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Phase III Data Show Greater Compliance Across Demographic Groups With Agile Therapeutics' Contraceptive Patch Compared to an Oral Contraceptive

High Patch Compliance Not Affected by Age, Race, or Education

PRINCETON, NJ--(Marketwire - Nov 1, 2012) - Agile Therapeutics presented findings from a phase III pivotal trial of AG200-15, Agile's investigational once-weekly combination contraceptive patch containing ethinyl estradiol (EE) in combination with levonorgestrel (LNG). The data were presented during the North American Forum on Family Planning. In this comparative study, researchers found that compliance (defined as no missed days of contraception in the cycle based on patient diaries) for AG200-15 was significantly higher than with an oral contraceptive. The researchers also found that compliance with AG200-15 did not vary across demographic groups, while compliance for the oral contraceptive did vary across demographic groups. Both groups demonstrated non-compliance in 10-14% of patients based on serum drug levels. Also, compliance with AG200-15 was lower in new users of hormonal contraceptives than in current or recent users.

Data were presented from 1,328 women, of whom 998 received the patch and 330 received an oral contraceptive. Over the first six cycles, there was a significantly higher percentage of cycles with perfect compliance in the patch group than in the pill group (90.5% vs 78.8%, $P < 0.001$). In the pill group, compliance varied by age, race/ethnicity, and education level, while in the patch group, compliance was independent of these demographic factors. For both groups, compliance did not differ by body mass index.

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, "The high rate of compliance for Agile's contraceptive patch, and particularly the fact that compliance was not affected by demographic characteristics, is encouraging. Proper compliance is essential to obtain maximum effectiveness with a contraceptive, and AG200-15 is designed to make compliance as simple as possible for all users."

Agile recently filed the NDA for AG200-15 with the Food and Drug Administration and anticipates a response in the first quarter of 2013.

About AG200-15

AG200-15 is an investigational combination hormonal contraceptive patch, designed to deliver a low dose of ethinyl estradiol comparable to low-dose combination oral contraceptives. The phase III trials for AG200-15 enrolled nearly 2,000 women and formed the basis for the Company's application to the US Food and Drug Administration in 2012.

The AG200-15 patch is intended to be applied once weekly for three weeks, followed by a fourth, patch-free week. The patch is designed using a soft, flexible cloth, with a silky feel, and is intended to provide excellent adhesion, comfort, and appearance.

About Agile Therapeutics

Agile Therapeutics is a pharmaceutical development company specializing in Women's Healthcare, with an initial focus on providing women with more options for convenient methods of hormonal contraception. The company's lead investigational product, AG200-15, is a once-weekly contraceptive patch that has been submitted to the FDA for approval. In addition, Agile is also developing a 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 designed for dependable adhesion over seven days. For more information, please visit <http://www.agiletherapeutics.com>.

About the North American Forum on Family Planning

SFP's annual meeting is part of the new North American Forum on Family Planning, launched in 2011 and sponsored jointly by SFP and Planned Parenthood Federation of America (PPFA). This two-day meeting, along with the SFP pre-conference Career Development Seminar, is held each autumn in a different city. Session topics include new research and clinical practice issues related to contraception, abortion, STIs, sexuality, and how to translate the best evidence into clinical practice. Additionally, SFP will be the lead partner in managing the scientific abstracts.

Contact

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