Agile Therapeutics to Present Combined Safety Data from Three Phase 3 Studies at the 2019 ACOG Annual Meeting

May 3, 2019

PRINCETON, N.J., May 03, 2019 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc., (Nasdaq: AGRX), a women's healthcare company, today announced that the combined safety data from three Phase 3 studies of Twirla® (AG200-15), an investigational, once weekly, low-dose hormonal contraceptive patch, will be presented in an interactive ePoster session at the 2019 Annual Clinical and Scientific Meeting of the American Congress of Obstetricians and Gynecologists (ACOG) being held May 3rd – 6th, 2019 in Nashville, Tennessee. The poster, titled "*Safety of AG200-15, an Investigational Transdermal Patch, in Three Phase 3 Studies,"* will be presented by lead author Anita Nelson, M.D. Dr. Nelson, Professor and Chair of Obstetrics and Gynecology, Western University of Health Sciences, served as Principle Investigator for SECURE, the pivotal Phase 3 study of Twirla (AG200-15).

The presentation details are as follows:

Poster Title:	*Safety of AG200-15, an Investigational Transdermal Patch, in Three Phase 3 Studies*
Poster ID:	1J
Poster Session:	ePoster Session J
Date:	Saturday May 4, 2019
Time:	11:30 am – 12:30 pm CT

The presentation will report combined safety data in over 3,400 women, including treatment emergent adverse events (TEAEs) and serious adverse events (SAEs), from three Phase 3 studies: the SECURE study (ATI-CL23), single-arm, 13-cycle, open-label, conducted in 2014-2016; and ATI-CL12 and ATI-CL13, which were open-label, randomized, active-controlled (an approved oral contraceptive) trials, conducted in 2010-2011.

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 second quarter 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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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 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 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, 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 to retain key employees, regulatory and legislative developments in the United States, 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.

Contact:
Investor Relations
Agile Therapeutics
609-683-1880

Source: Agile Therapeutics, Inc.