UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

March 16, 2017
Date of report (Date of earliest event reported)

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36464**	**23-2936302**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

101 Poor Farm Road **Princeton, New Jersey** (Address of principal executive offices)	**08540** (Zip Code)

Registrant's telephone number, including area code **(609) 683-1880**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On March 16, 2017, Agile Therapeutics, Inc. ("Agile") a women's healthcare company, announced a poster presentation of data from the SECURE Phase 3 clinical trial for its lead product candidate, Twirla®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15. The poster, titled "*The SECURE Study, a Real-World Trial of a Low-Dose Contraceptive Patch: Addressing the Changing U.S. Population*," will be presented at the Contraceptive Technology Conferences on March 16-18, 2017 in San Francisco, CA and March 19 – April 1, in Boston, MA. The first author is Anita Nelson, MD, one of the Co-Primary Investigators for the SECURE trial.

The SECURE clinical trial was designed to evaluate the efficacy, safety, and tolerability of Twirla in a representative U.S. population of women seeking birth control. SECURE was a 1-year, multicenter, single-arm, open-label trial 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.

Copies of Agile's press release and poster presentation are attached hereto as Exhibit 99.1 and 99.2, respectively, and are hereby incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Agile Therapeutics, Inc. Press Release dated March 16, 2017.
99.2	Agile Therapeutics, Inc. Poster Presentation dated March 16, 2017.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Agile Therapeutics, Inc.

Dated: March 16, 2017

By: /s/ Alfred Altomari
Name: Alfred Altomari
Title: Chairman and Chief Executive Officer

Exhibit 99.1

Agile Therapeutics Announces a Poster Presentation of its SECURE Phase 3 Study at the Contraceptive Technology 2017 Conference

Princeton, New Jersey, March 16, 2017— Agile Therapeutics, Inc. (Nasdaq: AGRX) a women's healthcare company announced a poster presentation of data from the SECURE Phase 3 clinical trial for its lead product candidate, Twirla®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15. The poster, titled "*The SECURE Study, a Real-World Trial of a Low-Dose Contraceptive Patch: Addressing the Changing U.S. Population,*" will be presented at the Contraceptive Technology Conferences on March 16 - 18, 2017 in San Francisco, CA and March 29 - April 1, 2017 in Boston, MA. The first author is Anita Nelson, MD, one of the co-primary investigators for the SECURE trial.

The SECURE study was designed to evaluate the efficacy, safety, and tolerability of Twirla in a representative U.S. population of women seeking birth control. SECURE was a one-year, multicenter, single-arm, open-label trial 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.

The Company has filed the poster presentation on a form 8-K with the U.S. Securities Exchange Commission ("SEC"), which can be accessed either from the Company's website or the SEC's website.

About Agile Therapeutics

Agile Therapeutics is a forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product candidates are designed to provide women with contraceptive options that offer freedom from taking a daily pill, without committing to a longer-acting method. Our lead product candidate, Twirla®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch that recently completed Phase 3 trials. 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 adhesion and patient wearability. For more information, please visit the company website at www.agiletherapeutics.com.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" related to the Company's clinical trials and regulatory submissions. 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; 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.

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Source Agile Therapeutics

Contact: Mary Coleman 609-683-1880

Exhibit 99.2

The SECURE Study, a Real-World Trial of a Low-Dose Contraceptive Patch: Addressing the Changing U.S. Population

AUTHORS:

Anita Nelson, Andrew Kaunitz, Robin Kroll, James Simon, Alfred Poindexter, Joseph Chiodo, Lisa Flood, Elizabeth Garner

OBJECTIVES:

To evaluate the efficacy, safety, and tolerability of AG200-15 in a representative U.S. population of women who wish to use a transdermal contraceptive delivery system (TCDS).

