Agile Initiates Phase 3 SECURE Study for Twirla(TM)

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- *Twirla (AG200-15) is a Novel Low-Dose Combined Hormonal Contraceptive Patch Designed Using the Company's Proprietary Transdermal Skinfusion® Technology*

- *Confirmatory SECURE Study To Build Upon Data From Previous Phase 3 Studies in Support of the Company's New Drug Application to the U.S. Food And Drug Administration*

PRINCETON, N.J., Sept. 16, 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 the initiation of its Phase 3 study called SECURE (Study to Evaluate Contraceptive Use, Reliability and Effectiveness). The SECURE study is designed to assess the efficacy, safety and tolerability of Agile's investigational once-weekly transdermal contraceptive patch, Twirla™ (AG200-15). Twirla will be the only low-dose combined hormonal contraceptive patch and delivers 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.

"In planning the SECURE study, we focused on identifying experienced clinical sites with expertise in conducting contraceptive studies, and leveraging technology to support patient compliance and retention in the trial," said Elizabeth Garner, M.D., M.P.H., and Chief Medical Officer at Agile. "We believe we have the right measures in place to achieve our goal of making Twirla available to women as an effective and convenient contraceptive option."

The SECURE study is a single-arm, open-label, multicenter Phase 3 study of Twirla (AG200-15) that will enroll approximately 2,100 female subjects who 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 initiation of the confirmatory SECURE clinical study continues to proceed as planned. We are pleased to report that screening of patients is underway at some of the sites and we have our first subjects in the study run-in period using the e-diary," said Al Altomari, Chief Executive Officer and President of Agile. "We continue to believe there is a significant opportunity to provide women with a more convenient contraceptive option that adapts to their busy lifestyles and we remain committed to execute on our goal to address this important unmet need."

The Company continues to expect an enrollment period of four to six months. The results from the SECURE study are intended to support the Company's New Drug Application with the U.S. Food and Drug Administration for marketing approval of Twirla (AG200-15) in the United States.

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

About Twirla™ (AG200-15)

Twirla™, also known as AG200-15, is an investigational once-weekly prescription contraceptive patch. Twirla is a combined hormonal contraceptive, or CHC, patch that contains the active ingredients ethinyl estradiol, or EE, which is a synthetic estrogen, and levonorgestrel, or LNG, which is a type of progestin, a synthetic steroid hormone, both of which have an established history of efficacy and safety in currently marketed combination low-dose, oral contraceptives. Twirla is designed using our proprietary Skinfusion® technology to deliver both hormones over a seven-day period at levels comparable to currently marketed low-dose oral contraceptives. Twirla is designed to promote enhanced patient compliance. The patch is applied once weekly for three weeks, followed by a week without a patch.

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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