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Agile's Low-Dose Birth Control Patch Heads For Phase III

Betting that women long for more convenient options in birth control, Agile Therapeutics is readying its low-dose, once-weekly contraceptive patch for Phase III, after reporting good Phase II safety and efficacy results Sept. 3.

Princeton, N.J.-based Agile stresses that its flexible patch (ethinyl estradiol/levonorgestrel) delivers 60 percent less estrogen than the only marketed patch available today - the troubled **Ortho Evra** from Johnson & Johnson.

Though initially a hit, Ortho Evra (ethinyl estradiol/norelgestromin) sales suffered greatly from a link to increased risk for life-threatening blood clots and an FDA-mandated labeling change (["The Pink Sheet" DAILY, Nov. 11, 2005](#)).

In a Phase IIb study of three dosing regimens in 123 women, Agile's low-dose patch met its primary endpoint of ovulation suppression, cycle control and safety. The patch was well tolerated over seven days of use. and results helped the company determine that the model dubbed AG-200-15 offered the best dosing regimen.

Estrogen levels were comparable to the firm's low-dose oral contraceptive, **Levlen** (levonorgestrel/ethinyl estradiol) in a separate, open-label randomized pharmacokinetic study of 39 patients, the firm reported.

Research suggests low potential for interaction with other drugs and few problems with skin irritation, both of which have reportedly been problematic for the Ortho Evra product.

"We have a unique technology that looks good and feels good throughout the 7-day wear period," said CEO Thomas Rossi in an interview.

Based on findings from the two studies, the company is now in talks with FDA for further development of the product, with plans to firm up a Phase III program within the next three months.

The time frame for market introduction is dependent on the outcome of those talks and the scale of the Phase III work, but approval in 2011 seems a reasonable target, Rossi said. Experience with Ortho Evra suggests that a potentially large market for a birth control patch awaits Agile.

Surveys, Ortho Evra sales validate unmet need

It's estimated that more than 25 percent of women using contraception tried the patch. Peak annual sales hit \$400 million before the product fell in to disfavor due to safety fears. Public Citizen called on FDA to ban Ortho Evra, citing a possible two-fold increased risk of venous thrombosis (["The Pink Sheet" DAILY, May 8, 2008](#)).

Nevertheless, Agile argues, initial Ortho Evra uptake "validates the belief that women will accept a patch as a birth control method."

In a May 2008 telephone survey of 1,000 women of reproductive age, Agile noted strong demand for more options. About 30 percent of respondents were dissatisfied with birth control methods and 50 percent were open to talking to their doctors about the Agile patch, the firm said.

"There are a lot of options out there, but women are looking for something more convenient," said Chief Business Officer Jeff Frick.

Patches should appeal to the full spectrum of women of reproductive age, but may particularly take off with younger women, Rossi said.

It's possible that Agile's patch could become available in different dosing regimens, much as oral contraceptives have been developed in formulations that give women control over the number of menstrual cycles they have per year.

Furthermore, like oral birth control products, the Agile patch could find a place in other indications. For example, Rossi points out that Ortho McNeil's **Ortho Tri-Cyclen** (norgestimate/ethinyl estradiol) has been successful in treating acne.

Bayer Schering's low-dose **Yaz** (ethinyl/drospirenone) has shown value in treating premenstrual dysphoric disorder, he said.

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