miRagen Therapeutics Receives EU Orphan Medicinal Product Designation for MRG-106 for the Treatment of Cutaneous T-cell Lymphoma

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BOULDER, Colo., May 24, 2017 (GLOBE NEWSWIRE) -- miRagen Therapeutics, Inc. (NASDAQ:MGEN), a clinical-stage biopharmaceutical company focused on the discovery and development of RNA-targeted therapies, today announced that the European Commission (EC) granted orphan medicinal product designation to miRagen's product candidate, MRG-106, for the treatment of cutaneous T-cell lymphoma (CTCL). CTCL occurs when certain types of T-cells become cancerous and cause debilitating tumors in the skin and in other parts of the body.

The U.S. Food and Drug Administration (FDA) granted orphan drug designation to MRG-106 for the treatment of mycosis fungoides, the most common subtype of CTCL, earlier this year.

"The European orphan drug designation for MRG-106 is another regulatory milestone which we believe further validates the medical need for novel therapies in the treatment of CTCL," said miRagen President and Chief Executive Officer, William S. Marshall, Ph.D. "MRG-106 has now been granted orphan drug designation from the FDA and the EC, and we look forward to continuing to develop this product candidate as a potential therapy for patients suffering from this disease."

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'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 microRNA-29, which is found at abnormally low levels in a number of pathological fibrotic conditions, including cutaneous, 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.miragenrx.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 orphan drug status in the European Union is subject to exclusions similar to those in the United States, and miRagen may be unsuccessful in maintaining orphan drug designation for its product candidates.

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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