Morphic Announces Corporate Highlights and Financial Results for the First Quarter 2024

April 25, 2024

- Enrollment continued on target in EMERALD-2 Phase 2b trial of MORF-057 in ulcerative colitis-

-Appointed Dr. Simon Cooper as Chief Medical Officer-

-Anticipate dosing first patient in GARNET Phase 2 study of MORF-057 in patients with moderate-to-severe Crohn's disease in second quarter-

-Ended first quarter with $658.8 million in cash, cash equivalents, and marketable securities; cash runway into second half of 2027-

WALTHAM, Mass., April 25, 2024 (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 2024.

"Morphic continues to execute our strategy with the EMERALD-2 phase 2b study in ulcerative colitis (UC) recruiting on target, and we are excited to begin enrollment in the GARNET phase 2 study in patients with moderate to severe Crohn's disease (CD)," commented Praveen Tipirneni, CEO of Morphic Therapeutic. "We look forward to continued progress both with MORF-057 and our earlier-stage pipeline, including our program in pulmonary hypertensive diseases. Morphic is well positioned as the EMERALD-2 data approaches and GARNET commences, with a strong cash position and a strengthened leadership team following the addition of Dr. Simon Cooper as Chief Medical Officer."

First Quarter 2024 and Recent Corporate Highlights

Updates to ongoing MORF-057 EMERALD Phase 2 Development Program

- Enrollment continues on track for EMERALD-2 global phase 2b randomized, double-blind, placebo-controlled trial of MORF-057 in 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
- Anticipate the first patient to be dosed in GARNET phase 2 study of MORF-057 in patients with moderate to severe CD in the second quarter of 2024
  - The primary endpoint of GARNET is the proportion of patients with endoscopic response (≥50% reduction) at week 14 as determined using the Simple Endoscopic Activity Score for CD (SES-CD)

Key Additions to Morphic Leadership Team

- Appointed Simon Cooper, M.B.B.S., to the role of Chief Medical Officer
  - Dr. Cooper brings successful and highly relevant therapeutic area drug development experience, having played a key role in the development of risankizumab in multiple indications including UC and CD at AbbVie. Dr. Cooper also held the role of Vice President, Global Project Head for the sarilumab program at Sanofi and led the submission of secukinumab in psoriasis at Novartis
  - Dr. Cooper has served as Chief Medical Officer of Keros Therapeutics, Kadmon Holdings and Anokion, and held roles of increasing responsibility at research and development organizations including Wyeth Research, Napp Pharmaceutical Research, Roche, Human Genome Sciences and MedImmune
  - Dr. Cooper holds a Bachelor of Medicine and a Bachelor of Surgery from the University of Newcastle upon Tyne Medical School

Financial Results for the First Quarter 2024

- Net loss for the quarter ended March 31, 2024, was $45.3 million or $0.91 per share compared to net loss of $36.1 million or $0.90 per share for the same quarter last year
- Research and development expenses were $42.4 million for the quarter ended March 31, 2024, as compared to $30.4 million for the same quarter last year. The increase was primarily attributable to higher development costs along with increased clinical trial costs to support phase 2 clinical studies and development activities for MORF-057, as well as other research costs to support early development candidates
- General and administrative expenses were $11.2 million for the quarter ended March 31, 2024, compared to $9.3 million for the same quarter last year. The increase was primarily attributable to increased non-cash stock-based compensation

expenses

Based on its current operating plan, Morphic believes its existing cash, cash equivalents and marketable securities as of March 31, 2024, will be sufficient to fund operating expenses and capital expenditure requirements into the second half of 2027.

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 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 primary endpoint of EMERALD-1, change in Robarts Histopathology Index (RHI) from baseline at twelve weeks, was achieved with statistical significance. RHI is a validated instrument that measures histological disease activity in ulcerative colitis. Patients were eligible to continue for an additional 40 weeks of maintenance therapy followed by a 52-week assessment as well as an open-label extension period. 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 the EMERALD-2 Study

EMERALD-2 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 (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.

About the GARNET Study

GARNET is a global Phase 2b randomized, double-blind, placebo-controlled trial of MORF-057 in Crohn's disease. The primary endpoint of GARNET is the proportion of participants in endoscopic response (>=50% reduction) at week 14 as determined using Simple Endoscopic Score for Crohn's Disease, or SES-CD. The secondary endpoints will include the change in Crohn's Disease Activity Index, or CDAI, measures, as well as safety parameters. Patients enrolled in the GARNET study will be randomized to receive one of two active doses or a placebo: 200 mg BID (twice daily), 100 mg BID or a placebo that will cross over to MORF-057 after the 14-week induction phase. Following the 14-week induction phase, patients will move to a 38-week maintenance phase.

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 Platform's ability to discover drug candidates; our plans to develop and commercialize oral small-molecule integrin therapeutics and any proposed timing thereof; the initiation, execution and completion of clinical trials of MORF-057; any expectations about safety, efficacy, timing and ability to commence or complete clinical and pre-clinical studies and/or trials and to obtain regulatory approvals for MORF-057 and other candidates in development; and the ability of MORF-057 to treat inflammatory bowel disease, including UC, CD, and other 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 our 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, among others, our or a partner's ability to complete a current or future clinical trial of any of our current or future product candidates, our ability to develop or obtain regulatory approval for or commercialize any product candidate, our ability to protect our intellectual property, 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 we specifically disclaim 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.

-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,	
	2024	2023
Collaboration revenue	$ —	$ 521
Operating expenses:		
Research and development	42,441	30,449
General and administrative	11,163	9,277
Total operating expenses	53,604	39,726
Loss from operations	(53,604)	(39,205)
Other income:		
Interest income, net	8,390	3,100
Other income, net	—	2
Total other income, net	8,390	3,102
Loss before provision for income taxes	(45,214)	(36,103)
Provision for income taxes	(80)	(32)
Net loss	$ (45,294)	$ (36,135)
Net loss per share, basic and diluted	$ (0.91)	$ (0.90)
Weighted average common shares outstanding, basic and dilutive	50,009,032	40,112,416

Morphic Holding, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands)

	March 31, 2024	December 31, 2023
Assets		
Cash, cash equivalents and marketable securities	$ 658,766	$ 704,349
Other current assets	17,175	12,579
Total current assets	675,941	716,928
Other assets	6,824	5,586
Total assets	$ 682,765	$ 722,514
Liabilities and Stockholders' Equity		
Current liabilities	$ 17,711	$ 24,776
Long-term liabilities	1,474	716
Total liabilities	19,185	25,492
Total stockholders' equity	663,580	697,022
Total liabilities and stockholders' equity	$ 682,765	$ 722,514

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