



Morphic Therapeutic Announces Initiation of EMERALD-1 Phase 2a Clinical Trial of MORF-057 in Patients with Ulcerative Colitis

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MORF-057, an oral $\alpha4\beta7$ integrin inhibitor candidate, holds potential for treating inflammatory bowel diseases

Phase 2b EMERALD-2 clinical trial of MORF-057 expected to begin mid-year 2022

WALTHAM, Mass., March 25, 2022 (GLOBE NEWSWIRE) -- [Morphic Therapeutic](#) (Nasdaq: MORF), today announced the initiation of MORF-057-201, the EMERALD-1 study. EMERALD-1 is a phase 2a trial of MORF-057 in patients with moderate to severe ulcerative colitis. MORF-057 is a potent and selective, oral small molecule inhibitor of the $\alpha4\beta7$ integrin being studied in patients with GI disorders, initially targeting inflammatory bowel disease (IBD).

"In the United States, over 1 million people are affected by IBD, a lifelong illness that can have a profound physical, emotional and social impact on patients," said Praveen Tipirneni, M.D., President and Chief Executive Officer of Morphic Therapeutic. "Each of the preclinical and clinical studies of MORF-057 to date have strongly supported the potential for MORF-057 to replicate the actions of vedolizumab, an IV-infused biologic inhibitor of $\alpha4\beta7$. MORF-057 is designed to provide an even broader group of patients with access to this proven therapeutic mechanism in pill form. With EMERALD-1 underway, we now look forward to progress in global clinical studies to advance MORF-057 as a potential new therapeutic option for people living with IBD."

About the EMERALD-1 Study

[EMERALD-1 \(MORF-057-201\)](#) is an open-label multi-center phase 2a trial designed to evaluate the efficacy, safety and tolerability of MORF-057 in adults with moderate to severe ulcerative colitis. The EMERALD-1 study is planned to enroll up to 35 patients with moderate to severe ulcerative colitis who will be treated with 100 mg BID (twice daily) at sites in the United States and Europe. The primary endpoint of the trial is the change in Roberts Histopathology Index (RHI), a validated instrument that measures histological disease activity in ulcerative colitis at 12 weeks compared to baseline. Patients will then continue for an additional 40 weeks of maintenance therapy followed by a 52-week assessment. Secondary and additional outcome measures in the EMERALD-1 study include change in the modified Mayo clinic score, safety, pharmacokinetic parameters and key pharmacodynamic measures including $\alpha4\beta7$ receptor occupancy and lymphocyte subset trafficking.

EMERALD-2 (MORF-057-202) is a global phase 2b randomized controlled trial of MORF-057 that is expected to begin mid-year 2022 and then run in parallel with EMERALD-1.

About MORF-057

Morphic is developing MORF-057 as a selective, oral small molecule inhibitor of the $\alpha4\beta7$ integrin for patients with inflammatory bowel disease (IBD). $\alpha4\beta7$ 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 $\alpha4\beta7$ 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 and Crohn's disease are two most common types of IBD. In ulcerative colitis, 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 $\alpha4\beta7$.

About Morphic Therapeutic

Morphic Therapeutic is a biopharmaceutical company developing a new generation of oral integrin therapies for the treatment of serious chronic diseases, including autoimmune, cardiovascular, and metabolic diseases, fibrosis and cancer. In collaboration with AbbVie, Janssen, and Schrödinger, Morphic is advancing its pipeline and discovery activities 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 enrollment, execution and completion of the future MORF-057 phase 2 clinical trial, 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, Crohn's disease or related indications. Statements including words such as "believe," "plan," "continue," "expect," "will be," "develop," "signal," "potential," "anticipate," "designed to," 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 Morpic'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, Morpic'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 Morpic 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 or otherwise, except as required by law.

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