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Agile Therapeutics Announces Plans to Advance Contraceptive Pipeline

Preparations Underway for Phase 2 Clinical Trial of Novel Twirla® Line Extension

PRINCETON, N.J., July 12, 2016 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq:AGRX), a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products, today announced that preparations are underway for an initial Phase 2 clinical trial of a novel contraceptive regimen, which will begin the development of its pipeline beyond its current lead product candidate, Twirla®, a once weekly contraceptive patch currently in phase 3 development. The planned Phase 2 clinical trial will examine the use of Twirla in an innovative regimen designed to allow women to experience shorter, lighter periods.

"Today marks an important step for Agile as we begin to execute our strategic plan to develop our pipeline of new product candidates based on Twirla," said Elizabeth Garner, M.D., M.P.H., Chief Medical Officer of Agile. "Agile's pipeline is designed to build on our current patch regimen and offer women additional, convenient non-daily contraceptive options that provide flexibility to meet their needs."

Agile plans to conduct an initial phase 2 study of a novel 28-day contraceptive patch regimen (AG200-SP) designed to optimize the bleeding profile by delivering hormones beyond the typical 21 day regimen using a smaller lower dose combination ethinyl estradiol/levonorgestrel patch (SmP) in the fourth week of the cycle. The SmP regimen is intended to allow women to experience shorter, lighter periods, an attribute that research suggests is highly desirable to women seeking hormonal contraception. The planned study is aimed at identifying the optimal dose of the SmP, and will evaluate bleeding profiles, pharmacokinetic parameters, ovulation inhibition and safety over 3 cycles of treatment. Up to 150 subjects are expected to be enrolled at highly experienced sites that are also participating in the ongoing Phase 3 SECURE clinical trial. The Company has started preparations for the study and expects to initiate dosing in the first quarter of 2017. Agile also plans to develop an extended cycle regimen for Twirla (AG200-ER) that may also utilize the SmP with the goal of allowing women to have fewer periods each year.

"Expanding our pipeline is a key element of our strategic plan," said Al Altomari, Chief Executive Officer and President of Agile. "Based on patent protection expected to extend into 2029, we believe we are in a strong position to build a women's health franchise that will enable us to be commercially competitive and expand our market potential."

About Agile Therapeutics, Inc.
Agile Therapeutics is a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products. Our product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch currently in Phase 3 clinical development. 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 adherence and patient acceptability. 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, product candidate pipeline, timing and conduct of clinical trials 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 expectations 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. For example, our statements about the timing and conduct of our clinical trials and our ability to potentially commercialize our product candidates, could be affected by the potential that we experience slower than expected enrollment, we identify serious side effects or other safety issues, we do not have clinical supply of our product candidate that is adequate in amount and quality and supplied in a timely fashion, and the inherent risks of clinical development; 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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