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

October 31, 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**	**08540**
(Address of principal executive offices)	(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

Item 8.01. Other Events.

On October 31, 2017, the Company announced additional data from its Phase 3 SECURE trial of Twirla® (AG200-15), an investigational, once-weekly, low-dose hormonal contraceptive patch, which showed women experienced mean decreases in length of bleeding and spotting episodes. These data were presented during an oral presentation by Anita Nelson, MD, Professor and Chair, Obstetrics and Gynecology, College of Osteopathic Medicine of the Pacific, and Co-Principal Investigator of the Agile Therapeutics, Inc., SECURE Phase 3 clinical trial, at the American Society for Reproductive Medicine (ASRM) Scientific Congress & Expo 2017 in San Antonio, Texas, and the abstract was published in *Fertility and Sterility.*

The presentation reported, among other items, that over 12 months, women on Twirla reported a gradual decrease in the mean total number of bleeding and/or spotting episodes from 6.0 to 4.9 days from cycles two through 13. Scheduled bleeding, or withdrawal bleeding during the patch-free week, decreased from 4.7 days at cycle two to 4.1 days at the end of the trial. The mean number of days of unscheduled bleeding, or breakthrough bleeding, decreased from 6.3 to 5.2 from cycle two through 13. While the duration of scheduled and unscheduled bleeding decreased, the mean number of episodes were consistent during the trial. Only 2.2% of women discontinued from the trial due to bleeding-related adverse events. presented data which showed women experienced mean decreases in length of bleeding and spotting episodes.

SECURE was a Phase 3, one-year, multicenter, single-arm, open-label 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. Agile announced top-line results of the SECURE clinical trial in January 2017.The Company's new drug application ("NDA") for Twirla is currently under review by the U.S. Food and Drug Administration with a target Prescription Drug User Fee Act (PDUFA) goal date of December 26, 2017.

Copies of the press release and 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 October 31, 2017.
99.2	Agile Therapeutics, Inc. Presentation dated October 31, 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: November 3, 2017

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

Exhibit 99.1

Agile Therapeutics Presents Additional Phase 3 SECURE Trial Results for Twirla® at the American Society for Reproductive Medicine (ASRM) Scientific Congress & Expo 2017

Data Suggests Twirla May Decrease Mean Length of Bleeding and Spotting Episodes

PRINCETON, N.J., Oct. 31, 2017 — Agile Therapeutics, Inc., (NASDAQ: AGRX), a women's healthcare company, today announced additional data from its Phase 3 SECURE trial of Twirla® (AG200-15), an investigational, once-weekly, low-dose hormonal contraceptive patch, which showed women experienced mean decreases in length of bleeding and spotting episodes. These data were presented during an oral presentation at the American Society for Reproductive Medicine (ASRM) Scientific Congress & Expo 2017 in San Antonio, Texas, and the abstract was published in *Fertility and Sterility***.**

Over 12 months, women on Twirla reported a gradual decrease in the mean total number of bleeding and/or spotting episodes from 6.0 to 4.9 days from cycles two through 13. Scheduled bleeding, or withdrawal bleeding during the patch-free week, decreased from 4.7 days at cycle two to 4.1 days at the end of the trial. The mean number of days of unscheduled bleeding, or breakthrough bleeding, decreased from 6.3 to 5.2 from cycle two through 13. While the duration of scheduled and unscheduled bleeding decreased, the mean number of episodes were consistent during the trial. Only 2.2% of women discontinued from the trial due to bleeding-related adverse events.

"Women generally hope for contraceptive options that lessen bleeding and spotting over time," said Anita L. Nelson, M.D., Research Division, Access Essential Health, Los Angeles, California. "This is an important factor that affects selection of and long-term continuation with hormonal contraception."

In July 2017, the U.S. Food and Drug Administration (FDA) accepted resubmission of the Company's New Drug Application (NDA) for Twirla and assigned December 26, 2017 as the Prescription Drug User Fee Act (PDUFA) goal date.

"The SECURE trial comprised an ethnically diverse, real-world population, which is reflective of women who may select the Twirla patch as their contraceptive method, if approved by the FDA," said Elizabeth Garner M.D., M.P.H., senior vice president and chief medical officer, Agile Therapeutics, Inc. "We believe Twirla has the potential to be an important low-dose, non-daily birth control option for today's modern woman."