BACKGROUND:

AG200-15 a weekly transdermal contraceptive delivery system (TCDS) with the potential for improved compliance versus daily pills. Historical data regarding of the Ortho Evra® contraceptive patch showed that women and providers were enthusiastic regarding the product. AG200-15 has been shown to deliver similar drug exposure to daily oral doses of 30µg of ethinyl estradiol (EE). The progestin component of the AG200-15 patch, levonorgestrel (LNG), is considered as one of the safest progestins, with the lowest risk for venous thromboembolism (VTE) when combined with EE. AG200-15 delivers similar exposure to daily oral doses of 120ug of LNG.

The generic of Ortho Evra, Xulane®, the only contraceptive patch currently marketed in the U.S. delivers a dose of EE that has been shown, in area-under-the curve (AUC) analyses, to be 60% greater than an oral pill containing 35µg of EE.(1) The possibility that use of Xulane may be associated with an excess risk for cardiovascular events including VTE has resulted in a specific warning in the product label.

SECURE (Study to Evaluate Contraception Use, Reliability, and Effectiveness) a 1-year, single-arm, open-label, multicenter study was conducted to yield reliable data in a more real-world study population. Enrollment criteria and procedures were established to optimize clinical trial conduct and demonstrate efficacy as measured by Pearl Index (PI). The trial included 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 U.S. to assess efficacy across different groups but excluded women with conditions generally recognized to be contraindications to estrogen use. These entry criteria resulted in the inclusion of a substantial number of women with high BMI, who have frequently been under-represented in contraceptive studies.

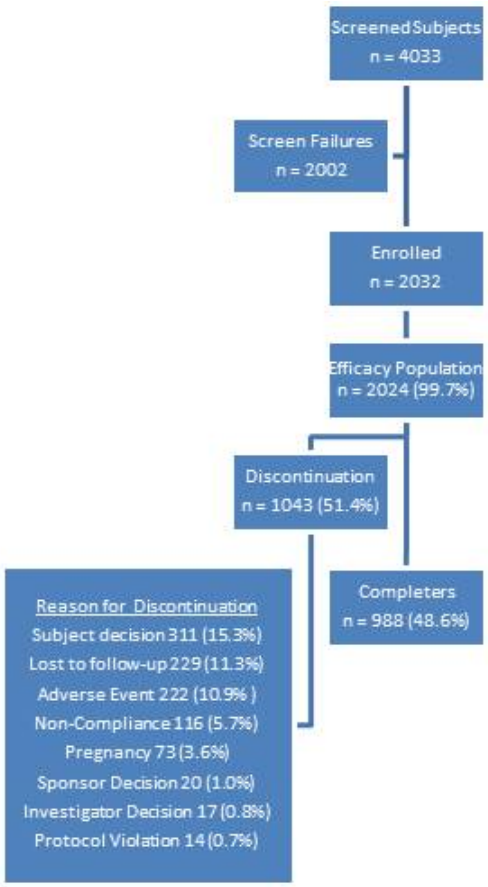
METHODS:

The SECURE study enrolled sexually active female subjects at risk for pregnancy. Medical history, physical and gynecological exams, and laboratory testing were performed at screening to determine eligibility. Subjects successfully completing screening were offered enrollment. There were 8 scheduled in-person visits and 6 telephone contact visits over the 12-month treatment period. Scheduled office visits included review of vital signs, urine pregnancy testing, patch application site inspection, review of medication and eDiary compliance, adverse events (AE) and concomitant medications (CMED). Documented phone contacts were completed to review study medication and eDiary compliance, as well as AEs and CMEDs. Subjects recorded the following information in daily electronic diaries: dates of patch application and patch change/removal, anatomic site of patch placement (lower abdomen, buttock, or upper torso), and reasons for any unscheduled patch changes. Subjects also recorded sexual activity and use of back-up contraception. In subjects with documented positive qualitative urine (β-hCG) test serum quantitative β-hCG, pelvic examination and a transvaginal ultrasound were performed to assess the estimated date of contraception. An independent expert Pregnancy Review Committee (PRC) reviewed data for each reported pregnancy. The primary efficacy analysis for the study was based on the calculation of pregnancy rates using the Pearl Index (calculated as the number of on-treatment pregnancies times divided by the number of 28-day on-therapy cycles, multiplied by 1300) in subjects aged 18 to 35 years old at study entry irrespective of BMI, excluding all cycles in which no intercourse occurred or other birth control methods (i.e., back-up contraception) were used. Supportive life table efficacy analyses were also performed. Patch wearability and tolerability were also assessed. Safety was assessed via collection of treatment emergent adverse events in all enrolled subjects who wore at least one patch for any period of time.

