



January 3, 2017

Agile Therapeutics Announces Positive Top-line Phase 3 Results

*Resubmission of Twirla[®] New Drug Application Expected to Address FDA's Complete Response Letter
Company Plans to Resubmit NDA in First Half of 2017
Company to Host Conference Call on January 3, 2017 at 5:00 p.m. Eastern Time*

PRINCETON, N.J., Jan. 03, 2017 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq:AGRX), a women's health specialty pharmaceutical company, today announced positive top-line results from its Phase 3 SECURE clinical trial of Twirla[®], its investigational low-dose combined hormonal contraceptive patch. SECURE was a multicenter, single-arm, open-label, 13-cycle trial that evaluated the safety, efficacy and tolerability of Twirla in 2032 healthy women, aged 18 and over, at 102 experienced investigative sites across the United States. The Company plans to resubmit its new drug application ("NDA") for Twirla in the first half of 2017 on the basis of the SECURE results and other information relating to the manufacture of Twirla.

SECURE was conducted to address issues raised by the U.S. Food and Drug Administration ("FDA") in its 2013 Complete Response Letter ("CRL") to the Company. The CRL recommended that the Company conduct a new clinical trial and focused on two key elements: improved clinical trial conduct and demonstration of efficacy as measured by an acceptable Pearl Index and related 95% confidence interval in a representative sample of U.S. women who are seeking hormonal contraception, including elements such as contraceptive user status, age, race, ethnicity, and body mass index ("BMI"). The trial was designed in consultation with the FDA, and comprised a number of stringent trial design elements, including exclusion of treatment cycles not only for use of back-up contraception but also for lack of sexual activity. SECURE had broad entry criteria, placed no limitations on BMI or other demographic factors during enrollment, and enrolled a large and diverse population from the United States in order to allow for efficacy to be assessed across different groups, as requested by the FDA. These entry criteria resulted in the inclusion of a substantial number of women with high BMI, who have frequently been under-represented in past contraceptive studies. The efficacy measure for SECURE was the Pearl Index in an intent to treat population of subjects 35 years of age and under. The FDA also requested inclusion of pre-specified efficacy analyses related to BMI and body weight.

Highlights of the top-line results include:

- | Consistent with its broad entry criteria, the SECURE study population was representative of the population of women in the United States with respect to key demographic criteria, including:
 - | Race (66.9% of subjects were white, 24.3% black and 8.8% other);
 - | Ethnicity (19.7% were Hispanic, 80.3% non-Hispanic); and
 - | BMI (39.4% of subjects had a normal baseline weight (BMI of under 25 kg/m²), 25.3% of subjects were overweight (BMI of at least 25 kg/m² but less than 30 kg/m²), and 35.3% were obese (BMI 30 kg/m² or more). When classified as obese (BMI 30 kg/m² or more) or non-obese (BMI less than 30 kg/m²), 35.3% of subjects were obese and 64.7% were non-obese).
- | Both new and experienced hormonal contraceptive users were enrolled (9.4% of subjects were new users).
- | 51.4% of subjects discontinued prematurely from the study and the loss to follow-up rate was 11.3%, which is in line with loss to follow-up rates observed in previous clinical trials of combined hormonal products and substantially better than the 20% loss to follow-up rate observed in the Company's previous Phase 3 trial.
- | The Pearl Index for the overall intent to treat population of subjects 35 years of age and under was 4.80 with an upper-bound of the 95% confidence interval of 6.06. As with all hormonal contraceptive trials, the number of pregnancies included in Agile's calculation of the Pearl Index is subject to review by the FDA as part of its overall review of the NDA for Twirla.
- | Consistent with other recent hormonal contraceptive clinical trials, including Ortho Evra[®] and Quartette[®], and the FDA's 2015 meta-analysis on the effect of obesity on the effectiveness of hormonal contraceptives, a relationship between obesity and efficacy was observed among subjects 35 years of age and under:

BMI Category	BMI (kg/m ²)	% of Trial Population	Pearl Index	Upper Bound of 95% CI
Normal	< 25	39%	3.03	4.62

Overweight	25 - < 30	25%	5.36	7.98
Obese*	≥ 30	35%	6.42	8.88
Non-Obese*	< 30	65%	3.94	5.35
Obese*	≥ 30	35%	6.42	8.88

*In its 2015 meta-analysis, the FDA examined the effect of obesity on two populations: non-obese (< 30 kg/m²) and obese (≥ 30 kg/m²). Non-obese includes subjects in the normal and overweight categories.