For more information, please visit the company website at www.agiletherapeutics.com.

About the SECURE Trial

The Phase 3 SECURE (Study to Evaluate Contraception Use, Reliability, and Effectiveness) trial was a single-arm, open-label, 13-cycle trial designed to evaluate the efficacy, safety and tolerability of Twirla in 2,032 healthy women, aged 18 years and over, at 102 investigational sites nationwide. Bleeding information was self-reported by subjects on a daily basis using electronic diaries. Subjects were asked about both scheduled and unscheduled bleeding and spotting, using definitions described by Mishell et al. (Recommendations for Standardization of Data Collection and Analysis of Bleeding in Combined Hormone Contraceptive Trials; *Contraception 75; 11-15*).

About Twirla

Twirla (ethinyl estradiol and levonorgestrel transdermal system) or AG200-15 is an investigational once-weekly prescription contraceptive patch. AG200-15 is a combined hormonal contraceptive (CHC) patch that contains the active ingredients ethinyl estradiol (EE), a synthetic estrogen, and levonorgestrel (LNG), a type of progestin, a synthetic steroid hormone. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch.

About Agile Therapeutics, Inc.

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. The company may occasionally disseminate material, nonpublic information on the company website.

Follow Agile on Linked In and Twitter: @AgileTher.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" related to the Company's 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 involves 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 may 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; our statements about the planned resubmission of our NDA for Twirla could be affected by the potential that additional analyses of issues identified in our complete response letter from the FDA are required to be completed that were not previously anticipated, that our ongoing tests to support our resubmission are not completed on time, that the third parties we rely on to perform services in support of our NDA resubmission do not complete their work in a timely fashion and that

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.

SOURCE: Agile Therapeutics, Inc.

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SELECTED EFFICACY AND BLEEDING/SPOTTING OUTCOMES FROM THE SECURE TRIAL: A PHASE 3 STUDY OF AG200-15, AN INVESTIGATIONAL WEEKLY TRANSDERMAL CONTRACEPTIVE PATCH

Anita L. Nelson,[1] Andrew M. Kaunitz,[2] Robin Kroll,[3] James A. Simon,[4] Alfred N. Poindexter,[5] Joseph A. Chiodo,[6] Lisa Flood,[6] Elizabeth I.O. Garner[6]

[1]Research Division, Access Essential Health, Los Angeles, CA, USA; [2]University of Florida College of Medicine-Jacksonville, Jacksonville, FL, USA; [3]Seattle Women's, Seattle, WA, USA; [4]George Washington University School of Medicine, Washington, DC, USA; [5]Baylor College of Medicine, Houston, TX, USA; [6]Agile Therapeutics, Princeton, NJ, USA

Agile THERAPEUTICS

Disclosures

- Anita L. Nelson has served as a consultant/advisor for Agile, AMAG Pharma, Bayer, ContraMed, Merck, and Pharmanest; received honoraria/served as a speaker for Allergan, Bayer, and Merck; and received grants/research support from Agile, ContraMed, Estetra SPRL, Evofem Inc., FHI (MonaLisa), and Merck
- This study was sponsored by Agile Therapeutics.

Study Objective

- To assess selected efficacy and bleeding/spotting outcomes with the use of AG200-15 in the Phase 3 Study to Evaluate Contraception Use, Reliability, and Effectiveness (SECURE)
  - ClinicalTrials.gov NCT02158572

AG200-15 Overview

- Investigational transdermal contraceptive delivery system (TCDS)
- Daily exposure (24-hour AUC) of levonorgestrel (LNG) and ethinyl estradiol (EE) similar to oral doses of 120 µg LNG and 30 µg EE
- 28-day cycle:
  - 3 weeks of 7-day patches
  - 1 patch-free week

AUC = area under the curve

SECURE Study Design Elements

- Single-arm, open-label, 1-year (13-cycle), healthcare-company funded, Phase 3, IRB-approved study
  - No eligibility restrictions for weight or body mass index (BMI)
  - Conducted at 102 US sites
  - Subjects were 18 years of age or older, sexually active, and with regular menses every 21-38 days
- Pearl Index (PI) calculations for pre-specified subgroups
  - BMI
  - Race
  - Ethnicity
- Electronic diaries were used to collect daily
  - Vaginal bleeding
  - Vaginal spotting
  - Patch placement
  - Patch adherence