RESULTS:

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. 2,032 women, 18-40 years old, were enrolled and 988 (48.6%) completed the study and used AG200-15 for up to thirteen 28-day cycles (**Figure 1**).

Figure 1: SECURE Subject Disposition



Of enrolled subjects, 66.9% were Caucasian, 24.3% were African-American, 3.2% were Asian, and 4.7% were other (including 0.5% American Indian or Alaska Native and 0.4% Native Hawaiian or other Pacific Islander). Regarding ethnicity, 19.7% were Hispanic and 80.3% were non-Hispanic. The BMI range of enrolled subjects was 15.1 — 60 kg/m^2 with 39.4% of the women being normal (BMI <25 kg/m^2), 25.3% overweight (BMI $\geq$ 25 to < 30), 35.3% obese (BMI $\geq$ 30 kg/m^2).

The PI for the overall intent to treat population of subjects $\leq$ 35 years of age was 4.80 with an upper-bound of the 95% confidence interval of 6.06. The PI for Caucasian subjects was 4.63 (3.03, 6.23), for African-American subjects 4.05 (1.41, 6.69), and for Hispanic subjects 2.70 (0.34, 5.06). A positive correlation was observed between BMI/weight and % of subjects reporting pregnancies (**Table 1**) and (**Figure 2 and 3)**.

Table 1: BMI and Pearl Index

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	$\geq$ 30	35%	6.42	8.88
Non-Obese	< 30	65%	3.94	5.35
Obese	$\geq$ 30	35%	6.42	8.88

Figure 2: % Pregnancy vs. Weight categories

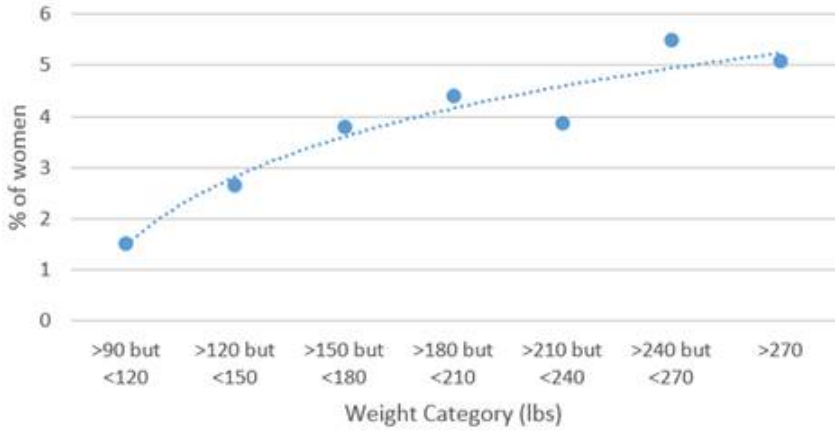
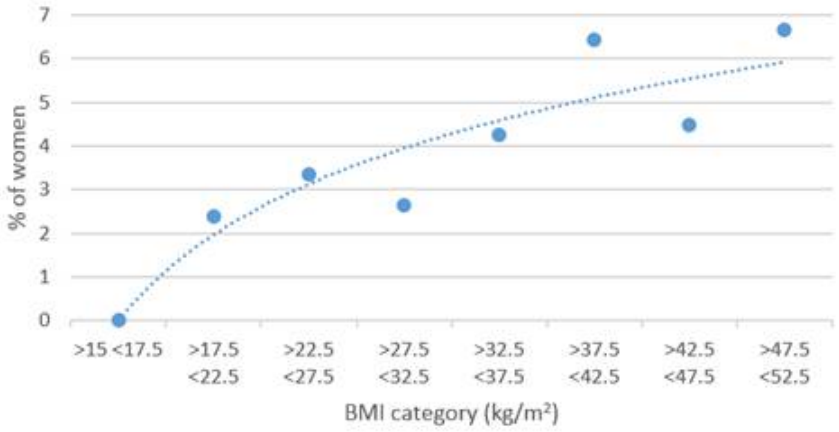


