



miRagen Announces Results of Meeting With FDA Regarding the Design of Pivotal Trial for Cobomarsen in ATLL

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BOULDER, Colo., Aug. 20, 2020 (GLOBE NEWSWIRE) -- miRagen Therapeutics, Inc. (NASDAQ: MGEN), a clinical-stage biopharmaceutical company focused on the discovery and development of proprietary RNA-targeted therapies with a specific focus on microRNAs, today announced that the company held a Type C meeting with the FDA Office of Oncologic Diseases on August 11, 2020 to discuss miRagen's future clinical development plans for cobomarsen for the potential treatment of Adult T-Cell Leukemia/Lymphoma (ATLL).

"We received clear guidance from the FDA on a potential path to registration in this ultra rare indication based upon a small randomized controlled trial with a primary endpoint of progression free survival that is appropriate for a maintenance therapy. With additional cobomarsen data from the ongoing Phase 2 SOLAR trial in Cutaneous T-cell lymphoma (CTCL) patients expected before the end of the year, we will be able to determine next steps for this program, which may include seeking a partner for the late-stage development and potential commercialization of cobomarsen in miR-155 elevated cancers including CTCL and ATLL" said William S. Marshall, Ph.D., miRagen's President and Chief Executive Officer.

MicroRNA-155 overexpression has been shown to be a poor prognostic indicator in a variety of hematological malignancies and solid tumors. Cobomarsen is an inhibitor of miR-155 that has demonstrated initial safety and efficacy data in a phase 1 clinical trial in which patients with CTCL, ATLL, DLBCL and CLL patients were treated. miRagen believes that the now defined regulatory pathway for potential approval of cobomarsen for both CTCL and ATLL is an important incremental step in its broader strategy to evaluate cobomarsen as a potential treatment for a variety of miR-155 elevated blood cancers. Cobomarsen has received orphan drug designation in the United States for the treatment of T-cell lymphomas, such as CTCL and ATLL. This designation can provide development and commercial incentives for designated compounds and medicines, including market exclusivity.

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, 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. 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, anticipated clinical development milestones, 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 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.

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