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

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BOULDER, Colo., March 27, 2018 (GLOBE NEWSWIRE) -- miRagen Therapeutics, Inc. (NASDAQ:MGEN), a clinical-stage biopharmaceutical company focused on the discovery and development of RNA-targeted therapies, announced today the initiation of a Phase 1 clinical trial of MRG-110 (S95010) by Servier. MRG-110 is a locked nucleic acid modified oligonucleotide inhibitor of microRNA-92. In preclinical models, MRG-110 appeared to accelerate the formation of new blood vessels, which resulted in improved vascularization and improved functional outcomes. MRG-110 is the third product candidate from miRagen to enter human clinical trials. miRagen has commercialization rights for MRG-110 in the United States and Japan and Servier has rights to commercialize MRG-110 in the rest of the world.

In this clinical trial, MRG-110 will be evaluated for safety and tolerability in a systemic dosing protocol that is intended to support potential further clinical trials that may lead to regulatory approval for the potential treatment of heart failure. Later this year, miRagen plans to sponsor a separate Phase 1 clinical trial in the United States assessing the local and systemic safety and tolerability of MRG-110 after intradermal injection. miRagen recently filed an investigational new drug application, or IND, for this study which it expects to initiate in the first half of this year. In the clinical trial, miRagen plans to also examine several exploratory endpoints that are intended to provide mechanistic proof of concept and biomarker validation to support a global development plan that may include use in patients with high risk for complications after surgical incisions or chronic wounds.

“This clinical development milestone is an important step in our long-standing collaboration with Servier. The aspiration of our collaboration is to address cardiovascular and other diseases that have been difficult to treat with traditional therapeutic approaches,” said miRagen President and CEO William S. Marshall, Ph.D. “Cardiovascular disease is the leading cause of death worldwide, and over a third of the adult U.S. population suffers from at least one form of the disease. We look forward to the next step of development of MRG-110 which should guide how this product candidate may potentially be used as an innovative therapy for patients in need.”

MRG-110 is designed to inhibit the activity of microRNA-92, which has been shown in miRagen’s preclinical studies, and reported in multiple peer reviewed scientific publications, to be a regulator of new blood vessel creation. The Phase 1 trial is designed to evaluate the safety, tolerability, and pharmacokinetics of MRG-110; and to potentially establish the recommended Phase 2 clinical trial dose for the treatment of patients with heart failure. The Phase 1 clinical trial is planned to enroll 49 male subjects, aged 18 to 45. In addition, the Phase 1 clinical trial results will be analyzed for biomarkers that may provide mechanistic proof of concept and support further potential clinical trials of MRG-110 in the treatment of cardiovascular disease and certain other conditions where vascular flow is compromised. Additional details on the ongoing Phase 1 clinical trial can be found at www.clinicaltrials.gov.

Under the terms of the collaboration, Servier will pay miRagen a €3.0 million milestone for the dosing of the first patient in the Phase 1 trial.

About the miRagen / Servier Cardiovascular Collaboration

In 2011, miRagen entered into a License and Collaboration Agreement with Servier for the research, development, and commercialization of RNA-targeting therapeutics in cardiovascular disease. Under the agreement, Servier has an exclusive license to research, develop, and commercialize MRG-110 outside the United States and Japan. Servier also has the right to name one additional target to the collaboration through September 2019. Servier’s rights are limited to therapeutics in the field of cardiovascular disease and in their territory, which is worldwide except for the United States and Japan. miRagen retains all other rights including commercialization of therapeutics developed under the collaboration. Servier is responsible for funding certain costs of research and development under the collaboration. miRagen is also eligible to receive research and development milestone payments, commercial milestone payments, and royalties on the sale of the products developed under the collaboration, if any.

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.

Investor/Media Contact:
Adam Levy
Chief Business Officer
(720) 407-4595
alevy@miragen.com

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