Bleeding and/or Spotting-Related Definitions

- Bleeding: requiring use of at least one tampon or sanitary pad
- Spotting: requiring use of pantyliners only or no sanitary protection
- Episode: one or more consecutive days of bleeding/spotting bounded on either end by ≥2 days of no bleeding or spotting
- Scheduled bleeding: occurring on days when not wearing a patch
- Unscheduled bleeding: occurring on days when wearing a patch, except bleeding/spotting that began in the previous hormone-free period and continued through Days 1-4 of the new treatment cycle

Study Populations

Parameter	Safety Population (n=2031)	Cycle Control Population (n=2017)	Primary Efficacy Cohort (n=1736)
Age, mean (SD)	27.5 years (6.2)	27.5 years (6.2)	26.0 years (4.5)
Weight, median (range)	71.9 kg (39 - 177)	72.0 kg (39 - 177)	71.40 kg (39 - 177)
BMI, median (range)	26.8 kg/m^2 (15 - 63)	26.8 kg/m^2 (15 - 63)	26.60 kg/m^2 (15 - 63)
BMI ≥30 kg/m^2 (obese), %	35.3%	35.4%	35.3%
Black/African American, %	24.3%	24.3%	24.1%
White, %	66.9%	66.8%	66.8%
Hispanic/Latino, %	19.7%	19.6%	19.0%

- Safety population: subjects who wore at least one patch
- Cycle Control Population: subjects in the safety population who had a negative enrollment serum ß-hCG, and provided information on bleeding and patch application in their eDiaries
- Primary efficacy cohort: subjects in the safety population aged ≤ 35 years at enrollment who had a negative enrollment serum ß-hCG

Pearl Indices for SECURE: Overall and by Subgroup for Primary Efficacy Cohort

	Pearl Index (95% CI)
Overall for women ≤35 years old	4.80 (3.55, 6.06)
BMI	
<median (26.8 kg/m^2)	4.22 (2.57, 5.87)
≥median (26.8 kg/m^2)	5.41 (3.51, 7.31)
Race	
White	5.06 (3.49, 6.62)
Black/African American	4.52 (1.97, 7.07)
Other	3.64 (0.08, 7.19)
Ethnicity	
Non-Hispanic/Latino	5.07 (3.64, 6.50)
Hispanic/Latino	3.65 (1.12, 6.17)

Pregnancy Rates Based on Life Table Analysis for Women ≤35 Years Old (Contraceptive Efficacy Population)

Cycle	No. of Subjects	Cumulative No. of On-treatment Pregnancies	Cumulative 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)

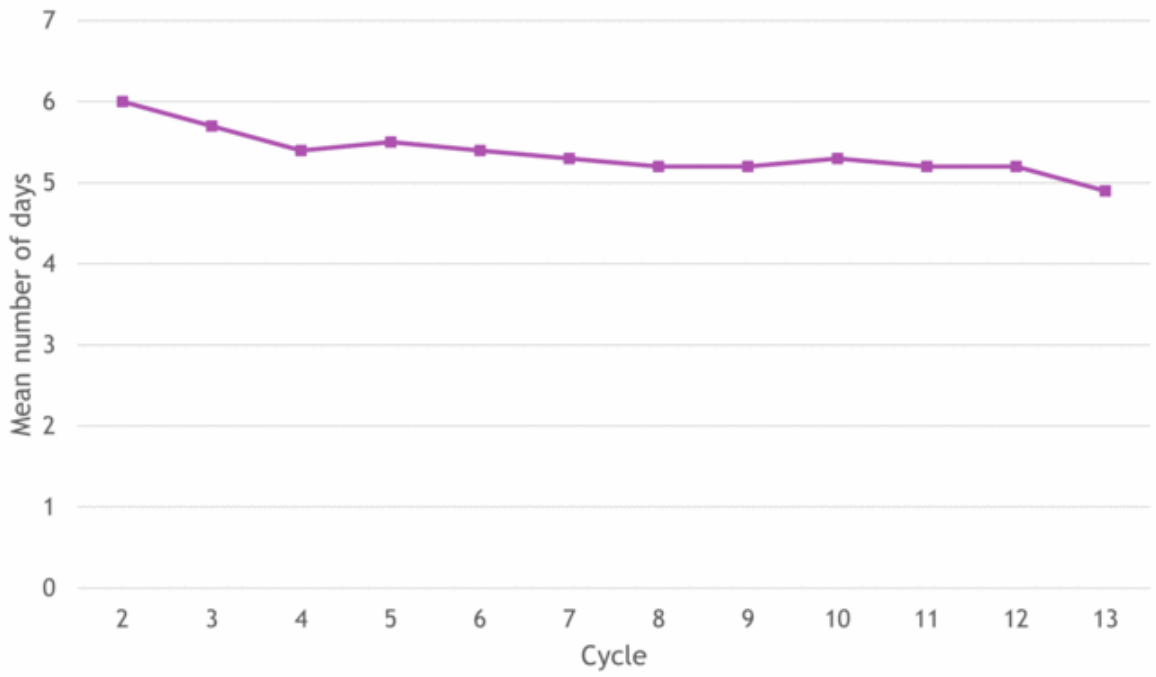
Cumulative probability of pregnancy calculated by the Kaplan-Meier method for Cycles 1-13.