Figure 3: % Pregnancy vs. BMI categories



Supportive life table analyses were performed. Results for subjects ≤ 35 years of age are presented in **Table 2**.

Table 2: Pregnancy Rates Based on Life Table Analysis in Subjects ≤ 35 Years of Age

Cycle	Number of Subjects	Number of on-treatment pregnancies	Probability of pregnancy	95% CI
1	1816	3	0.17	0.05, 0.51
2	1681	11	0.64	0.35, 1.15
3	1556	17	1.02	0.64, 1.64
4	1448	26	1.64	1.12, 2.40
5	1349	31	2.00	1.41, 2.84
6	1263	39	2.62	1.92, 3.58
7	1192	41	2.79	2.06, 3.77
8	1130	46	3.22	2.41, 4.28
9	1068	48	3.40	2.56, 4.50
10	1004	49	3.49	2.64, 4.61
11	968	51	3.69	2.81, 4.85
12	930	53	3.90	2.98, 5.10
13	893	56	4.22	3.25, 5.48

Prior to the start of the study, 34.7% were current hormonal contraceptive users, 43.1% were prior users (who had used hormonal contraceptives in the past), and 9.4% had never used hormonal methods. The overall completion rate for study subjects was 49.5%; 11.3% of subjects were lost to follow-up, 10.9% discontinued due to an adverse event, and 15.3% discontinued by withdrawing their consent. The most frequent hormone-related adverse events are shown in **Table 3**.

Table 3: Adverse Events

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%

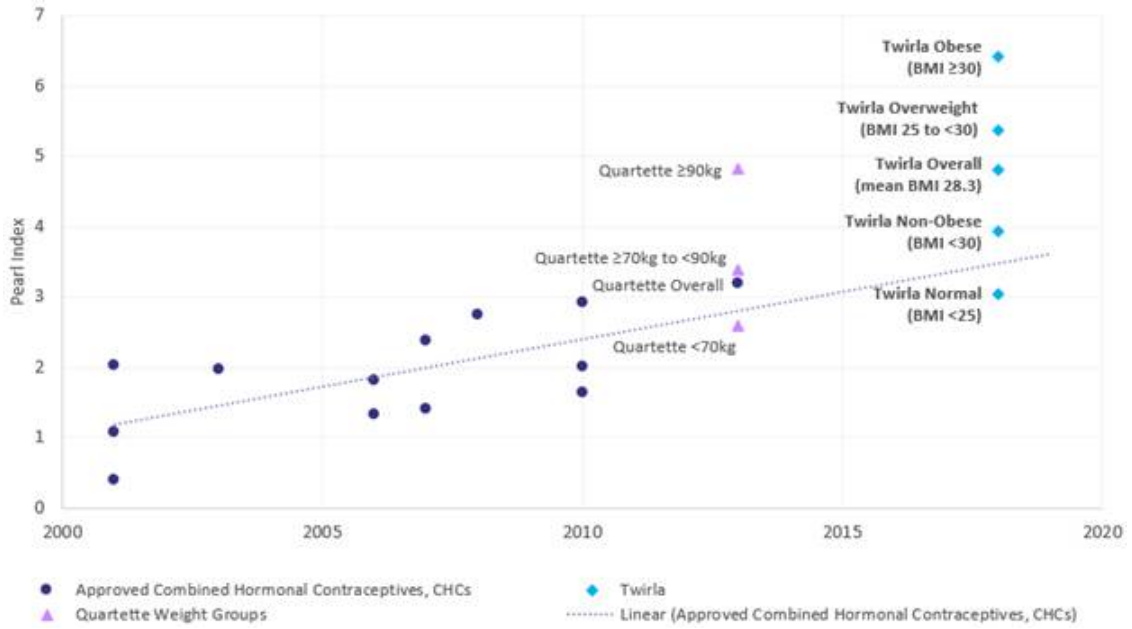
The most common (≥1%) adverse reactions leading to discontinuation were bleeding irregularities (1.8%) and any application site reaction (1.1%); all others were less than 1%. Subjects reported the presence and absences of bleeding as a study outcome in an electronic diary, these analyses are ongoing. Thus, bleeding patterns were rarely reported as an AE. Only 1.4% of women discontinued for bleeding issues. Serious adverse events were observed in 2% of subjects. The most common serious adverse events (occurring in ≥ 2 women) included cholelithiasis (n=4), deep vein thrombosis (n=3), pulmonary embolism (n=3), depression (n=3), gastroenteritis (n=2), cholecystitis (n=2), and ectopic pregnancy (n=2). Overall, patch-related irritation and itching rates 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. Of reported patches worn, the range of detachments was 10% in cycle 1 and reduced to 2% by cycle 13.

