Agile Therapeutics Announces Findings of First-Year Post-Marketing Pharmacovigilance in ACOG Poster Presentation

May 5, 2022

PRINCETON, N.J., May 05, 2022 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today publicly released the findings of its first year of post-marketing pharmacovigilance safety surveillance for Twirla® (levonorgestrel and ethinyl estradiol) transdermal system (LNG/EE TDS).

The contraceptive transdermal delivery system was approved by the U.S. Food and Drug Administration ("FDA") in February 2020 as a method of contraception for use in women of reproductive potential with a body mass index (BMI) < 30 kg/m^2. Approval of LNG/EE TDS was based on the SECURE study, which demonstrated safety in a large diverse group of women in a clinical trial setting. The current assessment provides an update of LNG/EE TDS safety based on real-world post-marketing adverse event reporting.

Prescriptions for LNG/EE TDS were dispensed during this post marketing period – December 2020 through December 2021 – with additional patches dispensed as samples (for a total of about 11,000 women-years). No venous thromboembolic events (VTEs) were reported, and two serious adverse events (SAEs) were reported, findings which are consistent with the safety profile reported in the SECURE study.

"These data from real-world use among a diverse US population further support the Twirla safety and tolerability profile established in the SECURE clinical trial," said Paul Korner, MD, MBA, Chief Medical Officer of Agile Therapeutics.

In addition to the safety findings, reports of TDS adhesion issues were rare, and only 14 individuals received a replacement patch over the 12-month period.

"As an investigator and clinician, it is encouraging to see that Twirla's safety and tolerability profile over the first year of real-world use is consistent with the phase 3 SECURE trial results. This level of data transparency and commitment to providing clinicians with information can further enable them to make informed decisions together with their patients," said Robin Kroll, MD, FACOG, SECURE Trial Investigator.

The poster, entitled *Postmarketing Safety of a Levonorgestrel/Ethinyl Estradiol Contraceptive Transdermal Delivery System*, was authored by Robin Kroll, MD, Andrew M. Kaunitz, MD, FACOG, Beata Teixeira de Mattos, Joseph A. Chiodo III, PharmD, Michelle L. Previtera, PhD, and Paul Korner, MD, MBA and will be available to meeting attendees in person, through the ACOG website at https://www.acog.org, and the ACPG's journal's website, greenjournal.org beginning May 5, 2022.

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 with a BMI ≥ 30 kg/m^2. Twirla is also contraindicated in women over 35 years old who smoke. Cigarette smoking increases the risk of serious cardiovascular events from CHC use. 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-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Twirla and 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. Twirla® and our pipeline products are 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.

Forward-Looking Statement

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 safety profile for Twirla. 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 market availability of Twirla and the consistency of Twirla's safety profile over time. 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 maintain regulatory approval of Twirla, the continued uptake of Twirla in a broader patient population, the possibility that Twirla could develop unexpected safety, efficacy or quality concerns, our ability to successfully commercialize Twirla, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for Twirla, our strategy, business plans and focus, 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.

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