



## **Agile Therapeutics Announces FDA Accepts New Drug Application for its Low-Dose, Once-Weekly Contraceptive Patch**

***-- Response from FDA Expected in Q1 2013 --***

**PRINCETON, N.J. [July 3, 2012]** -- Agile Therapeutics, a pharmaceutical company focused on developing and commercializing more convenient women's contraceptive products, today announced that its New Drug Application (NDA) for AG200-15, a once-weekly, low-dose contraceptive patch, has been accepted for filing by the U.S. Food and Drug Administration (FDA).

The application will be subject to a standard review, with a ten-month Prescription Drug User Fee Act (PDUFA) date and an anticipated response in Q1 2013.

"We are very pleased with the FDA's acceptance of our AG200-15 NDA filing," said Al Altomari, President and Chief Executive Officer of Agile. "This is an important milestone for our company and reflects the unwavering commitment of the entire Agile team to advance a new contraceptive option for women. We will work closely with the FDA to bring AG200-15 to market as soon as possible."

### **About AG200-15**

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 that of low-dose oral contraceptives. The phase III trials for AG200-15 enrolled more than 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 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 that has been submitted to the FDA for approval. 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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