



Agile Therapeutics, Inc. Presents Additional Analyses of AG200-15 (Twirla®) Phase 3 SECURE Study Results at the 2018 North American Forum on Family Planning (NAFFP)

October 24, 2018

PRINCETON, N.J., Oct. 24, 2018 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc., (Nasdaq: AGRX), a women's healthcare company, today announced an oral presentation regarding predictors of pregnancy in the Phase 3 SECURE study of the investigational low-dose, once-weekly contraceptive patch, AG200-15 (Twirla®). Thomas D. Kimble, MD, Associate Dean and Assistant Professor of Obstetrics and Gynecology at Eastern Virginia Medical School, presented the new analyses at the North American Forum on Family Planning (NAFFP), "The Forum", on October 20, 2018 in New Orleans, LA.

The presentation, entitled *Body Mass Index and Weight are Predictors of Pregnancy in a Phase 3 Multicenter Contraceptive Efficacy Study of AG200-15, a Low-Dose Combination Hormonal Contraceptive Patch*, included detailed findings of statistical modeling performed to identify variables predictive of pregnancy in the SECURE study. The abstract is published in the October 2018 issue of *Contraception*.

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 included a number of stringent design elements, including exclusion of treatment cycles for use of back-up contraception and for lack of sexual activity. The study 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.

About Twirla® (AG200-15)

Twirla (levonorgestrel/ethinyl estradiol transdermal system) or AG200-15 is an investigational low-dose, once-weekly contraceptive patch. AG200-15 is a combined hormonal contraceptive (CHC) patch that contains the active ingredients ethinyl estradiol (EE), a type of estrogen and levonorgestrel (LNG), a type of progestin. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch. Agile received a complete response letter (CRL) from the FDA on December 21, 2017 relating to the New Drug Application (NDA) for Twirla. In the CRL, the FDA informed the Company that the product could not be approved in its present form due to deficiencies related to quality adhesion test methods, observations identified during the pre-approval inspection of the manufacturing facility for Twirla, and because of questions the FDA had on the in vivo adhesion properties of Twirla and their potential relationship to the Company's Phase 3 clinical trial results. The FDA provided a path forward for resubmitting the Twirla NDA and suggested the Company conduct a comparative wear study to evaluate whether Twirla demonstrates generally similar adhesion performance to Xulane®. The Company plans to meet with the FDA to gain agreement on the specific design and success criteria for a wear study as soon as possible. The Company believes the FDA provided guidance on a path forward for addressing the manufacturing issues related to Twirla in its minutes from the End of Review Type A meeting, received by the Company in May 2018.

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® (levonorgestrel/ethinyl estradiol transdermal system) or AG200-15, is an investigational low-dose, non-daily, prescription contraceptive. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to allow drug delivery through the skin. For more information, please visit the company website at www.agiletherapeutics.com. The Company may occasionally disseminate material, nonpublic information on the Company's website.

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Xulane® is a registered trademark of Mylan N.V.

Forward-Looking Statements

Certain information contained in this press release includes "forward-looking statements", within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, related to our regulatory submissions for Twirla. We may, in some cases use terms such as "believes," "potential," "continue," "plans," "may," "might," 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 involve risks, potential changes in circumstances, assumptions, and uncertainties, including statements regarding our intention to meet with the FDA, the timing of which is subject to FDA's discretion and which may not result in a clear agreement on the issues discussed, and our belief that a reformulation of Twirla may not be necessary. 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. These forward looking statements are subject to risks and uncertainties including risks related to the FDA requiring us to reformulate Twirla, our ability to develop a reformulation that will address the FDA's concerns, including showing bioequivalence, if necessary, our ability to successfully complete the suggested wear study and that the results do not support a conclusion by the FDA that Twirla has demonstrated adequate adhesion, and, the potential that we may be required to conduct an additional Phase 3 trial, the likelihood that we will require additional correspondence with the FDA prior to the resubmission of our NDA, in addition to the planned correspondence regarding the design of the suggested wear study, our ability to resubmit and the timing of our resubmission of the NDA for Twirla, FDA acceptance and approval of the resubmitted NDA, or whether other issues will arise that will negatively impact acceptance, review, and approval of Twirla by the FDA, including a determination by the Advisory Committee that Twirla should not be approved, our ability to address the deficiencies identified by the FDA in the CRL issued in December 2017 and in the Type A meeting minutes issued in May 2018, the fact that our

existing cash and cash equivalents may not be sufficient to fund the completion of the development and regulatory review process for Twirla, our ability to raise capital when needed to complete the development and regulatory review process for Twirla, and unforeseen market factors or events in our clinical and manufacturing development plans and the other risks set forth in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. 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.

SOURCE: Agile Therapeutics, Inc.

Contact:

Investor Relations

Agile Therapeutics

609-683-1880



Source: Agile Therapeutics, Inc.