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Agile Therapeutics Reports Additional Phase 3 SECURE Study Results Relating to Twirla® at ACOG 2017

Newly Reported Bleeding Profile Shows Reduction in Unscheduled Bleeding/Spotting Days

PRINCETON, N.J., May 06, 2017 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc., (NASDAQ:AGRX), a women's healthcare company, today announced the presentation of additional results of its Phase 3 SECURE trial of its investigational low-dose combination hormone contraceptive patch, Twirla® (AG200-15). Anita Nelson, MD, Professor and Chair of Obstetrics and Gynecology at the College of Osteopathic Medicine of the Pacific, presented a summary of SECURE clinical trial results, which included new data on the bleeding profile of clinical trial subjects during a poster presentation at the 2017 Annual Clinical and Scientific Meeting of the American Congress of Obstetricians and Gynecologists (ACOG) in San Diego, CA.

Dr. Nelson presented a summary of efficacy and safety results from the company's SECURE clinical trial, which were previously reported in January 2017. The poster presentation also reported analyses on the bleeding profile, which demonstrated that unscheduled bleeding/spotting days per month decreased from a mean of 3.1 days in Cycle 1 to 1.6 days in Cycle 13. In addition, scheduled bleeding/spotting remained consistent during all cycles, with a reported mean of 3.1 to 3.7 days per month. Dr. Nelson also discussed the role of study designs and populations in contraceptive clinical trials.

"The SECURE trial was unique for its broad inclusion criteria and enrollment of diverse women with demographic backgrounds reflective of real-world settings," remarked Dr. Nelson. "It is important to provide women with a variety of contraceptive options and information so they can identify the hormonal combination and delivery method best suited to their needs and lifestyle."

The Phase 3 SECURE study was a multicenter, single-arm, open-label, 13 cycle trial designed to evaluate the efficacy, safety and tolerability of AG200-15, also known as Twirla, in 2032 healthy women, aged 18 years and over, at 102 investigational sites across the United States. The SECURE study design included a number of stringent elements, including exclusion of treatment cycles for use of back-up contraception and lack of sexual activity. The SECURE clinical trial also had broad entry criteria, placed no limitations on BMI or other demographic factors during enrollment, and enrolled a large and diverse patient population in order to allow efficacy to be assessed across different, real-world groups, as requested by the FDA. These entry criteria resulted in the inclusion of a substantial number of women with a high BMI, who have frequently been underrepresented in past contraceptive studies.

Elizabeth Garner, MD, MPH, Chief Medical Officer of Agile Therapeutics, commented, "We are pleased with the results of the SECURE trial and believe our study may set a new standard for hormonal contraceptive studies. Our study entry criteria resulted in the inclusion of a real-world study population, including women who have frequently been underrepresented in past contraceptive studies. We believe the SECURE trial has generated valuable new data that will contribute to the evolving understanding of how co-morbidities such as obesity and other factors impact hormonal contraceptive effectiveness."

For more information, please visit the company website at www.agiletherapeutics.com.

About Agile Therapeutics, Inc.
Agile Therapeutics is a forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product candidates are designed to provide women with contraceptive options that offer freedom from taking a daily pill, without committing to a longer-acting method. Our lead product candidate, Twirla®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch that recently completed Phase 3 trials. 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 adhesion and patient wearability. 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 regulatory submissions. 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 beliefs and expectations of our management team that involves 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. Our statements about the results and conduct of our clinical trial could be affected by the potential that there are changes in the data or interpretation of the data by the FDA (for example, the FDA may include additional pregnancies in its calculation of the Pearl Index, which would increase the Pearl Index), whether the results will be deemed satisfactory by the FDA (for example, we may describe the results of the SECURE trial as positive, the FDA may disagree with that characterization), and whether additional studies will be required or other issues will arise that will delay resubmission of our NDA or negatively impact acceptance, review and approval of Twirla by the FDA; 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; our statements about the planned resubmission of our NDA for Twirla could be affected by the potential that additional analyses of issues identified in our complete response letter from the FDA are required to be completed that were not previously anticipated, that our ongoing tests to support our resubmission are not completed on time, that the third parties we rely on to perform services in support of our NDA resubmission do not complete their work in a timely fashion and that other issues will arise that will delay resubmission of our NDA or negatively impact acceptance, review, and approval of Twirla by the FDA. 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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