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Agile Therapeutics Presents Additional Twirla® Phase 3 SECURE Study Results at NAFFP 2017

Detailed Bleeding Profile Data Provide Helpful Information for Patient Counseling

PRINCETON, N.J., Oct. 16, 2017 – Agile Therapeutics, Inc., (NASDAQ: AGRX), a women's healthcare company, today announced the presentation of additional results from the Phase 3 SECURE trial of its investigational low-dose combination hormonal contraceptive patch, Twirla® (AG200-15). Anita Nelson, MD, Professor and Chair of Obstetrics and Gynecology at the College of Osteopathic Medicine of the Pacific, presented new data on the Twirla bleeding profile during a poster presentation at the 2017 North American Forum on Family Planning (NAFFP), "The Forum" in Atlanta, GA.

The poster presentation provided detailed analyses on scheduled (withdrawal) and unscheduled (breakthrough) bleeding and/or spotting episodes. Rates of unscheduled bleeding and/or spotting decreased during the study period. Similarly, the mean length of both unscheduled and scheduled bleeding and/or spotting episodes decreased during the study period. Few subjects discontinued from the trial for bleeding-related issues, and rates of unscheduled bleeding and/or spotting decreased over the 12-month study period.

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 2032 healthy women, aged 18 years and over, at 102 investigational sites across the United States. Bleeding information was self-reported by subjects on a daily basis in 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*).

Dr. Nelson commented, "The use of electronic diaries to collect daily bleeding data during the SECURE trial has yielded a robust package of data on the bleeding profile of Twirla. These new analyses provide information that will be very helpful to providers to guide counseling of patients considering use of the Twirla patch, if approved."

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

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.

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.

Source: Agile Therapeutics

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