- Twirla was generally well tolerated and had an overall favorable safety profile, consistent with publicly available information relating to other low-dose combined hormonal products. The most frequent hormone-related adverse events, none of which were experienced by more than 5% of subjects, were generally in line with those events observed in other low dose combined hormonal products and included:

Adverse Event	SECURE (n=2032)
Headache	4.3%
Nausea	4.1%
Breast tenderness/pain/discomfort	2.0%
Mood swings/changes/depression	2.7%
Heavy/irregular vaginal bleeding	1.8%

- The percent of subjects reporting bleeding-related adverse events was low, 1.8%, and only 1.4% of women discontinued for bleeding issues.
- Serious adverse events were observed in 1.7% of subjects. The most common serious adverse events included deep vein thrombosis, pulmonary embolism, gallbladder disease, ectopic pregnancy and depression.
- Overall, patch-related irritation and itching rates were low. Of reported patches worn, 83% had no patch site irritation and 65% had no itching. Generally, reported irritation and itching was mild. Severe itching or irritation were observed in 2.3% and 1.5% of patches worn, respectively.
- The patch adhesion profile was favorable with a low rate of detachment. Of reported patches worn, the range of detachments was 10% in cycle 1 and reduced to 2% by cycle 13.

"We have now successfully completed our clinical trials for Twirla and added substantial clinical data to our existing body of information, in particular around the safety profile for the patch. SECURE represented an excellent opportunity to further examine the safety and effectiveness of Twirla in a trial designed to meet the FDA's recommendations for current contraceptive studies and focused on improved study conduct," said Dr. Elizabeth Garner, Senior Vice-President and Chief Medical Officer of Agile. "We believe we have addressed the clinical questions raised by the FDA in its CRL, and also produced important public health data in obese women that the FDA called for in its 2015 publication. We look forward to discussing these topics with the Agency. We greatly appreciate the hard work and dedication from our clinical team and wish to thank the clinical investigators, their staff, and most importantly, the 2032 women who participated in the SECURE trial."

Based on the results from the SECURE trial, Agile plans to prepare its response to the FDA's CRL, which will also include information relating to the manufacture of Twirla requested by the FDA. The Company plans to resubmit its NDA to the FDA in the first half of 2017.

"We are very pleased with having achieved this critical milestone for Agile," said Al Altomari, President and Chief Executive Officer of Agile. "Now that we have successfully completed SECURE, we are focused on preparing the resubmission of our NDA and continuing our progress towards seeking approval of Twirla and commercializing Twirla in the United States."

The Company also re-affirmed that based on its current business plan, it believes its cash and cash equivalents will be sufficient to meet its operating requirements through the end of 2017.

Additional information on the SECURE clinical trial is available at www.clinicaltrials.gov.

Company to Host Conference Call

Agile Therapeutics will host a conference call with slides today, January 3, 2017, at 5:00 p.m. Eastern Time to discuss the Company's results from the SECURE clinical trial. A question and answer session will follow Agile Therapeutics' remarks. To participate on the live call, please dial (844) 413-1773 (domestic) or (678) 865-8976 (international), and provide the conference ID 46605850, approximately five to 10 minutes ahead of the start of the call.

A live audio webcast of the call and accompanying slides will be available via the "Investor Relations" page of the Agile Therapeutics website, www.agiletherapeutics.com. Please log on through Agile Therapeutics' website approximately 10 minutes prior to the scheduled start time. A replay of the webcast and accompanying slides will be archived on Agile Therapeutics' website for 60 days following the call.

About Agile Therapeutics, Inc.

Agile Therapeutics is a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products. Our product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla[®], (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch currently in Phase 3 clinical development. Twirla is based on our proprietary transdermal patch technology, called Skinfusion[®], which is designed to provide advantages over currently available patches and is intended to optimize patch adherence and patient acceptability. For more information, please visit the company website at www.agiletherapeutics.com. The company may occasionally disseminate material, nonpublic information on the company website.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" related to the Company's clinical trials, regulatory submissions and potential market opportunity for its product candidates. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates", "estimates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current beliefs and expectations of our management team that involve risks, potential changes in circumstances, assumptions and uncertainties. Any or all of the forward-looking statements may turn out to be wrong, or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Our statements about the results and conduct of our clinical trial could be affected by the potential that there are changes in the data or interpretation of the data by the FDA (for example, the FDA may include additional pregnancies in its calculation of the Pearl Index, which would increase the Pearl Index), whether the results will be deemed satisfactory by the FDA (for example, we describe the results of the SECURE trial as positive, the FDA may disagree with that characterization), and whether additional studies will be required or other issues will arise that will delay resubmission of our NDA or negatively impact acceptance, review and approval of Twirla by the FDA; our statements about the potential commercial opportunity could be affected by the potential that our product does not receive regulatory approval, does not receive reimbursement by third party payors, or a commercial market for the product does not develop because of any of the risks inherent in the commercialization of contraceptive products. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. All forward looking statements are subject to risks detailed in our filings with the U.S. Securities and Exchange Commission, including the Company's Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

Contact: Mary Coleman -- 609-356-1921