miRagen Therapeutics Announces Initiation of Second Phase 1 Clinical Trial of MRG-110

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BOULDER, Colo., May 01, 2018 (GLOBE NEWSWIRE) -- miRagen Therapeutics, Inc. (NASDAQ:MGEN), a clinical-stage biopharmaceutical company focused on the discovery and development of RNA-targeted therapies, today announced the initiation of a second Phase 1 clinical trial of MRG-110 in collaboration with Servier. MRG-110 is an inhibitor of microRNA-92. In preclinical studies, MRG-110 accelerated the formation of new blood vessels, which resulted in improved perfusion of tissues and better functional outcomes in models of heart failure, peripheral artery disease and wound repair.

"We are enthusiastic about the continued development of MRG-110, which is now advancing in two ongoing Phase 1 clinical trials," said miRagen President and CEO William S. Marshall, Ph.D. "In preclinical studies, treatment with MRG-110 increased vascularization in a variety of different tissues. This resulted in increased reparative tissue formation and accelerated healing of injuries. We believe there is a significant need for therapies to treat a variety of wounds that are difficult to care for because of insufficient vascularization. The delay or lack of healing in these patients can result in significant morbidity including infection, herniation, and even death. We look forward to the continued advancement of this therapeutic approach in tissue healing applications in addition to the ongoing cardiovascular disease development plan."

In addition to evaluating the safety, tolerability and pharmacokinetics of MRG-110, the newly initiated Phase 1 clinical trial is designed to measure several exploratory endpoints that we believe to be important in establishing the intended mechanism of drug action. These endpoints include specific molecular biomarker changes, as well as pharmacodynamic endpoint analysis of increased new blood vessel growth, blood flow and effect on healing rate. MRG-110 will be administered by intradermal injection in healthy volunteers receiving induced wounds through biopsy. The biomarker information for MRG-110 obtained in this clinical trial is intended to also support clinical studies for the treatment of heart failure. miRagen and Servier believe that the outcome of the clinical trial could support development of MRG-110 for the treatment of surgical incisions in high risk populations, severe lacerations and chronic wounds. This is the second Phase 1 clinical trial to be initiated as part of the Company's MRG-110 clinical development program in collaboration with Servier, an independent international pharmaceutical company headquartered in France. MRG-110 is miRagen's third product candidate to commence human clinical trials.

About miRagen Therapeutics, Inc.
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 (MRG-106), MRG-201, and MRG-110. miRagen's clinical product candidate for the treatment of certain cancers, cobomarsen, is an inhibitor of microRNA-155, which is found at abnormally high levels in malignant cells of several blood cancers, as well as certain cells involved in inflammation. miRagen's clinical product candidate for the treatment of pathological fibrosis, MRG-201, is a replacement for microRNA-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 systemic sclerosis. MRG-110, an inhibitor of microRNA-92, is being developed under a license and collaboration agreement with Servier for the treatment of heart failure and other ischemic disease. In addition to these programs, miRagen is developing a pipeline of preclinical 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, pharmacodynamic, safety and manufacturability of the product candidate in preclinical studies. 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, future operations, 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 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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