Agile Therapeutics to Present In Vivo Adhesion Data from Two Phase 1 Studies at the 2nd Annual Formulation & Drug Delivery USA Congress

March 15, 2019

PRINCETON, N.J., March 15, 2019 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc., (Nasdaq: AGRX), a women's healthcare company, today announced that an abstract presenting data from two Phase 1 in vivo wear studies on the adhesion of Twirla® has been selected for a poster presentation during the 2nd Annual Formulation & Drug Delivery USA Congress being held March 18th – 19th, 2019 in San Diego, California. The poster, titled "*Results of Two Phase 1 Clinical Trials on the Adhesion Profile of AG200-15, An Investigational Transdermal Contraceptive Delivery System,"* will be presented by lead author Terrance Ocheltree, PhD. Dr. Ocheltree previously served as both an FDA Reviewer and as Director of the Division of New Drug Quality Assessment II at the FDA.

The adhesion profile of Twirla (AG200-15) was recently evaluated in two single-center studies. The company performed the first, a single-arm pilot wear study (ATI-CL26), to inform the design of the second, a crossover wear study (ATI-CL25) comparing Twirla to Xulane®, a marketed generic contraceptive patch. The poster presentation will include adhesion and safety data from both studies. The results of these studies support an acceptable in vivo adhesion profile for Twirla, and both patches were generally well tolerated.

About Twirla® (AG200-15)
Twirla (levonorgestrel/ethinyl estradiol transdermal system) or AG200-15 is an investigational low-dose, once-weekly 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. The Company plans to resubmit the Twirla NDA in the first half of 2019.

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.

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. 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 our conclusion that Twirla has acceptable adhesion and our expectations about Twirla and the timing of our planned resubmission of the Twirla NDA. 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 available cash and our ability to obtain additional funding to fund our business plan without delay and to continue as a going concern, our ability to adequately and timely respond to the deficiencies in the second Twirla CRL issued by the FDA on December 21, 2017, the potential that the FDA determines that our data do not support resubmission or approval of Twirla NDA, including the conclusion that Twirla has acceptable adhesion, and requires us to conduct additional studies to address the concerns raised in the 2017 CRL, our ability to resubmit the Twirla NDA and obtain and maintain regulatory approval of our product candidates, and the labeling under any approval we may obtain, our third-party manufacturer, Corium International, Inc.'s ("Corium") inability to complete any work or provide any data and other information necessary to support the resubmission and approval of our Twirla NDA, our ability along with Corium to complete successfully the scale-up of the commercial manufacturing process for Twirla, including the qualification and validation of equipment related to the expansion of Corium's manufacturing facility and to pass a likely FDA pre-approval inspection, the performance and financial condition of Corium or any of the suppliers to our third-party manufacturer, the success and timing of our clinical trials or other studies, our ability to retain key employees, regulatory and legislative developments in the United States and foreign countries, 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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