Morphic Reports Positive Topline Results of the EMERALD-1 UC Main Cohort; Orally Administered MORF-057 Achieves Primary Endpoint and Demonstrates Clinically Meaningful Improvements Across Secondary and Exploratory Measures

April 25, 2023

-MORF-057 demonstrates statistically significant reduction of 6.4 points (p=0.002) from baseline at Week 12 in the Robarts Histopathology Index (RHI) Score-

-MORF-057 achieves 25.7% clinical remission by Modified Mayo Clinic Score (mMCS)-

-MORF-057 generally well tolerated with no safety signal observed-

-MORF-057 achieves saturation of α4β7 receptor and demonstrates changes in α4β7 lymphocyte subsets that are consistent with Phase 1 MORF-057 data -

-Conference call and webcast to discuss results today at 8:00 AM ET-

WALTHAM, Mass., April 25, 2023 (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 reported positive topline data from the main cohort of the open-label EMERALD-1 Phase 2a study of MORF-057, an oral small molecule inhibitor of the α4β7 integrin, in adults with moderate to severe ulcerative colitis (UC).

“In EMERALD-1, patients with moderate-to-severe ulcerative colitis receiving MORF-057 experienced a statistically significant reduction in the RHI score and a 25.7% clinical remission rate as measured by the mMCS. In addition, MORF-057 was generally well tolerated in EMERALD-1 with no safety signal observed. We are emboldened by these positive results and excited to continue to enroll the ongoing EMERALD-2 Phase 2b study,” commented Praveen Tipirneni, MD, Chief Executive Officer of Morphic Therapeutic. “I couldn't be more thankful to these patients and investigators, and proud of our team for advancing MORF-057 much closer to our goal of providing a safe and effective treatment option for IBD patients, in pill form.”

“There are three desired attributes in an IBD treatment: favorable safety profile, meaningful clinical efficacy, and oral route of administration. Currently approved IBD treatments achieve at most two of these qualities and force patients to compromise; we need a new option to treat IBD patients that combines a high rate of clinical remission with a favorable safety profile in oral formulation,” commented Bruce Sands, M.D., M.S., the Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine at Mount Sinai, and Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at Mount Sinai Health System. Dr. Bruce Sands is a paid consultant for Morphic and a member of the Company’s Clinical Advisory Board. He has not been compensated for any media work.

Results from the EMERALD-1 Study of MORF-057 in Ulcerative Colitis

The main cohort of the EMERALD-1 open-label, single-arm Phase 2a trial of MORF-057 enrolled 35 patients with moderate to severe UC. In the trial, MORF-057 achieved the primary endpoint, demonstrating a statistically significant reduction in the RHI score of 6.4 points (p=0.002) from baseline to week 12. In the prespecified secondary endpoint, change in modified Mayo Composite Score, patients had a 2.3-point reduction from baseline. In the study, patients receiving MORF-057 experienced a 25.7% remission rate according to mMCS. MORF-057 was generally well tolerated at the dose of 100 mg BID (twice daily) with no serious adverse events (SAEs) and no safety signal. The most common adverse events were exacerbation of UC and anemia.

Summary Topline Results from the EMERALD-1 Study (All data as of 12 weeks)

Measurement	Overall
Mean change in RHI from baseline	-6.4 points (p=0.002)
mMCS Remission rate	25.7%
mMCS Response rate	45.7%
Mean α4β7 receptor occupancy (measured at trough)	>98%

CONFERENCE CALL INFORMATION

Time: 8:00 AM ET Tuesday, April 25th

Webcast: Available on the events section at investor.morphictx.com

To join the question and answer queue on the live conference call, please click here to register and receive a personalized dial in number.

Featured speaker: Bruce Sands, M.D., M.S., the Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine at Mount Sinai, and Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at Mount Sinai Health System.

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 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 35 patients enrolled in the main cohort of the EMERALD-1 study have been treated with 100 mg BID (twice daily) at sites in the United States and Poland. The primary endpoint of the trial was 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 continue for an additional 40 weeks of maintenance therapy followed by a 52-week assessment. Secondary and additional pre-specified 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 the EMERALD-2 Study

EMERALD-2 (MORF-057-202) is a global phase 2b randomized, double-blind, placebo-controlled trial of MORF-057 that is currently enrolling 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 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.

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 collaboration with 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 technology 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 execution, timing and completion of the EMERALD-1 and EMERALD-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; the timing of further data presentation; and the ability of MORF-057 to treat inflammatory bowel disease, including UC, 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 disclosed in this press release and other risks set forth in our filings with the Securities and Exchange Commission, including Morphic's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the SEC on February 23, 2023 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 filed with the SEC on April 25, 2023. These forward-looking statements speak only as of the date hereof and Morphic specifically disclaims any obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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