October 10, 2017

Agile Therapeutics Inc. Hosts First Analyst Day Focused on Previewing its Corporate Vision and Commercial Strategy

Company Also Announces Four New Patents Granted for its Novel Transdermal Contraceptive Dosing Regimens

PRINCETON, N.J., Oct. 10, 2017 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq:AGRX), a women's healthcare company, today hosted the Company's first analyst day in New York City to showcase its corporate vision and commercial strategy for the potential launch of Twirla® (AG200-15), its investigational low dose hormonal contraceptive patch product candidate. 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 U.S. combined hormonal contraceptive market is currently worth an estimated 3.9 billion dollars," said Al Altomari, chairman and chief executive officer, Agile Therapeutics, Inc. "We are rapidly preparing our commercial organization to deliver on our vision of answering unmet needs for women who want to be in control of their contraceptive choice with a non-daily option. We eagerly await the FDA decision on Twirla by our PDUFA goal date."

In addition to Twirla, its lead investigational product candidate, Agile Therapeutics is continuing to explore ways to address additional needs in the contraceptive market through its pipeline. Agile expects to begin planning the clinical development for its investigational small patch program, including AG200-SP and AG200-ER in 2018.

Underscoring Agile's prospective growth and position to capitalize on the large scale potential of the hormonal contraceptive market, the Company has been granted 17 United States patents to date, with counterparts in several important markets worldwide. Most recently, the U.S. Patent and Trademark Office issued the Company four new patents with claims directed to novel transdermal contraceptive dosing regimens. These new patents provide an expanded proprietary platform not only for the development of Twirla and Agile's pipeline, but also for potential new products utilizing a broad selection of other progestins and estrogens.

"It's an exciting time for Agile as we continue to build and grow our commercial infrastructure for our lead product candidate and beyond," said Renee Selman, chief commercial officer, Agile Therapeutics, Inc. "We are adding the best and brightest talent in women's health to support our commercial efforts and bolster our commercial operations, supply chain and sales and marketing teams."

The analyst day presentation was webcast live and can be accessed on the Investor Relations section of Agile Therapeutics website at www.agiletherapeutics.com.

For more information, please visit the Company website at www.agiletherapeutics.com. The Company may occasionally disseminate material, nonpublic information on the Company website.

About Agile Therapeutics

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.

Follow Agile on social media: @agilether. The company may occasionally disseminate material, nonpublic information on the company website.

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.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" related to the Company's clinical trials, regulatory submissions, projected cash position and potential market opportunity for its product candidates. 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 involve 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 describe the results of the SECURE trial as positive, the FDA may disagree with that characterization), whether the FDA requires labeling restrictions, and whether additional studies will be required or other issues will arise that will negatively impact acceptance, review, and approval of Twirla by the FDA; our statements about our projected cash position could be affected by market factors, the inherent risks in our business, our ability to execute the Company's operational and budget plans, the FDA does not approve Twirla, the FDA's timeline for review is not completed by the target PDUFA goal date, our ability to timely complete the qualification and validation of our commercial manufacturing process, the fact that our existing cash and cash equivalents will not be sufficient to fund our current and planned operations through the next 12 months, which raises substantial doubt about our ability to continue as a going concern, and which, in turn, may create negative reactions to the price of our common stock making it more difficult to obtain financing in the future, and unforeseen events in our clinical and manufacturing development plans; and 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, potential limitations of the federal insurance mandate for contraception, delays in our potential launch as a result of unforeseen product supply and/or manufacturing constraints or a commercial market for the product does not develop because of any of the risks inherent in the commercialization of contraceptive products. 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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