



The Biden-Harris Administration Announces New Guidance to Enable Expanded Access to All FDA-Approved Contraceptives Without Cost

January 23, 2024

Implementation of the New Guidance Could Eliminate Financial Barriers for Contraceptive Products like Twirla[®] for 49 Million Women

These Actions Follow Several Months of Activity by the Biden Administration to Strengthen Access to All FDA Approved Contraceptives as Defined in President Biden's June 2023 Executive Order

The Company Commends the Administration for their Continued Commitment to Reproductive Health

PRINCETON, N.J., Jan. 23, 2024 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc., (Nasdaq: AGRX), a women's healthcare company, commends the Biden-Harris Administration for their continued commitment to reproductive health including increasing access to no-cost contraception.

Following several months of focus by the Biden Administration and lawmakers on contraception and impermissible barriers to reproductive healthcare, the Departments of Labor, Health and Human Services, and the Treasury (the "Tri-Agencies") jointly released new guidance in the form of Frequently Asked Questions ("FAQ") on Monday, January 22, 2024. The FAQ outlines a "new pathway for plans and issuers to meet existing obligations under federal law by covering, at no cost, a broader range of FDA-approved contraceptive drugs and certain devices."^{1,2} The Tri-Agencies describe how plans may comply with the ACA requirement to cover contraception without cost sharing by "covering all [FDA] approved drugs and drug-led devices other than those for which there is a covered therapeutic equivalent" as identified in the Orange Book.^{1,2} This new pathway comes after reports of many plans and issuers imposing impermissible barriers to no-cost contraceptive coverage.

The new guidance follows the President's Executive Order in June 2023, which directed the Secretaries to consider actions, to the greatest extent permitted by law, that will ensure coverage of comprehensive contraceptive care including all contraceptives approved, granted, or cleared by the Food and Drug Administration, without cost sharing for enrollees, participants, and beneficiaries.³

In concert with the FAQ, Secretary Becerra, the head of Health and Human Services also sent a letter² to health plans and insurers highlighting the issuance of new guidance and noting that, "as we have previously made clear, we will continue to call on group health plan sponsors and issuers to remove impermissible barriers and ensure individuals in your plans have access to the contraceptive coverage they need, as required under the law. It is more important than ever to ensure access to contraceptive coverage without cost-sharing, as afforded by the ACA."

"We recognize the importance of reproductive freedom for women and applaud the administration for taking concrete actions to ensure women have access to the contraceptive product that is right for them without barriers and cost-sharing," said Agile Therapeutics, Inc.'s Chairperson and Chief Executive Officer Al Altomari. "We believe the new guidelines take a significant step towards eliminating financial barriers to contraceptives and we look forward to working with patients and providers interested in a low dose patch option like Twirla[®]."

¹ HHS Secretary Xavier Becerra Announces New Actions to Increase Contraceptive Care Coverage on 51st Anniversary of Roe v. Wade [HHS Announces New Actions to Increase Contraceptive Care Coverage January 22 2024](#)

² Frequently Asked Questions About the Affordable Care Act Part 64, January 22, 2024 [FAQ Part 64 January 22 2024](#)

³ President Biden Executive Order June 23, 2023 [Executive-order-on-strengthening-access-to-affordable-high-quality-contraception-and-family-planning-services June 23, 2023](#)

About Agile Therapeutics, Inc.

Agile Therapeutics is a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product and 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 initial product, Twirla[®], (levonorgestrel and ethinyl estradiol), a transdermal system, is a 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. The Company may occasionally disseminate material, nonpublic information on the Company's website and [LinkedIn](#) account.

About Twirla[®]

Twirla (levonorgestrel and ethinyl estradiol) transdermal system is a once-weekly combined hormonal contraceptive (CHC) patch that contains the active ingredients levonorgestrel (LNG), a type of progestin, and ethinyl estradiol (EE), a type of estrogen. Twirla is indicated for use as a method of contraception by women of reproductive potential with a body mass index (BMI) < 30 kg/m² for whom a combined hormonal contraceptive is appropriate. Healthcare providers (HCPs) are encouraged to consider Twirla's reduced efficacy in women with a BMI ≥ 25 to <30 kg/m² before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m². Twirla is also contraindicated in women over 35 years old who smoke. Cigarette smoking increases the risk of serious cardiovascular events from CHC use. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch.

Forward-Looking Statements

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. 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 potential impact of and response to the recent guidance FAQs issued by the Tri-Agencies including, but not limited to the potential increase in access to no cost contraception. 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 the likelihood that the Tri-Agencies will enforce the new FAQs regarding ACA implementation, the response of commercial payors to the FAQs and any impact on coverage for Twirla, our ability to successfully enhance the commercialization of and increase the uptake for Twirla, the size and growth of the markets for Twirla and our ability to serve those markets our strategy, business plans and focus, 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 circumstance.

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