Agile Therapeutics, Inc. Provides Regulatory Update and Reiterates Cash Guidance

January 10, 2019

Discussions with FDA on Design of Comparative Wear Study of Twirla® and Xulane®Completed

Cash Expected to Enable Company to Fund Operations into Second Quarter of 2019

PRINCETON, N.J., Jan. 10, 2019 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc., (Nasdaq: AGRX), a women's healthcare company, today announced that on January 9, 2019 it received final meeting minutes from its December 11, 2018 meeting with the U.S. Food and Drug Administration's ("FDA") Division of Bone, Reproductive, and Urologic Products ("DBRUP"). The Company met with DBRUP to discuss the design of a comparative wear study between Twirla® and Xulane® (the "comparative wear study") as suggested by FDA's Office of New Drugs ("OND") in its decision on the Company's previously announced formal dispute resolution request.

In its meeting with DBRUP, the Company discussed the specific design and success criteria of the comparative wear study, which is intended to demonstrate adequate adhesion via non-inferiority of Twirla to Xulane, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion. After consultation with DBRUP, the Company has initiated a crossover wear study in approximately 80 healthy women with a Body Mass Index of less than 35 kg/m^2 who will be randomized to wear either Twirla or Xulane for the first week and then switched to the patch not initially worn for the second week. The overall design of this comparative wear study follows the FDA's guidance with respect to abbreviated new drug applications, entitled *Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs*.

"Now that we have completed our discussions with the FDA, we are eager to complete the comparative wear study and resubmit our Twirla new drug application ("NDA"). I can confirm, as we previously stated, that we expect to complete the study in the first quarter of 2019 and to resubmit our NDA in the first half of 2019, which gives us the opportunity to receive approval by the end of 2019," said Al Altomari, Chairman and Chief Executive Officer of Agile Therapeutics, Inc.

The FDA has previously informed the Company that in connection with its review of the Twirla NDA, the FDA plans to bring the safety and efficacy of Twirla to an Advisory Committee. The Company also expects that the FDA will conduct a pre-approval inspection of the Company's third-party manufacturer's facility, which must be successfully completed prior to approval.

The Company believes that its unaudited cash and cash equivalents as of December 31, 2018, will be sufficient to meet its projected operating requirements into the second quarter of 2019, which will include completion of the comparative wear study. The Company will require additional capital to fund operating needs for the remainder of the second quarter of 2019 and beyond, including among other items, preparation for an anticipated Advisory Committee meeting to discuss safety and efficacy of Twirla, the completion of its commercial plan for Twirla, which primarily includes validation of the commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of its other potential product candidates.

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. The Company has completed its Phase 3 clinical trials of Twirla and is pursuing regulatory approval in the U.S. Agile received a complete response letter (CRL) from the FDA in December 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, among other things, the *in vivo* adhesion properties of Twirla and their potential relationship to the Company's Phase 3 clinical trial results. The Company initiated formal dispute resolution with the FDA in June 2018 in response to the FDA's position on Twirla's *in vivo* adhesion properties, and in October 2018, the FDA's Office of New Drugs formally denied the Company's appeal but provided a path forward for seeking regulatory approval for Twirla, which the Company is in the process of pursuing.

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), also known as 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., and Ortho Evra® is a registered trademark of Johnson & Johnson.

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 and projected cash position. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "likely," "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 involve risks,

potential changes in circumstances, assumptions, and uncertainties, including statements regarding the fact that our existing cash and cash equivalents likely will not be sufficient to fund our current and planned operations beyond the second quarter of 2019, which raises substantial doubt about our ability to continue as a going concern, and which, in turn, may create negative reactions to the price of our common stock making it more difficult to obtain financing in the future, our intention to complete a comparative wear study of Twirla and Xulane, which may not yield positive results, 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 our ability to manage costs and execute on our operational and budget plans, 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 comparative wear study as discussed with DBRUP and that the results of such comparative wear study do not support a conclusion by the FDA that Twirla has demonstrated adequate adhesion, and, the potential that we will not complete the comparative wear study in the timeframe we expect, 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, 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.

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Source: Agile Therapeutics, Inc.