Agile® THERAPEUTICS

Just What Women Want in Healthcare

New Phase III Data Show Agile Therapeutics' Low-Dose Patch is Comparable to Combination Oral Contraceptive in a Comparator Study

– Contraceptive Patch Studied for First Time in Highly Diverse Population including Obese Women, Minorities and First-time Users –

PRINCETON, N.J. – May 7, 2012 – Agile Therapeutics today announced new results from a Phase III pivotal trial of AG200-15 (the Agile Patch), Agile's once-weekly low-dose combination contraceptive patch containing ethinyl estradiol (EE) in combination with levonorgestrel (LNG). The data were presented at the American College of Obstetricians and Gynecologists' 60th Annual Clinical Meeting, taking place in San Diego from May 5-9, 2012. The pivotal Phase III trial was conducted in a highly diverse population of over 1,500 women, including obese women, minorities, and new users of hormonal contraceptives. This comparative study demonstrated that AG200-15 has contraceptive efficacy comparable to that of an approved low-dose oral contraceptive comparator, as well as a similar safety and tolerability profile. The study confirmed that AG200-15 is delivering a low daily dose of ethinyl estradiol. Andrew Kaunitz, MD, Associate Chair and Professor of the Department of Obstetrics and Gynecology at the University of Florida, and the Principal Investigator for the AG200-15 Phase III trial, commented, "Unlike many contraceptive clinical trials, this study was conducted in a population that reflects all US reproductive age women. The results demonstrate that the Agile Patch will be an important new contraceptive option for women." Agile has submitted a New Drug Application (NDA) for AG200-15 to the Food and Drug Administration (FDA).

Two additional studies were presented by David F. Archer, MD, Professor of Obstetrics and Gynecology at Eastern Virginia Medical School. The first demonstrates that the Agile Patch can be worn on any of the three administration sites (abdomen, buttock, or upper torso), without any clinically significant differences in blood levels of the active ingredients, ethinyl estradiol and levonorgestrel. The second study demonstrated that the Agile Patch can be worn under various conditions, including whirlpool, sauna, and vigorous exercise, without any clinically significant difference in blood levels, and that the patch showed excellent adherence under these conditions.

"The results of our study on the adhesiveness of AG200-15 showed that the patch will stay in place and continue to deliver hormones under a variety of external conditions," said Dr. Archer. "The data suggest that the product could provide women with a contraceptive option that fits in with their lifestyles and daily activities."

About AG200-15

AG200-15, the Agile Patch, is a combination hormonal contraceptive patch that has been shown in clinical studies to simultaneously deliver low doses of ethinyl estradiol and levonorgestrel, consistent with the efficacy and safety profile of low-dose oral contraceptives.

The AG200-15 patch is applied once-weekly for three weeks, followed by a fourth, patch-free week. The patch may be applied to the abdomen, buttocks, or upper torso, is soft and flexible with a cloth-like, silky feel, and is designed to provide excellent adhesion, comfort, and appearance. The most common adverse reactions (>2%) in clinical trials were cervical dysplasia (6.2%), nasopharyngitis (5.7%), nausea (4.4%), upper respiratory infection (3.8%), sinusitis (3.6%), headache (3.6%), urinary tract infection (3.3%), human papilloma infection (3.0%), breast tenderness (2.2%), weight gain (2.1%), and vaginal infection (2.0%).

About Agile Therapeutics

Agile Therapeutics is a pharmaceutical development company specializing in Women's Healthcare products, with an initial focus on providing women with more options and more convenient methods of hormonal contraception. The company's lead product, AG200-15, is a once-weekly contraceptive patch that recently completed Phase III clinical trials. In addition, Agile is also developing a low dose, progestin-only contraceptive patch, AG890 (formerly AG900). Both AG200-15 and AG890 incorporate proprietary transdermal delivery technology, Skinfusion®, developed by Agile, 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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