD," commented Praveen Tipirneni, CEO of Morphic Therapeutic. "We are therefore extremely excited to begin the EMERALD-2 study of MORF-057. In addition, we are now eagerly looking forward to the results of the EMERALD-1 phase 2a study of MORF-057 that we expect in second quarter of 2023."

About the EMERALD-2 Study

[EMERALD-2 \(MORF-057-202\)](#) is a global phase 2b randomized, double-blind, placebo-controlled trial of MORF-057 in patients with moderate-to-severe ulcerative colitis. The primary endpoint of EMERALD-2 is clinical remission rate as measured by the Modified Mayo Clinic Score (mMCS) at 12 weeks. EMERALD-2 will also measure several secondary and exploratory endpoints based on the mMCS as well as histologic, pharmacokinetic and pharmacodynamic measures, and safety parameters. Patients in the EMERALD-2 study will be randomized to receive either 200 mg BID (twice daily) MORF-057, 100 mg BID MORF-057, a QD (once daily) dose of MORF-057, or a placebo dose. Following the 12-week induction phase, all patients will receive MORF-057 for 40 weeks of maintenance dosing. For more information about the EMERALD clinical trials of MORF-057, please click [here](#).

Top line results from EMERALD-2 are expected in the first half of 2025.

About MORF-057

Morphic is developing MORF-057 as a selective, oral small molecule inhibitor of the $\alpha 4\beta 7$ integrin for patients with inflammatory bowel disease (IBD). $\alpha 4\beta 7$ has been clinically validated as a target for the treatment of IBD by the success of the approved injectable antibody therapeutic vedolizumab. MORF-057, like vedolizumab, is designed to block the interactions between $\alpha 4\beta 7$ on the surface of lymphocytes and the mucosal endothelial cell ligand MAdCAM-1, substantially reducing lymphocyte migration from the bloodstream into intestinal mucosal tissues and avoiding inflammation that is associated with IBD.

About Inflammatory Bowel Disease

Inflammatory Bowel Disease (IBD) comprises several autoimmune and immune-mediated conditions characterized by chronic inflammation of the gastrointestinal tract. Ulcerative colitis (UC) and Crohn's disease are two most common types of IBD. In UC, inflammation is limited to the lining of the colon, whereas in Crohn's disease inflammation can segmentally affect any part of the gastrointestinal tract through the entire thickness of the bowel wall. Symptoms of these conditions include persistent diarrhea, abdominal pain, rectal bleeding, weight loss, and fatigue. Approved medications may not adequately control symptoms for many patients, and some develop complications that require surgical removal of the colon and rectum. Among FDA approved therapies for use in moderate-to-severe IBD is vedolizumab, an injectable monoclonal antibody inhibitor of the integrin $\alpha 4\beta 7$.

About Morphic Therapeutic

Morphic Therapeutic is a biopharmaceutical company developing a portfolio of oral integrin therapies for the treatment of serious chronic diseases, including autoimmune, cardiovascular, and metabolic diseases, fibrosis, and cancer. Morphic is also advancing its pipeline and discovery activities in collaborations with Janssen and Schrödinger using its proprietary MInT technology platform which leverages the Company's unique understanding of integrin structure and biology. For more information, visit www.morphictx.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, and of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: the MInT Platform's ability to discover drug candidates, Morphic's plans to develop and commercialize oral small-molecule integrin therapeutics and any proposed timing thereof, the initiation, execution and completion of MORF-057 phase 2 clinical trials, any expectations about safety, efficacy, timing and ability to commence or complete clinical studies and/or trials and to obtain regulatory approvals for MORF-057 and other candidates in development, the timing of further data presentation and the ability of MORF-057 to treat inflammatory bowel disease, including ulcerative colitis, or related indications. Statements including words such as "believe," "plan," "continue," "expect," "will be," "develop," "signal," "potential," "anticipate" or "ongoing" and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements are subject to risks and uncertainties that may cause Morphic's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties in this press release and other risks set forth in our filings with the Securities and Exchange Commission, including Morphic's or a partner's ability to complete a current or future clinical trial of any of our current or future product candidates, develop or obtain regulatory approval for or commercialize any product candidate, Morphic's ability to protect intellectual property, the potential impact of the COVID-19 pandemic, and the sufficiency of our cash, cash equivalents and investments to fund our operations. These forward-looking statements speak only as of the date hereof and Morphic specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events

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