Agile Therapeutics Announces Peer-Reviewed Publication of Phase 3 SECURE Study Results for Twirla® (levonorgestrel and ethinyl estradiol) Transdermal System in Contraception

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PRINCETON, N.J., Nov. 30, 2020 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today announced that *Contraception*, an international, peer-reviewed, reproductive health journal, published the primary safety, efficacy, and tolerability results from the Phase 3 SECURE study evaluating Twirla® (levonorgestrel and ethinyl estradiol) transdermal system. The results have been published online in *Contraception* (https://bit.ly/SECUREStudy) and will also appear in a future print edition of the journal.

"We at Agile are proud to have the primary data from the SECURE trial published in this well-respected journal," said Paul Korner, MD, MBA, Chief Medical Officer for Agile Therapeutics. "Twirla represents a new and important contraceptive option for women, and we hope the publication of these Phase 3 results ensures that healthcare providers have the most relevant and comprehensive information on the product ahead of the commercial launch. We want to once again thank all the women and researchers who were involved in this pivotal study."

The Phase 3 SECURE Trial was a multicenter, single-arm, open-label, 13 cycle trial designed to evaluate the efficacy, safety and tolerability of Twirla in 2,032 healthy women, aged 18 years and over, at 102 investigational sites across the United States. Based on the results of this study, Twirla was approved by the U.S. Food and Drug Administration (FDA) on February 14, 2020 for the prevention of pregnancy in women with a BMI < 30 kg/m^2 for whom a combined hormonal contraceptive is appropriate.

"The study was unique in its rigorous design and did not have restrictions on body weight or BMI, which resulted in enrollment of a diverse and demographically representative population of U.S. women," said Anita Nelson, MD, Lead Author and Primary Investigator in the SECURE study. "The publication communicates important information to Health Care Providers which affords them the opportunity to engage in a meaningful shared decision-making process with their patients."

About Twirla®
Twirla (levonorgestrel and ethinyl estradiol) transdermal system is a once-weekly combined hormonal contraceptive (CHC) patch that contains the active ingredients levonorgestrel (LNG), a type of progestin, and ethinyl estradiol (EE), a type of estrogen. Twirla is indicated for use as a method of contraception by women of reproductive potential with a body mass index (BMI) < 30 kg/m^2 for whom a combined hormonal contraceptive is appropriate to prevent pregnancy. Healthcare providers (HCPs) are encouraged to consider Twirla's reduced efficacy in women with a BMI ≥ 25 to <30 kg/m^2 before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m^2. 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 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 initial product, Twirla®, (levonorgestrel and ethinyl estradiol) transdermal system is a non-daily prescription contraceptive. Twirla uses 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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Contact:
Matt Riley
Head of Investor Relations & Corporate Communications
mriley@agiletherapeutics.com

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