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Agile Therapeutics Resubmits New Drug Application (NDA) for its Transdermal Contraceptive Patch, Twirla®

PRINCETON, N.J., June 27, 2017 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc., (NASDAQ:AGRX), a women's healthcare company, today announced it has resubmitted to the U.S. Food and Drug Administration (FDA) the NDA for its lead product candidate, Twirla®, an investigational low-dose combined hormonal contraceptive patch (AG200-15). Agile resubmitted the NDA in response to a February 2013 Complete Response Letter (CRL) from the FDA, which recommended that Agile conduct a new clinical trial and provide additional information on the manufacturing process for Twirla. The resubmitted NDA includes efficacy and safety data from the new Phase 3 clinical trial (also known as the SECURE trial), the requested manufacturing information, and a summary response to the CRL.

"We have resubmitted our NDA for Twirla as planned and look forward to working with the FDA during the review process," said Al Altomari, Chairman and Chief Executive Officer of Agile. "Our achievement of this milestone reflects our commitment to changing the paradigm of available contraceptive treatment options for today's women and brings us one step closer to commercializing our low-dose contraceptive patch and offering an option to women seeking novel methods best suited to their needs and lifestyle. Once the FDA has acknowledged our submission as a complete response, we expect to receive a Prescription Drug User Fee Act (PDUFA) date that we anticipate will be based on a six-month review."

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 negatively impact acceptance, review and approval of Twirla by the FDA; the FDA may delay its review longer than we expect; 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, 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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