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Agile Therapeutics Presents Additional Phase 3 SECURE Trial Results for Twirla® at the American Society for Reproductive Medicine (ASRM) Scientific Congress & Expo 2017

Data Suggests Twirla May Decrease Mean Length of Bleeding and Spotting Episodes

PRINCETON, N.J., Oct. 31, 2017 /PRNewswire/ -- Agile Therapeutics, Inc., (NASDAQ: AGRX), a women's healthcare company, today announced additional data from its Phase 3 SECURE trial of Twirla® (AG200-15), an investigational, once-weekly, low-dose hormonal contraceptive patch, which showed women experienced mean decreases in length of bleeding and spotting episodes. These data were presented during an oral presentation at the American Society for Reproductive Medicine (ASRM) Scientific Congress & Expo 2017 in San Antonio, Texas, and the abstract was published in *Fertility and Sterility*.

Over 12 months, women on Twirla reported a gradual decrease in the mean total number of bleeding and/or spotting episodes from 6.0 to 4.9 days from cycles two through 13. Scheduled bleeding, or withdrawal bleeding during the patch-free week, decreased from 4.7 days at cycle two to 4.1 days at the end of the trial. The mean number of days of unscheduled bleeding, or breakthrough bleeding, decreased from 6.3 to 5.2 from cycle two through 13. While the duration of scheduled and unscheduled bleeding decreased, the mean number of episodes were consistent during the trial. Only 2.2% of women discontinued from the trial due to bleeding-related adverse events.

"Women generally hope for contraceptive options that lessen bleeding and spotting over time," said Anita L. Nelson, M.D., Research Division, Access Essential Health, Los Angeles, California. "This is an important factor that affects selection of and long-term continuation with hormonal contraception."

In July 2017, the U.S. Food and Drug Administration (FDA) accepted resubmission of the Company's New Drug Application (NDA) for Twirla and assigned December 26, 2017 as the Prescription Drug User Fee Act (PDUFA) goal date.

"The SECURE trial comprised an ethnically diverse, real-world population, which is reflective of women who may select the Twirla patch as their contraceptive method, if approved by the FDA," said Elizabeth Garner M.D., M.P.H., senior vice president and chief medical officer, Agile Therapeutics, Inc. "We believe Twirla has the potential to be an important low-dose, non-daily birth control option for today's modern woman."

For more information, please visit the company website at www.agiletherapeutics.com.

About the SECURE Trial

The Phase 3 SECURE (Study to Evaluate Contraception Use, Reliability, and Effectiveness) trial was a 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 nationwide. Bleeding information was self-reported by subjects on a daily basis using electronic diaries. Subjects were asked about both scheduled and unscheduled bleeding and spotting, using definitions described by Mishell et al. (Recommendations for Standardization of Data Collection and Analysis of Bleeding in Combined Hormone Contraceptive Trials; *Contraception 75; 11-15*).

About Twirla

Twirla (ethinyl estradiol and levonorgestrel transdermal system) or AG200-15 is an investigational once-weekly prescription contraceptive patch. AG200-15 is a combined hormonal contraceptive (CHC) patch that contains the active ingredients ethinyl estradiol (EE), a synthetic estrogen, and levonorgestrel (LNG), a type of progestin, a synthetic steroid hormone. 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. 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, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch that recently completed Phase 3 trials. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to provide advantages over currently available patches and is intended to optimize patch adhesion and patient wearability. For more information, please visit the company website at www.agiletherapeutics.com. The company may occasionally disseminate material, nonpublic information on the company website.

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Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" related to the Company's regulatory submissions. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates", "estimates," "expects," "plans," "intends," "may," "could," "might," "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 involves risks, potential changes in circumstances, assumptions and uncertainties. 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. Our statements about the results and conduct of our clinical trial could be affected by the potential that there are changes in the data or interpretation of the data by the FDA (for example, the FDA may include additional pregnancies in its calculation of the Pearl Index, which would increase the Pearl Index), whether the results will be deemed satisfactory by the FDA (for example, we may describe the results of the SECURE trial as positive, the FDA may disagree with that characterization), and whether additional studies will be required or other issues will arise that will delay resubmission of our NDA or negatively impact acceptance, review and approval of Twirla by the FDA; our statements about the potential commercial opportunity could be affected by the potential that our product does not receive regulatory approval, does not receive reimbursement by third party payors, or a commercial market for the product does not develop because of any of the risks inherent in the commercialization of contraceptive products; our statements about the planned resubmission of our NDA for Twirla could be affected by the potential that additional analyses of issues identified in our complete response letter from the FDA are required to be completed that were not previously anticipated, that our ongoing tests to support our resubmission are not completed on time, that the third parties we rely on to perform services in support of our NDA resubmission do not complete their work in a timely fashion and that other issues will arise that will delay resubmission of our NDA or negatively impact acceptance, review, and approval of Twirla by the FDA. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. All forward-looking statements are subject to risks detailed in our filings with the U.S. Securities and Exchange Commission, including the Company's Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. 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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