December 22, 2017

Agile Therapeutics, Inc. Receives a Complete Response Letter from the FDA for Twirla® (AG200-15) for the Prevention of Pregnancy

PRINCETON, N.J., Dec. 22, 2017 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc., (NASDAQ:AGRX), a women's healthcare company, today announced that the U.S. Food and Drug Administration (FDA) issued a complete response letter (CRL) in response to the New Drug Application (NDA) resubmission for the Company's investigational non-daily, low dose combination hormonal contraceptive patch, Twirla (AG200-15). The resubmission of the NDA, which is seeking approval for Twirla was accepted for review earlier this year. The Prescription Drug User Fee Act (PDUFA) goal date was December 26, 2017. The CRL states that the FDA has determined that it cannot approve the NDA in its present form.

The CRL identifies deficiencies relating to quality adhesion test methods. The CRL also noted that observations identified during an inspection of a facility of the Company's third-party manufacturer, Corium International Inc., (Corium), for the Twirla NDA must be resolved. Lastly, the CRL questions the in vivo adhesion properties of Twirla and their potential relationship to the SECURE phase 3 clinical trial results. The CRL contains recommendations for developing manufacturing in-process tests for ensuring the quality and in vivo adhesion of the commercial scale product as well as the finished drug specifications and release test method for adhesion. The CRL also recommends that the Company assess the in vivo adhesion properties demonstrated in the SECURE clinical trial. Finally, the CRL recommends that the Company address the implications of clinical trial subject patch compliance and the withdrawal and dropout rates. The CRL does not identify any specific issues relating to the safety of Twirla.

During the review cycle, the Company submitted an amendment to the NDA in response to an information request from the FDA on the issues related to quality adhesion test methods cited in the CRL. In addition, Corium also provided the FDA responses addressing each of the observations made during the FDA's facility inspection on November 20, 2017 and December 1, 2017. The CRL acknowledges receipt of the Company's NDA amendment submitted on December 1, 2017, and states that the amendment was not reviewed prior to the FDA's action. The FDA indicated that applicable sections of the amendment submitted by Agile could be incorporated when responding to deficiencies noted in the CRL.

"We are clearly disappointed, and we are evaluating the FDA's response," said Al Altomari, chairman and chief executive officer, Agile Therapeutics. "We intend to request a meeting with the FDA as soon as possible to discuss the points raised in the CRL and discuss a path to approval for Twirla. We will work closely with the FDA to address the points raised in the CRL as quickly as possible."

Company to Host Conference Call

Agile Therapeutics will host a conference call on December 22, 2017 at 8:00 a.m. Eastern Time to discuss the Company's regulatory update. A question and answer session will follow Agile Therapeutics' remarks. To participate on the live call, please dial (844) 413-1773 (domestic) or (678) 865-8976 (international), and provide the conference ID number: 3979609.

A live audio webcast of the call will be available via the "Investor Relations" page of the Agile Therapeutics website, www.agiletherapeutics.com. Please log on through Agile Therapeutics' website approximately 10 minutes prior to the scheduled start time. A replay of the webcast will be archived on Agile Therapeutics' website for 60 days following the call.

About Twirla® (AG200-15)
Twirla (levonorgestrel/ethinyl estradiol 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 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.

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 a 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 while optimizing patch adhesion and comfort for the patient. 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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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 our ability to adequately and timely respond to the deficiencies in the Twirla CRL issued by the FDA may be affected by whether any such response will be accepted by the FDA, our ability and timing to resubmit the NDA for Twirla, FDA acceptance and approval of the resubmitted NDA, the FDA may require additional studies to address the concerns raised in the CRL (for example, if it is determined that the product adhesion concerns are due to the design or formulation of the drug product, the FDA may recommend that we design a new transdermal system and conduct another clinical trial with the new transdermal system in a U.S. population), or whether other issues will arise that will negatively impact acceptance, review, and approval of Twirla by the FDA: our statements about the results of our clinical trial could be affected by the potential that there are changes in the interpretation of the data by the FDA (for example, the FDA continues to question the number of pregnancies included in our results and they may adjudicate additional pregnancies); our statements about the potential commercial opportunity could be affected by potential labeling restrictions, 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.

SOURCE: Agile Therapeutics, Inc.

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