Agile Therapeutics Announces Presentation of Safety and Efficacy Data of Twirla® (Levonorgestrel and Ethinyl Estradiol) Transdermal System in Women of Differing BMI Categories at ACOG Annual Meeting

April 30, 2021

PRINCETON, N.J., April 30, 2021 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today announced that a post hoc analysis of the Phase 3 SECURE Trial evaluating the safety and efficacy of Twirla® (levonorgestrel and ethinyl estradiol) transdermal system in women with BMI < 25 kg/m^2 and women with BMI 25-30 kg/m^2 will be presented at the American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting from April 30 – May 2.

Twirla was approved based on the Phase 3 SECURE Trial, a United States, multicenter, single-arm, open-label, 13-cycle trial that evaluated the efficacy, safety and tolerability of Twirla in 2,032 healthy women. Twirla is a combination of levonorgestrel and ethinyl estradiol indicated as a method of contraception for use in women of reproductive potential with a BMI < 30 kg/m^2 for whom a combined hormonal contraceptive is appropriate. The U.S. package insert also includes a Limitation of Use statement guiding prescribers to consider Twirla's reduced effectiveness 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. This post hoc analysis of SECURE assessed the efficacy, safety and tolerability of Twirla in women with BMI < 25 kg/m^2 and BMI 25-30 kg/m^2. When compared to women with BMI < 25 kg/m^2, Twirla demonstrated lower but acceptable efficacy while maintaining similar safety and tolerability in women with BMI 25-30 kg/m^2.

"The results of this post hoc analysis help to inform providers counseling women that fall within BMI 25-30 kg/m^2 who may be considering a non-oral, noninvasive contraception option," said Anita Nelson, MD, Lead Author and Primary Investigator in the SECURE study. "These data support the safety and tolerability of Twirla in women within BMI 25-30 kg/m^2 as well as those with BMI < 25 kg/m^2."

"At Agile, we are committed to addressing the needs of women through our products and the generation of new analyses that better enable healthcare providers to counsel their patients. This is directly reflective of the population enrolled in our SECURE trial," said Paul Korner, MD, MBA, Chief Medical Officer for Agile Therapeutics. "This post hoc analysis provides additional information about Twirla relative to the BMI categories for which Twirla is indicated that could facilitate data-driven conversations between healthcare providers and 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. 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 over 35 years old who smoke. Cigarette smoking increases the risk of serious cardiovascular events from CHC use. Twirla is contraindicated in women with a BMI ≥ 30 kg/m^2. Compared to women with a lower BMI, women with a BMI ≥ 30 kg/m^2 had reduced efficacy and may have a higher risk for venous thromboembolic events. 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-looking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product and 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), a transdermal system, 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. 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.

Contact:
Matt Riley
Head of Investor Relations & Corporate Communications
mriley@agiletherapeutics.com

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