Morphic Announces Corporate Highlights and Financial Results for the First Quarter 2023

April 25, 2023

-In EMERALD-1 Phase 2a trial in patients with ulcerative colitis, MORF-057 meets primary endpoint and demonstrates clinically meaningful improvements across secondary and exploratory measures with no safety signal observed-

-EMERALD-2 Phase 2b Trial of MORF-057 progressing on track-

-Ended first quarter 2023 with $421 million in cash, cash equivalents, and marketable securities, extending runway into second half of 2026-

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 corporate highlights and financial results for the first quarter 2023.

First Quarter 2023 and Recent Corporate Highlights

EMERALD Phase 2 trials of MORF-057 in ulcerative colitis

- Announced positive topline results from the main cohort of the EMERALD-1 open-label, single-arm Phase 2a trial of MORF-057 at a dose of 100 mg BID (twice daily) in patients with moderate to severe ulcerative colitis (UC)
- In EMERALD-1, MORF-057
  - Achieved primary endpoint with statistical significance, demonstrating a reduction of 6.4 points (p=0.002) from baseline at week 12 in the Robarts Histopathology Index (RHI) Score
  - Achieved a 25.7% remission rate according to Modified Mayo Clinic Score (mMCS)
  - Was generally well tolerated and with no safety signal observed
  - Achieved saturation of α4β7 receptor and demonstrated changes in α4β7 lymphocyte subsets that are consistent with Phase 1 MORF-057 data
- Continued ramp-up and enrollment of EMERALD-2 Phase 2b study of MORF-057 in patients with moderate to severe UC
  - EMERALD-2 is a global Phase 2b randomized, double-blind, placebo-controlled trial of MORF-057 enrolling patients with moderate-to-severe UC
  - The primary endpoint of EMERALD-2 is the clinical remission rate as measured by mMCS at 12 weeks and is expected to report in the first half of 2025

MORF-057 Preclinical and Phase 1 Studies

- Presented new MORF-057 preclinical data at European Crohn's and Colitis Organization Annual Meeting 2023 demonstrating the activity of α4β7 inhibition in animal models of inflammatory bowel disease (IBD), further support the ongoing EMERALD Phase 2 clinical trials of MORF-057 in IBD

Emerging Pipeline

- Defined myelofibrosis as a new therapeutic area, for development of Morphic's selective αvβ8 small molecule inhibitors and the role of αvβ8 inhibition in the suppression of TGFB activation, which is implicated in myelofibrotic disease
- Announced a new small molecule integrin inhibitor program for the treatment of pulmonary hypertensive diseases targeting an undisclosed integrin receptor

"Q1 was a pivotal quarter for Morphic, with the EMERALD-1 study reporting positive topline results, including clinically meaningful activity and favorable tolerability. In addition, we extended our cash runway into the second half of 2026, well beyond the primary endpoint readout of EMERALD-2, the phase 2b randomized study of MORF-057 in UC, in the first half of 2025," commented Praveen Tipirneni, MD, Chief Executive Officer of Morphic Therapeutic. "Our clinical team has done an excellent job executing on the EMERALD studies and we are thrilled with the potential benefit that MORF-057 has now demonstrated in patients. The significant extension of cash runway enables the later stage clinical development of MORF-057 and development of our pipeline of emerging integrin therapies."

Financial Results for the First Quarter 2023

- Net loss for the quarter ended March 31, 2023, was $36.1 million or $0.90 per share compared to a net loss of $31.5 million or $0.85 per share for the same quarter last year
- Revenue was $0.5 million for the quarter ended March 31, 2023, compared to $2.4 million for the same quarter last year
- Research and development expenses were $30.4 million for the quarter ended March 31, 2023, as compared to $26.5 million for the same quarter last year. The increase was primarily attributable to higher clinical and development costs along with higher pre-clinical and Phase 2 clinical trial costs to support our lead product candidate MORF-057
- General and administrative expenses were $9.3 million for the quarter ended March 31, 2023, compared to $7.6 million for the same quarter last year. The increase was primarily due to increased non-cash stock-based compensation expense and higher payroll costs

As of March 31, 2023, Morphic had cash, cash equivalents and marketable securities of $421 million, compared to $348 million as of December 31, 2022, with the increase primarily due to a private placement of Morphic's common stock and pre-funded warrants with certain existing investors that was completed in February 2023. Morphic believes its cash, cash equivalents and marketable securities as of March 31, 2023, will be sufficient to fund operating expenses and capital expenditure requirements into the second half of 2026.

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 and other candidates in development; the timing of further data presentation; the ability of MORF-057 to treat IBD, including ulcerative colitis, or related indications; the ability of αvβ8 small molecule inhibitors to treat myelofibrosis and pulmonary hypertensive diseases; the company's cash position and anticipated runway. 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.

Financial Tables to Follow

Morphic Holding, Inc.

Condensed Consolidated Statements of Operations

(unaudited)

(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	2022
Collaboration revenue	$ 521	$ 2,382
Operating expenses:		
Research and development	30,449	26,463
General and administrative	9,277	7,591
Total operating expenses	39,726	34,054
Loss from operations	(39,205)	(31,672)
Other income:		
Interest income, net	3,100	187
Other income, net	2	1
Total other income, net	3,102	188
Loss before provision for income taxes	(36,103)	(31,484)
Provision for income taxes	(32)	—
Net loss	(36,135)	(31,484)
Net loss per share, basic and diluted	$ (0.90)	$ (0.85)
Weighted average common shares outstanding, basic and diluted	40,112,416	37,133,412

Morphic Holding, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	March 31, 2023	December 31, 2022
Assets		
Cash, cash equivalents and marketable securities	$ 421,279	$ 348,248
Other current assets	14,466	13,934
Total current assets	435,745	362,182
Other assets	6,202	6,407
Total assets	$ 441,947	$ 368,589
Liabilities and Stockholders' Equity		
Current liabilities	$ 13,481	$ 17,126
Long-term liabilities	1,951	2,344
Total liabilities	15,432	19,470
Total stockholders' equity	426,515	349,119
Total liabilities and stockholders' equity	$ 441,947	$ 368,589

Contacts
Morphic Therapeutic
Chris Erdman
chris.erdman@morphictx.com
617.686.1718