Pregnancy Rates Based on Life Table Analysis for Women ≤35 Years Old by BMI Category (Contraceptive Efficacy Population)

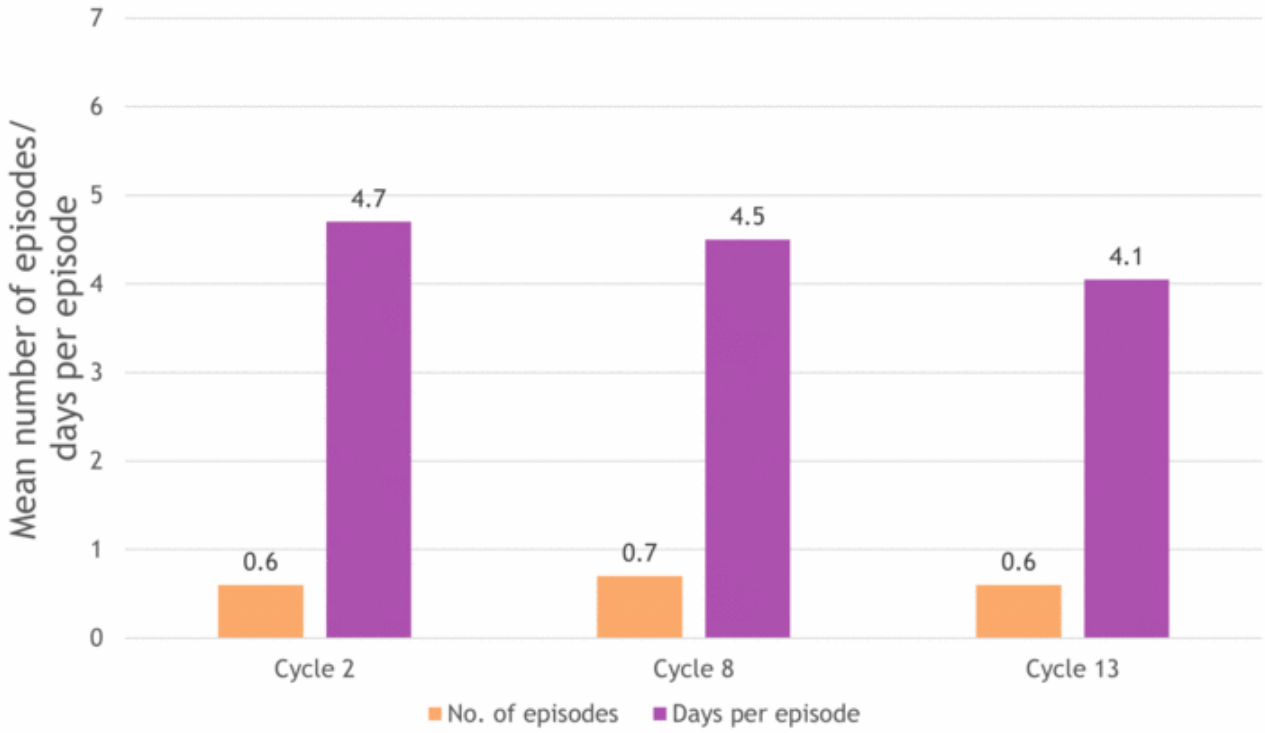
	Normal (BMI <25 kg/m^2)		Overweight (BMI ≥25 to < 30 kg/m^2)		Obese (BMI ≥30 kg/m^2)	
Cycle	n	Cumulative Probability of Pregnancy (95% CI)	n	Cumulative Probability of Pregnancy (95% CI)	n	Cumulative Probability of Pregnancy (95% CI)
1	721	0.28 (0.07, 1.10)	456	0.22 (0.03, 1.55)	638	0
2	659	0.58 (0.22, 1.54)	423	0.69 (0.22, 2.13)	598	0.67 (0.25, 1.77)
3	613	0.74 (0.31, 1.78)	388	0.95 (0.36, 2.51)	554	1.39 (0.70, 2.75)
4	574	1.09 (0.52, 2.28)	365	1.49 (0.67, 3.29)	508	2.36 (1.37, 4.03)
5	535	1.46 (0.76, 2.79)	338	1.78 (0.85, 3.71)	475	2.77 (1.68, 4.56)
6	499	2.05 (1.16, 3.60)	321	2.39 (1.25, 4.57)	442	3.43 (2.17, 5.40)
7	475	2.05 (1.16, 3.60)	301	2.39 (1.25, 4.57)	415	3.89 (2.52, 5.99)
8	453	2.05 (1.16, 3.60)	287	3.07 (1.70, 5.52)	389	4.63 (3.09, 6.92)
9	428	2.28 (1.32, 3.92)	273	3.07 (1.70, 5.52)	366	4.89 (3.29, 7.25)
10	400	2.28 (1.32, 3.92)	259	3.45 (1.96, 6.04)	344	4.89 (3.29, 7.25)
11	380	2.28 (1.32, 3.92)	253	3.83 (2.22, 6.56)	334	5.18 (3.51, 7.61)
12	366	2.55 (1.50, 4.30)	247	3.83 (2.22, 6.56)	316	5.48 (3.74, 8.00)
13	351	2.55 (1.50, 4.30)	238	5.04 (3.09, 8.18)	303	5.48 (3.74, 8.00)