DISCUSSION:

Pearl Indices for approved hormonal contraceptives have steadily risen over time as study design, pregnancy test sensitivity, and characteristics of study participants have changed.(2)

(**Figure 4**) As described by Trussell, the growing enrollment of more diverse, real-world populations appear to be increasingly representative of the likely actual users once the product is marketed. Therefore, “the rates of contraceptive failure in methods requiring adherence will be much higher than those previously observed”. (2) Considering the historical evolution in contraceptive trial outcomes, and with the emerging role of obesity has a key factor in CHC failure, the SECURE trial results appear to be consistent with expected outcomes for modern contraceptive trials, and within a range consistent with efficacy reported for more recently approved Tier 2 contraceptive methods.

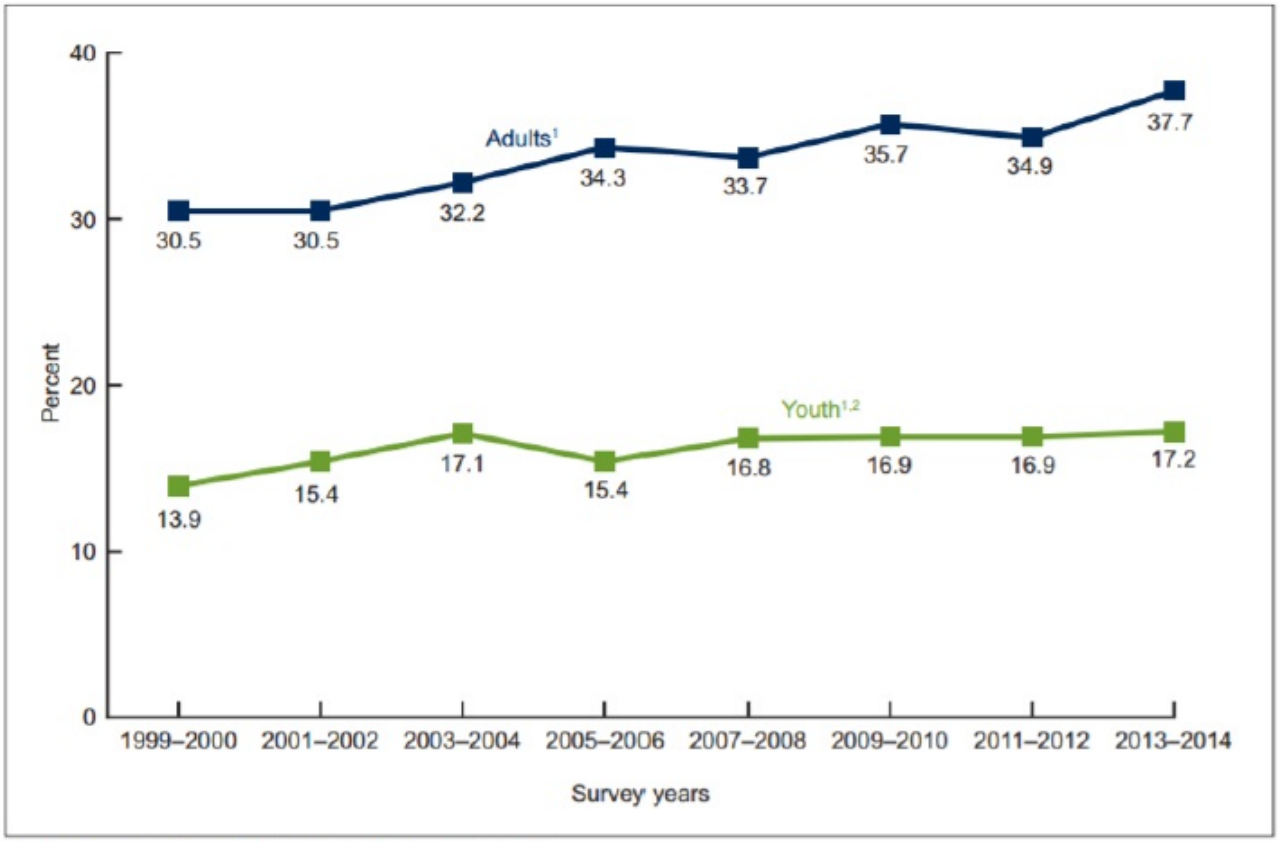
Figure 4: Historical Pearl Indices for CHCs Approved Since 2000 and the Pearl Indices Observed in the SECURE Trial



