



*Just What Women
Want in Healthcare*

Agile Therapeutics AG200-15 Contraceptive Patch Shows Hormonal Exposure Similar to Low-Dose Oral Contraceptives in Phase II Data

-- Phase III Studies with AG200-15 on Schedule to Complete in Late 2011--

--Two abstracts presented at The American College of Obstetricians and Gynecologists' Annual Clinical Meeting --

WASHINGTON, D.C. – May 2, 2011 – Agile Therapeutics, a pharmaceutical company focused on developing and commercializing more convenient women's contraceptive products, today announced the presentation and publication of three studies highlighting Phase II data with AG200-15, the company's combination hormonal contraceptive patch. The definitive pharmacokinetic study demonstrated that AG200-15 delivers a daily estrogen (ethinyl estradiol) dose of 30ug, comparable to low-dose oral contraceptives. The studies also reported the safety and tolerability profile of AG200-15 in addition to data on ovulation in obese and non-obese women. Two abstracts were presented at the American College of Obstetricians and Gynecologists' 59th Annual Clinical Meeting (ACM) taking place in Washington, DC, from April 30th through May 4th. Data has also been published in the April 2011 volume of *Hormone Molecular Biology and Clinical Investigation*.

"These studies demonstrate that our contraceptive patch (AG200-15) is delivering 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," said Marie Foegh, M.D., Dr.Sc., Chief Medical Officer, Vice President, Clinical Research and Development, Agile Therapeutics. "The results of these studies supported our decision to initiate our Phase III program, which has enrolled over 2,000 women and will provide the basis for an application to the US Food and Drug Administration. Our Phase III program population is reflective of the US population, including women across a wide range of body mass index (BMI)".

Two abstracts presented today at the American College of Obstetricians and Gynecologists' ACM highlight data from Phase II studies evaluating the safety, tolerability and pharmacokinetic profile of AG200-15. The first abstract is a study conducted in thirty-six healthy women to establish the pharmacokinetic profile of ethinyl estradiol (EE) and levonogrestrel (LNG) in AG200-15, and to compare the EE exposure with the AG200-15 contraceptive patch to a low-dose oral



*Just What Women
Want in Healthcare*

contraceptive. The EE exposure was lower in those women using the AG200-15 patch versus the low-dose oral contraceptive. The calculated daily dose of AG200-15 was equivalent to 30 µg of EE. AG200-15 was found to be generally safe and well tolerated.

The second abstract presented an evaluation of ovarian suppression in obese versus non-obese women enrolled in the AG200-15 Phase II multicenter clinical study. AG200-15 was evaluated in thirty-three women with BMI ranging from 17-52 kg/m²; 24% of subjects were considered obese (BMI >30kg/m²). Serum progesterone was measured twice weekly as an indicator of ovarian suppression, and study authors observed a trend of higher serum progesterone levels during week one of treatment cycles two and three in the obese population. No difference in ovulation was reported between obese and non-obese women. Researchers suggested that there is likelihood that ovarian activity (luteinization) may be more frequent in obese women using the AG200-15 patch. Phase III studies are currently underway to further assess the efficacy of the AG200-15 patch in women of various weights, including subjects with BMI > 30 and BMI > 35 kg/m², with study completion on schedule for late 2011. The Agile Phase III study is fairly unique for contraceptive studies in that women with high BMI were not excluded.

In addition to the data presented at the ACM, Agile Therapeutics also announced the publication of data from two Phase II studies to evaluate the pharmacokinetic profile, cycle control, safety and tolerability of three transdermal contraceptive delivery systems. The study, "Pharmacokinetics, tolerability and cycle control of three transdermal contraceptive delivery systems containing different doses of ethinylestradiol and levonorgestrel," by lead author Frank Z. Stanczyk, Ph.D. Professor of Research, Departments of Obstetrics and Gynecology and Preventive Medicine, Keck School of Medicine, University of Southern California, appears in *Hormone Molecular Biology and Clinical Investigation*, a peer-review journal dedicated to providing data on molecular aspects of hormones in physiology and in pathophysiology.

The results of these studies supported the further testing of the AG200-15 contraceptive patch in Phase III contraceptive efficacy and safety studies, which will be completed this year.

The studies described above were supported by Agile Therapeutics, Inc.

About Agile Therapeutics



*Just What Women
Want in Healthcare*

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 currently in Phase III clinical trials. In addition, Agile is also developing a low-dose, progestin-only contraceptive patch, AG900. Both AG200-15 and AG900 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>.

Contact:

Courtney DeSisto for Agile Therapeutics

<mailto:cdesisto@lazarpartners.com>

212-867-1762