



Agile Therapeutics Acknowledges New Government Guidance Reinforcing Requirement to Cover Contraceptives that a Woman and Her Healthcare Provider Determine are Medically Appropriate at No Cost

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PRINCETON, N.J., Jan. 12, 2022 (GLOBE NEWSWIRE) -- On January 10, 2022, the tri-agencies, Department of Labor (DOL), Health and Human Services (HHS) and Treasury issued new guidance that supports women's access to U.S. Food and Drug Administration (FDA) approved contraceptive products. Additionally, on January 11, 2022, the Health Resources and Services Administration (HRSA) updated the Women's Preventative Services Guidelines including contraception services.

In their guidance, the tri-agencies reminded plans and issuers of their responsibility to fully comply with the requirements of the Affordable Care Act and the HRSA Guidelines, including the requirement that, if an individual and their attending provider determine that a particular service or FDA-approved, cleared, or granted contraceptive product is medically appropriate for the individual (whether or not the item or service is identified in the current FDA Birth Control Guide), the plan or issuer must cover that service or product without cost sharing.

They also provided a path for consumers to report concerns if they experience issues obtaining the contraceptive deemed most medically appropriate for them.

The updated [HRSA Women's Preventive Services Guidelines](#), which take effect for plan years beginning 2023, restates the requirement that women have access to the full range of FDA-approved, granted or cleared contraceptives as part of preventative services available without cost sharing.

"Birth control is a very individual decision, and we agree that women should have access to the contraceptive product determined to be most appropriate for them based on discussions with their healthcare provider. The recent guidelines and recommendations will help reduce barriers by providing women with access to the birth control most appropriate for them at no cost." said Kimberly Whelan, Agile Therapeutics Vice President, Policy, Advocacy and Market Access.

Agile Therapeutics Chairman and CEO Al Altomari added, "We agree with the recent recommendations that will help eliminate barriers to contraceptive access for women and we will work with the plans and issuers to achieve this goal."

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) 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.

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 third party coverage of contraceptives and women's affordable access to the contraceptives of their choice. 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 regulatory and legislative developments in the United States and foreign countries, legal and regulatory compliance of third parties outside our control, 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.

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