A drawback of the PI, an efficacy parameter whose use in clinical trials of new contraceptives is mandated by the FDA, is that it assumes a constant failure rate over time. In fact, risk of pregnancy changes as clinical trials continue. Extensive data characterizing the efficacy of contraceptives utilizes the PI, as presented in Figure 5. In contrast with the PI, life table analysis has the advantage of eliminating time-related biases. As a result, the life table analysis is a better representation of a contraceptives effect over time, especially with the use of a patch which requires some learning. In Phase 3 clinical trials in the United States, first year failure rates for products approved before 2011 ranged from 2.1-3.5%.(3) Estimates of typical use failure for OC use in the general population were closer to 8%.(4) Therefore, the rate of 4.22% after 1 year in SECURE may be expected when compared to clinical trial results in trials run in less generalizable, more restrictive trial designs.

The demographics of the U.S. population are changing. Between 1999 and 2014, the prevalence of obesity increased significantly (Figure 5).(5)

Figure 5. Trends in obesity prevalence among adults aged 20 and over and youth aged 2-19 years: United States, 1999-2000 through 2013-2014



[1]Significant increasing linear trend from 1999–2000 through 2013–2014.
[2]Test for linear trend for 2003–2004 through 2013–2014 not significant ($p > 0.05$).
NOTE: All adult estimates are age-adjusted by the direct method to the 2000 U.S. census population using the age groups 20–39, 40–59, and 60 and over.
SOURCE: CDC/NCHS, National Health and Nutrition Examination Survey.

According to the American College of Obstetricians and Gynecologists, obesity represents “the most common health care problem in women of reproductive age,”(6) However, the role of weight and/or BMI as potential risk factors for hormonal contraception failure has remains inadequately studied in prospective

clinical trials. In initial 2001 product labeling for Ortho Evra, the first combined HC patch approved in the U.S., a Limitation of Use states: "Ortho Evra may be less effective in preventing pregnancy in women who weigh 198 lbs. (90 kg) or more."(1) In 2015, the FDA published a seminal paper which brought attention to the increasingly important issue of obesity and effectiveness of hormonal contraception and reported that obesity may increase the risk of unintended pregnancy in women using hormonal contraception.(6) Historically, obese women have often been excluded from and/or under-represented in contraceptive trials. As a result, there has been a paucity of clinical trial data on hormonal contraceptive safety and effectiveness in obese women.

