Morphic Announces Complete Enrollment of EMERALD-1 Main Cohort Ahead of Projections

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Phase 2a trial of MORF-057 in patients with ulcerative colitis will extend enrollment to allow patients currently screened to enter study if eligible

WALTHAM, Mass., Oct. 24, 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 the completion of targeted enrollment of 30 patients ahead of schedule for the main cohort of the EMERALD-1 phase 2a study of MORF-057 in patients with moderate to severe ulcerative colitis (UC).

"The completion of enrollment in the main cohort of the EMERALD-1 ahead of target is a significant accomplishment and a testament to the efficiency and commitment of the Morphic development teams," commented Carolyn Soo, PharmD, Vice President of Clinical Operations of Morphic Therapeutic. "MORF-057 was designed to treat IBD via the validated mechanism of inhibition of the α4β7 integrin and the EMERALD-1 study was planned to provide proof of concept that an oral inhibitor of α4β7 has the potential to benefit patients suffering from UC. This milestone brings us one step closer to realizing this important vision and I would like to thank the patients and investigators for their ongoing commitment this program."

Based on the rapid enrollment and substantial demand accrued to enter EMERALD-1, there were a significant number of patients in screening at the time of the 30th patient's enrollment; these patients will be eligible to enter the study if the eligibility criteria are met. Enrollment in the exploratory cohort of up to ~10 patients who have previously failed treatment with vedolizumab is ongoing.

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 30 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 and 5 patients who have previously failed on advanced UC therapies. The primary endpoint of the trial is the change in Robarts 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 α4β7 receptor occupancy and lymphocyte subset trafficking.

About MORF-057
Morphic is developing MORF-057 as a selective, oral small molecule inhibitor of the α4β7 integrin for patients with inflammatory bowel disease (IBD). α4β7 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 α4β7 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 α4β7.

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 or otherwise, except as required by law.

Contact
Chris Erdman
617.686.1718
chris.erdman@morphictx.com