



## **Agile Therapeutics Announces Study Results Demonstrating Contraceptive Patch AG200-15 Delivers a Low Dose of Estrogen**

### **Study Findings Presented at the American Society for Reproductive Medicine Annual Meeting**

PRINCETON, N.J. – October 26, 2010 --Agile Therapeutics announced results today from a Phase 2 clinical study of AG200-15, Agile's weekly contraceptive patch containing ethinyl estradiol (EE) in combination with levonorgestrel (LNG). According to the clinical findings, AG200-15 provides a low daily dose of estrogen equivalent to 30 micrograms EE, similar to that in low-dose, oral contraceptive (OC) pills. The study findings were delivered in an oral presentation at the American Society for Reproductive Medicine (ASRM) 66th Annual Meeting.

AG200-15 incorporates Agile's proprietary SKINFUSION™ transdermal delivery technology and is applied once weekly for three weeks followed by a patch-free week. Earlier this October, Agile announced the completion of patient enrollment ahead of schedule in its pivotal, Phase 3 NEW CHOICE Study of AG200-15.

Dr. Marie Foegh, Chief Medical Officer and Vice President, Clinical Research and Development of Agile Therapeutics, stated, "The reported Phase 2 results demonstrate AG200-15 delivers a dose of estrogen sufficiently low to avoid increased risk of adverse events, but still effective in preventing unwanted episodes of breakthrough (nonscheduled) bleeding. We believe this innovation, delivering the right dose of estrogen in combination with levonorgestrel can address women's desire for greater safety, convenience and ease of compliance in their choice of hormonal contraception."

Al Altomari, Agile's President and CEO, commented, "The daily estrogen exposure demonstrated in the Phase 2 study confirms our estimates based on the dose-ranging studies performed earlier by Agile. This is the first head-to-head study with a contraceptive patch vs. an OC to demonstrate EE exposure comparable to a low-dose OC. We have designed AG200-15

to answer the market need for a contraceptive patch that provides convenience and compliance, with a low dose of estrogen.”

Mr. Altomari continued, “Previous studies have demonstrated that AG200-15 is well-tolerated with a favorable breakthrough bleeding profile, very low rates of irritation, and adhesion in real-world conditions over the 7-day period of application. Agile’s patch is an elegant solution to meet the promise of contraceptive patch technology.”

Agile’s Phase 2 open-label, crossover study compared the EE pharmacokinetic (PK) profile of AG200-15 to an oral contraceptive in healthy female volunteers. Thirty-two subjects were included in the analyses. The maximum plasma concentration level (C<sub>Max</sub>) was approximately 60% lower for AG200-15, and steady state concentration levels (C<sub>ss</sub>) were 15%-20% lower for AG200-15 compared to a 35 micrograms OC (P < 0.02). According to the oral presentation at ASRM, “Daily EE exposure with the novel, low-dose transdermal contraceptive delivery system AG200-15 is comparable with that of a low-dose OC.” The daily dose of AG200-15 is approximately 30 micrograms EE and is well within the range reported for low-dose OCs.

#### **About Agile’s Low-Dose Contraceptive Patch (AG200-15)**

AG200-15 is an innovative, low-dose, weekly contraceptive patch that offers a new advancement in the women’s healthcare market. As a convenient, low-dose patch alternative to oral contraceptives, the patch will fill an unmet need, so that women will not have to take a pill every day.

In addition to the Phase 2 estrogen dose results being reported at the ASRM meeting, Agile previously reported Phase 2 findings showing AG200-15 met its primary endpoints of ovulation suppression, cycle control and safety. Based on these encouraging results, Agile initiated enrollment in the NEW CHOICE pivotal, Phase 3 study of AG200-15 in August 2010. The study is designed to compare the efficacy and tolerability of AG200-15 to a low-dose, oral contraceptive. Target enrollment of 1,500 women at over 100 sites throughout the U.S. was completed ahead of schedule in October 2010.

#### **About Agile Therapeutics, Inc.**

Agile Therapeutics is a pharmaceutical development company specializing in women’s healthcare products, with an initial focus on providing patients with more options and more convenient methods of hormonal contraception. In addition to Agile’s lead, advanced-stage program to develop AG200-15, the Company also is developing a low-dose, progestin-only contraceptive patch, AG900. Both AG200-15 and AG900 incorporate Agile’s proprietary SKINFUSION™ technology, consisting of an active and peripheral adhesive system that allows

stable drug delivery and dependable adhesion over seven days. For more information, please visit <http://www.agiletherapeutics.com>.

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