Cum Prob of Pregnancy: Cumulative probability of pregnancy calculated by the Kaplan-Meier method for Cycles 1-13.

Mean Number of Days of Bleeding and/or Spotting by Cycle (Cycle Control Population)

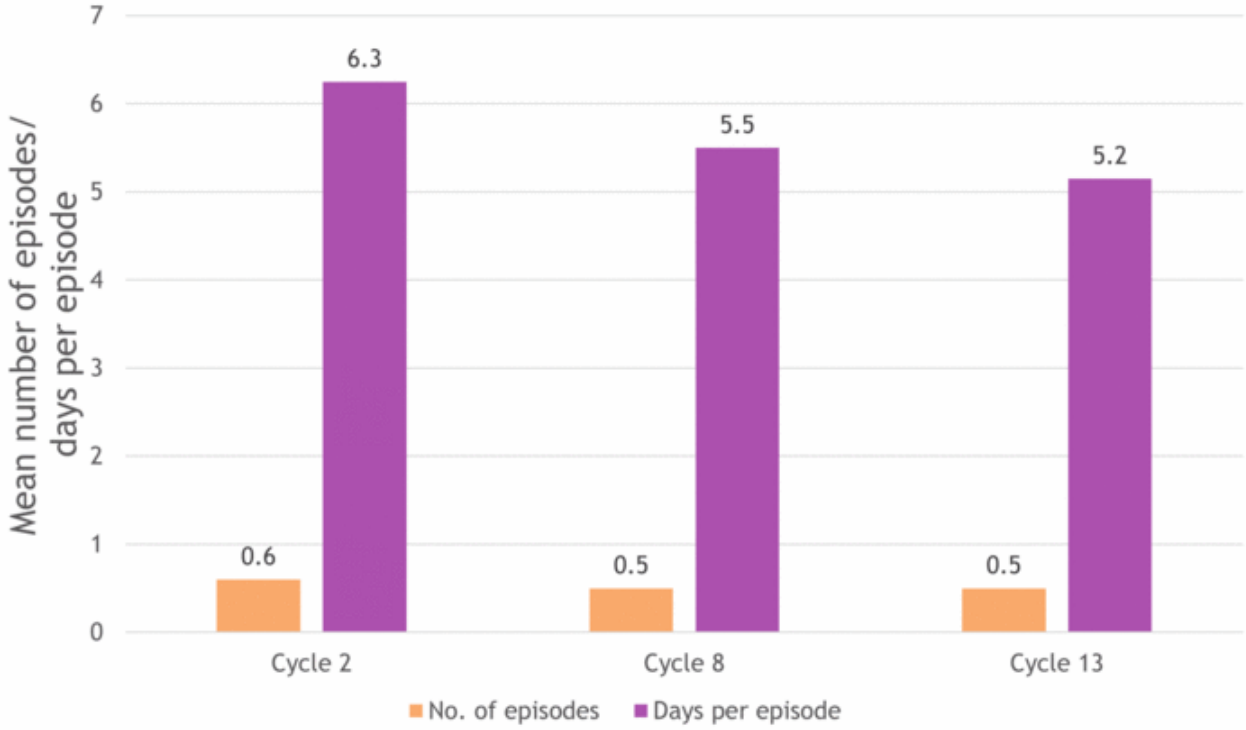


Mean Number and Length of Scheduled Bleeding and/or Spotting Episodes by Cycle



