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Agile Therapeutics Announces Completion of Patient Recruitment in Twirla(R) Phase 3 SECURE Clinical Trial

Company on Track to Complete Study Enrollment for Its Combined Hormonal Contraceptive Patch by the End of Third Quarter 2015

PRINCETON, N.J., Aug. 31, 2015 (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, announced today that active recruitment has closed in its ongoing single-arm, open-label Phase 3 SECURE clinical trial of Twirla® (AG200-15), its investigational contraceptive patch. Participating sites will complete screening over the next two weeks, and the Company expects to complete enrollment by the end of the third quarter 2015.

"We have completed active recruitment of patients into our Phase 3 SECURE clinical trial, which is a crucial milestone in the trial and for Agile," said Al Altomari, President and Chief Executive Officer of Agile. "Together with all of our partners, including our CRO and manufacturing partner, we believe we have the right development plan in place to achieve our goal of making Twirla available as a convenient contraceptive option for women. We will continue our focus on quality management of the trial and execution of our broader business plan for developing women's contraceptive products."

Twirla is the Company's lead product candidate and 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. Twirla was 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.

"The Phase 3 SECURE clinical trial is progressing with continued focus on excellent study conduct," stated Elizabeth Garner, M.D, M.P.H, Chief Medical Officer of Agile. "Our clinical investigators and their teams have worked diligently to identify quality subjects through the multi-step screening and enrollment process, which includes an electronic diary run-in period of no less than 2 weeks. In addition to successful completion of the eDiary run-in, all enrolled subjects must meet a number of entry criteria designed to optimize compliance with the study patch and electronic diary. As of today, we believe there are currently sufficient subjects in the screening process to allow us to achieve our target enrollment by the end of the third quarter 2015."

The SECURE study is a multicenter Phase 3 clinical trial of Twirla which will enroll approximately 2,100 female subjects who will receive treatment 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.

About Agile Therapeutics, Inc.

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. The company may occasionally disseminate material, nonpublic information on the company website.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" related to the Company's, projected 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 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 Annual Report on Form 10-K and our Quarterly Reports 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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