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Agile Announces Dosing of First Patients in Twirla(R) Phase 3 SECURE Study

PRINCETON, N.J., Sept. 29, 2014 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc., (Nasdaq:AGRX) a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products, today announced that the first patients have been dosed in its SECURE study. The SECURE study is a single-arm, open-label, multicenter Phase 3 trial that will assess the efficacy, safety and tolerability of Agile's investigational once-weekly transdermal contraceptive patch, Twirla® (AG200-15).

"The successful dosing of the first patients marks a critical milestone in the SECURE development program. Throughout the planning of this trial, we focused on selecting the right investigators who will identify patients with a high potential for compliance and on implementing measures that will facilitate conducting a trial with rigor and close oversight," said Elizabeth Garner, M.D., M.P.H., Chief Medical Officer and Senior Vice President at Agile. "We are encouraged by the high level of interest in this study shown by both investigators and patients and anticipate completing the enrollment period within the next four to six months."

Approximately 2,100 female subjects are expected to be enrolled at up to 70 sites in the United States. Patients meeting all eligibility criteria will use the patch for up to one year. The study will assess the effectiveness of the patch in preventing pregnancy using the Pearl Index as the primary contraceptive efficacy measure. Safety and tolerability will also be evaluated.

"The start of the SECURE study is an important milestone towards achieving our goal of addressing the substantial unmet need for a more convenient method of contraception for today's busy young women," said Al Altomari, President and Chief Executive Officer at Agile. "The commencement of patient dosing marks a significant achievement for all involved."

Twirla, an investigational prescription contraceptive patch, is a combined hormonal contraceptive patch that contains the active ingredients ethinyl estradiol and levonorgestrel, both of which have an established history of efficacy and safety in currently marketed combination low-dose oral contraceptives. Developed using Agile's proprietary Skinfusion® technology to deliver both hormones over a seven-day period at levels comparable to currently marketed low-dose oral contraceptives, Twirla is applied once weekly for three weeks followed by a patch-free week, and is designed to promote patient compliance.

More information on the clinical trial is available at www.clinicaltrials.gov.

About Agile

Agile Therapeutics is a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products. Our product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch currently in Phase 3 clinical development. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to provide advantages over currently available patches and is intended to optimize patch adherence and patient acceptability. For more information, please visit the company website at www.agiletherapeutics.com.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" related to the Company's timeline for clinical trials and potential market opportunity for its product candidates. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates", "estimates," "expects," "plans," "intends," "may," "could," 'might," "will," "should" or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current expectations that involve risks, potential changes in circumstances, assumptions and uncertainties. Any or all of the forward-looking statements may turn out to be wrong, or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. For example, our statements about the timing and conduct of our clinical trial could be affected by the potential that we experience difficulty in identifying and initiating sites and enrolling subjects, we identify serious side effects or other safety issues, we do not have clinical supply of our product candidate that is adequate in amount and quality and supplied in a timely fashion, and the inherent risks of clinical development; our statements about the potential commercial opportunity could be affected by the potential that our product does not receive regulatory approval, does not receive reimbursement by third party payors, or a commercial market for the

product does not develop because of any of the risks inherent in the commercialization of contraceptive products. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. All forward looking statements are subject to risks detailed in our filings with the U.S. Securities and Exchange Commission, including the Company's Registration Statement on Form S-1, and the prospectus filed in connection therewith and our Report on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

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