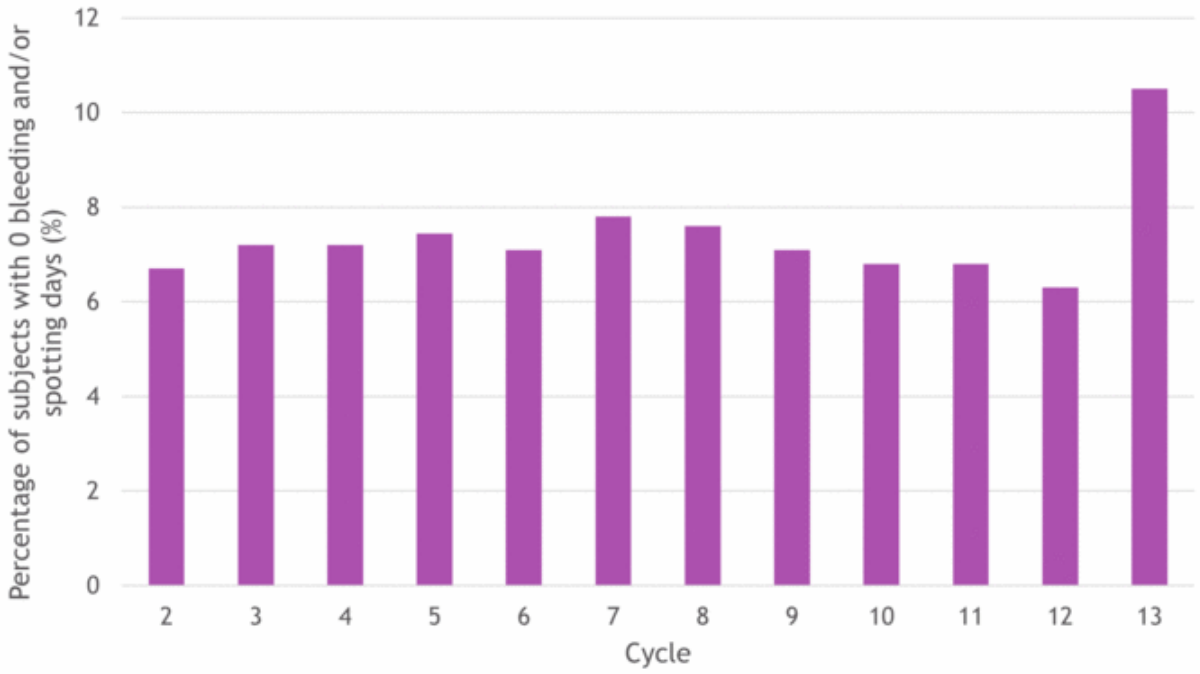
An episode of bleeding and/or spotting was defined as one or more consecutive days of bleeding/spotting bounded on either end by ≥2 days of no bleeding or spotting. Scheduled bleeding and/or spotting occurred on days when not wearing a patch.