Based on a review of publicly available FDA NDA review documents and relevant published literature, it is likely that the SECURE trial population is the most overweight on record for a pivotal Phase 3 contraceptive trial. In the SECURE trial, AG200-15 failure rate was lowest in

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normal weight subjects (BMI < 25 kg/m^2), with a Pearl Index (PI) of 3.03 (95% CI 1.44, 4.62). When women with a BMI between 25 and $\leq$ 30 kg/m^2 were combined with normal weight women, the combined PI was marginally higher at 3.94 (95% CI 2.53, 5.35), but still within the range of approved combined hormonal contraceptive products. The PIs for overweight and obese subjects were 5.36 (95% 2.74, 7.98) and 6.42 (95% CI 3.96, 8.88), respectively. Although higher, the PI values in overweight and obese subjects in the SECURE trial are not substantially different from PI values that have been observed in sub-population analyses in a number of more recent NDA reviews of approved products consistent with heavier/higher BMI subjects experiencing lower contraceptive efficacy. A PI for those not using contraception is approximately 190 (James Trussell, personal communication, 5 August 2016). Pearl Indices, reported here, are somewhat lower in non-obese and normal-weight women compared to obese women, but both populations are substantially better than non-hormonal barrier methods. Other factors such as race and ethnicity, did not appear to impact the Pearl Index results.

In summary, AG200-15 has demonstrated contraceptive efficacy that is comparable to products that are currently in use in the U.S. population, particularly for non-obese women. AG200-15 was generally well tolerated and had an overall favorable safety profile, consistent with publicly available information for other low-dose combined hormonal products. Overall, patch-related irritation and itching rates were low and the patch adhesion profile was favorable with a low rate of detachment. Consistent with the emerging literature on the role of obesity in hormonal contraceptive efficacy, a weight effect was observed for AG200-15.

CONCLUSIONS:

- The SECURE trial was conducted in a diverse, real-world population of women that reflects current U.S. obesity trends.
- Pearl Index and life table results from the SECURE trial suggest that AG200-15 is an important contraceptive option for women who prefer a non-daily hormonal method.
- AG200-15 was well tolerated and rates of hormone related adverse events were comparable to approved combined hormonal contraceptives.
- Patch-related irritation and itching rates were low and the patch adhesion profile was favorable.
- The SECURE trial has provided substantial new data on HC effectiveness in obese and very obese women and supports the hypothesis that for short-acting combined hormonal contraceptives, obesity is associated with higher failure rates.
- Additional analyses of clinical trial data are needed to understand not only the magnitude of the impact of obesity, but also to better understand why obese women experience higher contraception failure rates.

REFERENCES:

(1) Ortho Evra label. Accessed Feb. 2017; http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021180s035lbl.pdf
(2) Trussell J, Portman D. The creeping pearl: why has the rate of contraceptive failure increased in clinical trials of combined hormonal contraceptive pills? *Contraception* 2013; 88; 604-10.
(3) Dinger J, et al. Effectiveness of oral contraceptive pills in a large U.S. cohort comparing progestogen and regimen. *Obstet Gynecol* 2011;117:33-40.
(4) Kost K. et al. Estimaters of contraceptive failure from the 2002 National Survery of Family Growth. *Contraception* 2008; 77(1): 10-21.
(5) Ogden CL, Carroll MD, Fryar CD, Flegal KM. Prevalence of obesity among adults and youth: United States, 2011—2014. NCHS data brief, no 219. Hyattsville, MD: National Center for Health Statistics. 2015ACOG Practice Bulletin No. 156, Dec 2015.
(6) Yamazaki M, et al. Effect on obesity on the effectiveness of hormonal contraceptives: an individual participant data meta-analysis. *Contraception* 2015;92,445-452.
