



July 27, 2017

Agile Therapeutics Announces FDA Acceptance of the NDA Resubmission of Twirla®

FDA Assigns Prescription Drug User Fee Act (PDUFA) Goal Date of December 26, 2017

PRINCETON, N.J., July 27, 2017 (GLOBE NEWSWIRE) -- [Agile Therapeutics, Inc.](#) (Nasdaq:AGRX), a forward-thinking women's healthcare company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's New Drug Application (NDA) resubmission for Twirla® (AG200-15), an investigational low-dose combined hormonal contraceptive patch. The NDA resubmission was submitted on June 26, 2017 and is intended to address a Complete Response Letter (CRL) issued by the FDA in February 2013, which recommended that Agile conduct a new clinical trial and provide additional information on the manufacturing process for Twirla. The FDA stated that it considers the resubmission to be a complete response to the CRL and established December 26, 2017 as the Prescription Drug User Fee Act (PDUFA) goal date.

"We are pleased that the FDA has acknowledged our NDA resubmission as a complete response to the CRL. The acceptance of our data package for substantive review represents a significant milestone for the Company and we look forward to continuing to work with the FDA during their review," said Al Altomari, Chairman and Chief Executive Officer of Agile. "Now that we have received our expected PDUFA goal date, we intend to turn our full attention to implementing our commercialization plans for Twirla, if approved, and continue to work towards our goal of offering women a new low-dose contraceptive patch."

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. Follow Agile on social media: [@agilether](#). The company may occasionally disseminate material, nonpublic information on the company website.

About Twirla®

Twirla (ethinyl estradiol and levonorgestrel transdermal system) or AG200-15 is an investigational once-weekly prescription contraceptive patch. AG200-15 is a combined hormonal contraceptive (CHC) patch that contains the active ingredients ethinyl estradiol (EE), a synthetic estrogen, and levonorgestrel (LNG), a type of progestin, a synthetic steroid hormone. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch.

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 negatively impact 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. 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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