miRagen Therapeutics Presents Interim Results from MRG-201 Phase 1 Clinical Trial Demonstrating Pharmacodynamic Activity in Human Skin Incisions

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MRG-201 has been generally well-tolerated in volunteers

Findings support further investigation of MRG-201 as a novel therapeutic for fibrotic diseases

BOULDER, Colo., April 27, 2017 (GLOBE NEWSWIRE) -- Miragen Therapeutics, Inc. (Nasdaq:MGEN), a clinical-stage biopharmaceutical company focused on the discovery and development of microRNA-targeted therapies, today presented at the Society for Investigative Dermatology (SID) 76th Annual Meeting. miRagen discussed previously announced interim results from its ongoing Phase 1 clinical trial of MRG-201. MRG-201 is designed to mimic the activity of microRNA-29, which has been shown to decrease the expression of certain genes that are involved in scar formation.

MRG-201 is being evaluated in a single center, Phase 1, double-blind, placebo-controlled, single and multiple-dose escalation clinical trial. As of mid-March 2017, 54 volunteers had participated in the clinical trial. Expression of microRNA-29 and its pharmacodynamic biomarkers was assessed in untreated skin incisions and following single or multiple administrations of MRG-201 at the site of a skin incision. Data from the trial include the following:

- Where volunteers' skin was incised without receiving MRG-201, microRNA-29 expression was decreased and direct target genes were upregulated as compared to unincised skin;
- Where volunteers received intradermal injections of MRG-201, pharmacokinetic analysis of the volunteers' plasma revealed that very little drug (less than 150 ng/mL) was generally detectable in the volunteers' blood;
- MRG-201 was generally well tolerated at all dose levels evaluated;
- Pharmacodynamic activity was seen after MRG-201 treatment: single and multiple doses of MRG-201 were generally accompanied by reduced expression of certain genes associated with fibrosis as compared to a placebo injected incision in the same volunteer; and
- Multiple administrations of MRG-201 were generally accompanied by reduced fibroplasia, a marker of scar formation, as assessed by histopathology ($p<0.01$)

"Previous studies by miRagen researchers have suggested that microRNA-29 may be an attractive therapeutic target for the treatment of cutaneous and other forms of pathological fibrosis," said Paul Rubin, M.D., miRagen's Executive Vice President of Research and Development. "We are pleased that our interim Phase 1 trial results demonstrate that MRG-201 target engagement may correlate with the impact on fibroplasia and that the treatment was generally well tolerated in intact and incised skin."

"We believe that the interim results from the MRG-201 Phase 1 clinical trial are encouraging, as we explore this initial application in scar formation. It is also an excellent example of how we apply our "foothold" clinical development strategy. We view the trial data and mechanistic evidence observed from our approach to treating fibrosis in the skin as supportive of our assertion that MRG-201 may have broader applications in other pathological fibrotic conditions," said miRagen President and CEO William S. Marshall, Ph.D. "We believe these findings support further investigation of MRG-201 as a therapeutic to inhibit scar formation, and may also provide support for applications in additional indications."

About Miragen Therapeutics, Inc.

Miragen Therapeutics, Inc. is a clinical-stage biopharmaceutical company discovering and developing proprietary RNA-targeted therapeutics with a specific focus on microRNAs and their role in diseases where there is a high unmet medical need. miRagen's two lead product candidates, MRG-106 and MRG-201, are currently in Phase 1 clinical trials. miRagen's clinical product candidate for the treatment of certain cancers, MRG-106, is an inhibitor of microRNA-155, which is found at abnormally high levels in several blood cancers. miRagen's clinical product candidate for the treatment of pathological fibrosis, MRG-201, is a replacement for miR-29, which is found at abnormally low levels in a number of pathological fibrotic conditions, including cardiac, renal, hepatic, and pulmonary fibrosis, as well as systemic sclerosis. In addition to miRagen's clinical programs, it is developing a pipeline of pre-clinical product candidates. The goal of miRagen's translational medicine strategy is to progress rapidly to first in human studies once it has established the pharmacokinetics, pharmacodynamics and safety of the product candidate in pre-clinical studies. For more information, please visit www.miragentherapeutics.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, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management 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; and miRagen's product candidates may cause undesirable side effects or have other properties that could delay or prevent the regulatory approval.

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 in under the heading "Risk Factors" in miRagen's Annual Report on Form 10-K and subsequent periodic 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.

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