

Just What Women Want in Healthcare

## Agile Therapeutics Announces Completion of AG200-15 Phase III Clinical Program

-- On track to Submit NDA for New Low-Dose Contraceptive Patch in Q1 2012 --

**PRINCETON, N.J. – January 2, 2012 –** Agile Therapeutics, a pharmaceutical company focused on developing and commercializing more convenient women's contraceptive products, announced today that the database has been locked for the final Phase III clinical trial of AG200-15, the company's combination hormonal contraceptive patch. The company also confirmed that it is on track to submit the New Drug Application (NDA) for AG200-15 to the US Food and Drug Administration (FDA) during the first quarter of 2012.

"We would like to thank all of the investigators and patients who participated in these important studies and helped to allow us to complete them on schedule," said Marie Foegh, M.D., Dr.Sc., Chief Medical Officer, Vice President, Clinical Research and Development, Agile Therapeutics. "We have locked the last database and are beginning statistical analysis on the data from the study. We are on track to submit the NDA to the FDA during the first quarter of 2012 and look forward to working with the agency in 2012. "

AG200-15 is a combination hormonal contraceptive patch, which in clinical studies has been shown to deliver a low dose of ethinyl estradiol, as well as a dose of levonorgestrel that is consistent with the efficacy and safety profile of low-dose oral contraceptives. Agile Therapeutics initiated the Phase III clinical trials, NEW CHOICE STUDY and NEW CHOICE II, for AG200-15 in August 2010. The phase III trials, which enrolled more than 2,000 women, will form the basis for the Company's application to the US Food and Drug Administration during the first quarter of 2012.

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 designed to provide excellent adhesion, comfort, and appearance.

## **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



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currently in Phase III clinical trials. In addition, Agile is also developing a lowdose, progestin-only contraceptive patch, AG890 (formerly AG900). Both AG200-15 and AG890 incorporate proprietary transdermal delivery technology, Skinfusion<sup>®</sup>, 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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