miRagen Announces Internal Review of Preliminary Topline Data for the Phase 2 SOLAR Clinical Trial of Cobomarsen in Patients with Cutaneous T-Cell Lymphoma (CTCL)

October 5, 2020

miRagen decides to discontinue further internal development of cobomarsen

BOULDER, Colo., Oct. 05, 2020 (GLOBE NEWSWIRE) -- miRagen Therapeutics, Inc. (NASDAQ: MGEN), a clinical-stage biopharmaceutical company focused on the discovery and development of RNA-targeted therapies, announced today that it has conducted an internal review of preliminary topline data from its Phase 2 SOLAR clinical trial of cobomarsen in patients with Cutaneous T-Cell Lymphoma (CTCL). Based on investigator assessments, these preliminary data in 37 patients suggest that cobomarsen lacks a compelling result for the study's primary endpoint, objective skin response of at least four months duration (ORR4) relative to the vorinostat control arm. Progression free survival (PFS), a secondary endpoint for the study, indicates a treatment effect in favor of cobomarsen. In addition, cobomarsen was well tolerated, with no patient discontinuations due to cobomarsen-related adverse events.

The SOLAR study was designed to evaluate the safety and efficacy of cobomarsen given by intravenous infusion in an active control comparison trial for patients with the mycosis fungoides subtype of CTCL. In December 2019, miRagen announced it would halt enrollment in the SOLAR trial well short of the intended 126 CTCL patients in order to reduce the time and resource expenditure to evaluate the drug's potential. The downsized SOLAR study is not statistically powered for superiority or equivalence.

"We have completed this preliminary evaluation and will continue to analyze the final topline data and other secondary SOLAR data as we seek a partner for cobomarsen," stated Ms. Lee Rauch, President and Chief Executive Officer. "Our research and development strategy remains focused on the advancement of our lead program MRG-229 for Idiopathic Pulmonary Fibrosis (IPF)."

In addition, as recently announced, the Board of Directors continues to evaluate strategic alternatives for the Company. Potential strategic alternatives may include, but are not limited to, an acquisition, merger, business combination, in-licensing, or other strategic transactions. There can be no assurance that this process will result in any such transaction. miRagen has not set a timetable for completion of this process and does not intend to comment further on this process unless or until the Board of Directors has approved a definitive agreement.

About miRagen Therapeutics

miRagen Therapeutics, Inc. is a clinical-stage biopharmaceutical company discovering and developing proprietary RNA-targeted therapies with a specific focus on microRNAs and their role in diseases where there is a high unmet medical need. miRagen has three clinical stage product candidates, cobomarsen, remlarsen, and MRG-110. miRagen's clinical product candidate for the treatment of certain cancers, cobomarsen, is an inhibitor of miR-155, which is found at abnormally high levels in malignant cells of several blood cancers. miRagen's clinical product candidate for the treatment of pathological fibrosis, remlarsen, is a replacement for miR-29, which is found at abnormally low levels in a number of pathological fibrotic conditions, including cutaneous, cardiac, renal, hepatic, pulmonary and ocular fibrosis, as well as in systemic sclerosis. MRG-110, an inhibitor of miR-92, is miRagen's product candidate for the treatment of heart failure and other ischemic disease. In addition to these programs, miRagen is developing a pipeline of preclinical product candidates. For more information, please visit www.miragen.com. For information on clinical trials please visit www.clinicaltrials.gov.

Note Regarding Forward-Looking Statements

This press release may contain forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical fact, including statements regarding miRagen's strategy, anticipated clinical development milestones, future operations, ability to negotiate or complete any future strategic transaction, future financial position, future revenue, projected expenses, prospects, plans and objectives of management or the expected features of or potential indications for miRagen's product candidates are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "plan," "expect," "predict," "potential," "opportunity," "goals," or "should," and similar expressions are intended to identify forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation: that miRagen has incurred losses since its inception, and anticipates that it will continue to incur significant losses for the foreseeable future; future financing activities may cause miRagen to restrict its operations or require it to relinquish rights; miRagen may fail to demonstrate safety and efficacy of its product candidates; miRagen's product candidates are unproven and may never lead to marketable products; miRagen's product candidates are based on a relatively novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all; miRagen's product candidates may cause undesirable side effects or have other properties that could delay or prevent the regulatory approval; and the results of miRagen's clinical trials to date are not sufficient to show safety and efficacy of miRagen's product candidates and may not be indicative of future clinical trial results.

miRagen has based these forward-looking statements largely on its current expectations and projections about future events and trends. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading "Risk Factors" in miRagen's Annual Report on Form 10-K and subsequent periodic and current reports filed with the Securities and Exchange Commission. Moreover, miRagen operates in a very competitive and rapidly changing environment. New risks emerge from time to time.

It is not possible for its management to predict all risks, nor can it assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements it may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. miRagen undertakes no obligation to revise or publicly release the results of any revision to such forward-looking statements, except as required by law. Given these risks and uncertainties, readers are

cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

Investor Relations Contact:
Dan Ferry
LifeSci Advisors
(617) 430-7576
daniel@lifesciadvisors.com

Source: miRagen Therapeutics, Inc.