Morphic Reports Positive Interim Results from Single Ascending Dose Phase 1 Clinical Trial of MORF-057

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MORF-057 well tolerated in all dose cohorts

MORF-057 achieved greater than 95% mean receptor occupancy of α4β7 *integrin at three highest dose levels; demonstrates ability to saturate* α4β7 *receptor*

Data provide early clinical proof of concept for MORF-057 as an oral, selective α4β7 *inhibitor*

Phase 1 multiple ascending dose and food effect trials ongoing

WALTHAM, Mass., March 01, 2021 (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 positive interim results from its Phase 1 clinical trial of MORF-057, an oral small molecule inhibitor of the α4β7 integrin in development for the treatment of inflammatory bowel disease (IBD). α4β7 inhibition for the treatment of IBD is a clinically validated biologic mechanism but with no currently available oral treatment options. This single ascending dose (SAD) clinical trial was designed to evaluate the safety, pharmacokinetics, and pharmacodynamics of MORF-057 in healthy volunteers.

“MORF-057 was designed to be a potent and selective oral inhibitor of the integrin α4β7 and these data exceeded our expectations for the Phase 1 SAD trial of MORF-057. Importantly, the robust receptor occupancy data provide early clinical proof-of-concept for MORF-057 as a potential oral treatment option for those suffering from IBD,” commented Peter Linde, M.D., chief medical officer of Morphic Therapeutic. “We’re excited to present the totality of the Phase 1 trial data later this year and to leverage this emerging data set to inform the optimal study design for Phase 2 trials in ulcerative colitis and beyond.”

In the Phase 1 SAD trial, MORF-057 was well tolerated in all 5 cohorts receiving MORF-057 in single doses ranging from 25 mg to 400 mg with no serious adverse events (SAEs) and no significant lab abnormalities in any subject. In the study, MORF-057 exhibited a generally dose proportional and predictable pharmacokinetic profile. The key pharmacodynamic measurement in the trial was receptor occupancy (RO), which indicated the percentage of α4β7 bound by MORF-057 12 hours after the dose. MORF-057 achieved greater than 95% mean α4β7 RO across the three highest dose cohorts, including the observation of >99% RO in subjects in each cohort above 25mg. These single dose data demonstrate the potential that MORF-057 will be able to maintain saturating levels of receptor occupancy following twice daily oral administration. MORF-057 was specifically designed to be highly selective for α4β7 and not α4β1, a related integrin. Notably, we did not observe quantifiable levels of α4β1 RO in the study.

MORF-057 SAD Phase 1 Safety and Receptor Occupancy Data

	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5
MORF-057 Dose	25 mg	50 mg	100 mg	150 mg	400 mg
Safety Measures	Well tolerated	Well tolerated	Well tolerated	Well tolerated	Well tolerated
Mean α4β7 RO 12 hours Post-dose	>70%	>85%	>95%	>95%	>95%

“Morphic’s mission is to create new oral therapies to treat serious chronic diseases by modulating integrins, through our unique understanding of this critical, bi-directional receptor. To achieve this goal, Morphic built a talented team and invested heavily in the MInT Platform to mine the integrin family for new therapeutic opportunities and these data represent the first clinical realization of that ambitious founding strategy,” said Bruce Rogers, Ph.D., chief scientific officer of Morphic. “These results for MORF-057 further validate the MInT Platform’s ability to design small molecules that potently and selectively target this class of receptors with tremendous therapeutic potential.”

About the MORF-057 Phase 1 Trials

The clinical trial is currently enrolling two additional groups in the MORF-057 Phase 1 program: a multiple ascending doses (MAD) study evaluating three dose cohorts of MORF-057 as well as a concurrent food-effect study in both fed and fasting states. Morphic expects to present the full data set from the MORF-057 Phase 1 clinical trial at an appropriate medical meeting in mid-2021 after completion of the MAD and food effect portions of MORF-057’s clinical program.

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 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 causing inflammation that is associated with IBD.

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 Morphic Integrin Technology (MInT) 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 "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, the execution and completion of the MORF-057 Phase 1 clinical trial as designed, any expectations about safety, efficacy, timing and ability to commence or complete clinical studies 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 or related indications.

Statements including words such as "believe," "plan," "continue," "expect," "will," "develop," "signal," "potential," 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 develop, 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.

Contacts

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

Media Contact
Tom Donovan, Ten Bridge Communications
tom@tenbridgecommunications.com
857.559.3397