Mean Number and Length of Unscheduled Bleeding and/or Spotting Episodes by Cycle



An episode of bleeding and/or spotting was defined as one or more consecutive days of bleeding/spotting bounded on either end by ≥2 days of no bleeding or spotting. Unscheduled bleeding/spotting occurred on days when wearing a patch, except bleeding/spotting that began in the previous hormone-free period and continued through Days 1-4 of the new treatment cycle.

Subjects with No Bleeding or Spotting Days by Cycle



Safety Findings

- The most frequent Treatment Emergent Adverse Events (TEAEs) (≥2%) possibly related to hormonal contraceptives included:

	AG200-15 (N=2031) n (%)
Nausea	84 (4.1)
Headache	72 (3.6)
Mood swings/changes/depression*	57 (2.8)
Dysmenorrhoea	47 (2.3)
Acne	41 (2.0)
Weight increased	41 (2.0)

*MedDRA preferred terms: mood swings, depression, mood altered, major depression, and depressed mood.
TEAE: treatment-emergent adverse event.

Treatment Emergent Bleeding or Spotting Adverse Events (AEs) Leading to Discontinuation

Preferred Term	AG200-15 (n = 2031)
Metrorrhagia	15 (0.7%)
Vaginal hemorrhage	13 (0.6%)
Menorrhagia	10 (0.5%)
Dysmenorrhea	7 (0.3%)
Dysfunctional uterine bleeding	2 (0.1%)
Menstruation irregular	2 (0.1%)
Menstrual disorder	1 (0.1%)
Any Treatment-Emergent Bleeding or Spotting AEs Leading to Study Drug Discontinuation	45 (2.2%)

AEs: adverse events.

Conclusions

- With a median BMI of 26.8 kg/m^2, the SECURE trial population is the most overweight on record for a pivotal Phase 3 contraceptive trial
- The efficacy of AG200-15, as assessed by the PI, differed by subgroups based on BMI, weight, and race/ethnicity
  - There was a trend toward higher PIs as BMI increased
  - This is consistent with increases in Pearl Indices reported in studies of newer, combination hormonal contraceptives
- The mean number of bleeding/spotting episodes were generally similar throughout the study, while the length of episodes generally decreased

THANK YOU

Mean Number of Bleeding/Spotting Episodes and Days Per Episode (±SD) By Cycle

	Cycle 2		Cycle 8		Cycle 13	
	No. of episodes	Days per episode	No. of episodes	Days per episode	No. of episodes	Days per episode
Scheduled bleeding and/or spotting	0.6±0.56	4.70±1.90	0.7±0.58	4.50±2.03	0.6±0.60	4.05±2.06
Scheduled bleeding-only	0.6±0.54	3.71±1.57	0.7±0.54	3.55±1.58	0.7±0.56	3.22±1.57
Scheduled spotting-only	0.6±0.71	1.62±1.07	0.6±0.69	1.52±0.99	0.6±0.74	1.41±0.77
Unscheduled bleeding and/or spotting	0.6±0.67	6.25±4.02	0.5±0.65	5.50±3.84	0.5±0.64	5.15±3.31
Unscheduled bleeding-only	0.4±0.58	4.66±2.96	0.4±0.56	3.96±2.52	0.4±0.54	3.74±2.25
Unscheduled spotting-only	0.5±0.71	2.20±1.72	0.4±0.65	2.18±1.81	0.4±0.64	2.09±1.73

An episode of bleeding and/or spotting was defined as one or more consecutive days of bleeding/spotting bounded on either end by ≥2 days of no bleeding or spotting. Scheduled bleeding and/or spotting occurred on days when not wearing a patch. Unscheduled bleeding/spotting occurred on days when wearing a patch, except bleeding/spotting that began in the previous hormone-free period and continued through Days 1-4 of the new treatment cycle.