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Agile Therapeutics Announces Results of its Pre-Submission Meeting with FDA

Confirms Plans to Re-submit New Drug Application for Twirla® by the end of the Second Quarter of 2017

PRINCETON, N.J., April 11, 2017 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq:AGRX), a women's healthcare company, today announced it has received the final meeting minutes from its recent New Drug Application (NDA) pre-submission meeting with the U.S. Food and Drug Administration (FDA) for its lead product candidate, Twirla®, an investigational low-dose combined hormonal contraceptive patch. Based on the feedback from the FDA, Agile believes it has the necessary information to complete the resubmission of its NDA, which is expected to be submitted by the end of the second quarter of 2017.

The Company reported top-line results from its Phase 3 SECURE clinical trial in January 2017, and plans to prepare the resubmission of its NDA for Twirla based primarily on the results from the SECURE trial.

Agile requested the meeting with the FDA, which took place on March 14, 2017, in order to share preliminary data from the SECURE trial, including key safety data and BMI-related efficacy findings, and to seek FDA input as to whether the trial results constitute a basis for addressing the clinical deficiencies cited in the FDA's prior Complete Response Letter (CRL). Agile also requested feedback on whether the proposed NDA content will meet the FDA's requirements for submission.

The FDA indicated that based on the preliminary information provided by the Company, the SECURE trial results appear acceptable for resubmission. The FDA provided responses to the Company regarding the presentation of efficacy, safety and clinical pharmacology analyses in the NDA and requested that subgroup analysis of efficacy by body weight be provided. The FDA also provided feedback on the Company's proposed approach to the FDA's other questions in the CRL, including those questions relating to analysis to support manufacturing controls and release specifications and use of laser etching on the Twirla patches.

Pre-submission meetings with the FDA are typically requested by a sponsor company and intended to provide a sponsor company the opportunity to ask the FDA process questions about a company's planned NDA submission, not to discuss the potential for approval. Therefore, the FDA did not provide the Company any feedback on whether the results of the SECURE trial and the contents of the planned, resubmitted NDA will be sufficient to obtain regulatory approval of Twirla. Consistent with other NDAs, product labeling will be addressed as part of the FDA's review of the resubmitted NDA and will be based on the product's overall efficacy and safety profile.

About Agile Therapeutics

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.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" related to the Company's clinical trials and 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," "appears" 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. Any or all 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, while

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, or potentially delay commercial launch of Twirla. 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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