



## Agile Therapeutics Announces FDA Acceptance of the NDA Resubmission of Twirla®

May 22, 2019

### **FDA Assigns Prescription Drug User Fee Act (PDUFA) Goal Date of November 16, 2019**

PRINCETON, N.J., May 22, 2019 (GLOBE NEWSWIRE) -- [Agile Therapeutics, Inc.](#) (Nasdaq:AGRX), a women's healthcare company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's New Drug Application (NDA) resubmission for Twirla® (AG200-15), an investigational low-dose combined hormonal contraceptive patch. The NDA resubmission was submitted on May 16, 2019 and is intended to address a Complete Response Letter (CRL) issued by the FDA in December 2017, which identified deficiencies relating to (i) quality control adhesion test methods for the Twirla manufacturing process, (ii) observations identified during an inspection of a facility of our third-party manufacturer for the Twirla NDA that must be resolved, and (iii) questions on the *in vivo* adhesion properties of Twirla and their potential relationship to the SECURE clinical trial results. The resubmitted NDA includes the results from a comparative wear study that was conducted at the request of the FDA to address the FDA's questions on *in vivo* adhesion, additional information on the Company's manufacturing process, and other analyses responding to the 2017 CRL. The FDA stated that it considers the resubmission to be a complete, class 2 response to the CRL and established November 16, 2019 as the Prescription Drug User Fee Act (PDUFA) goal date.

"The acceptance of our NDA for review represents a significant milestone for Agile. Now that the FDA has acknowledged our NDA resubmission as a complete response to the CRL, we look forward to continuing to work with the FDA during their review," said Al Altomari, Chairman and Chief Executive Officer of Agile.

### **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 an investigational low-dose, non-daily prescription contraceptive. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to allow drug delivery through the skin. For more information, please visit the company website at [www.agiletherapeutics.com](http://www.agiletherapeutics.com). The Company may occasionally disseminate material, nonpublic information on the Company's website.

### **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.

### **Forward-Looking Statement**

Certain information contained in this press release includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, related to our regulatory submissions for Twirla. We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "likely," "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, including statements regarding the FDA's acknowledgment of the resubmission of the Twirla NDA as a complete response, the timing of such acknowledgment and our expectations regarding the receipt of a PDUFA date and the timing of such date. 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. These forward-looking statements are subject to risks and uncertainties including risks related to our ability to adequately and timely respond to the deficiencies in the second Twirla CRL issued by the FDA on December 21, 2017, the potential that the FDA determines that our resubmitted NDA is not a complete response and refuses to review the NDA, or that our data do not support resubmission or approval of Twirla NDA and requires us to conduct additional studies or reformulate Twirla to address the concerns raised in the 2017 CRL, our ability to obtain and maintain regulatory approval of our product candidates, the labeling under any approval we may obtain, our ability to obtain a favorable Advisory Committee vote in the likely event the FDA requires an Advisory Committee to review the benefit and risk profile of Twirla, our third-party manufacturer, Corium International, Inc.'s (Corium) inability to complete any work or provide any data and other information necessary to support the resubmission and approval of our Twirla NDA, our ability along with Corium to complete successfully the scale-up of the commercial manufacturing process for Twirla, including the qualification and validation of equipment related to the expansion of Corium's manufacturing facility and to pass a likely FDA pre-approval inspection, the performance and financial condition of Corium or any of the suppliers to our third-party manufacturer, the success and timing of our clinical trials or other studies, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for our product candidates, our inability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of our product candidates or other materials required for a clinical trial or other tests and studies, and the other risks set forth in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. 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

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