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FDA Advisory Committee Discusses Clinical Trial Designs for Obesity-Related Hypogonadism

THE WOODLANDS, Texas, Dec. 06, 2016 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc.® (Nasdaq:RPRX) participated in the industry presentation at the Bone, Reproductive and Urologic Drugs Advisory Committee Meeting today. The panel provided the FDA with advice regarding a clinical and regulatory path to approval for products, such as enclomiphene, in subjects with obesity-related hypogonadism who wish to maintain spermatogenesis. The panel voted 16 to 5 that the achievement of testosterone improvement while maintaining evidence of spermatogenesis was not sufficient, in and of itself, to provide evidence of clinical benefit.

At the meeting, numerous panel members suggested that an additional endpoint related to symptoms should be assessed. Repros expects its ongoing diet and exercise study to provide useful information toward the development of a symptom-related assessment tool. After completing this study and evaluating the data, Repros intends to meet with FDA to discuss the design of a definitive Phase 3 study that incorporates the advice of the committee.

Joe Podolski, President and CEO of Repros, states, "We remain encouraged that the FDA and the Committee held the committee meeting, indicating a recognition of obesity-related hypogonadism. Further, we appreciate that there was a complete discussion on the condition and that the committee clarified a path forward."

About Repros Therapeutics Inc.®

Repros Therapeutics focuses on the development of small molecule drugs for major unmet medical needs that treat male and female reproductive disorders.

Forward-Looking Statements

Any statements made by the Company that are not historical facts contained in this release are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and are subject to various risks, uncertainties and other factors that could cause the Company's actual results, performance or achievements to differ materially from those expressed or implied by such forward-looking statements. These statements often include words such as "may," "will," "expect," "anticipate," "continue," "estimate," "project," "intend," "believe," "plan," "seek," "could," "can," "should" or similar expressions. These statements are based on assumptions that the Company has made in light of the Company's experience in the industry, as well as the Company's perceptions of historical trends, current conditions, expected future developments and other factors the Company believes are appropriate in these circumstances. Forward-looking statements include, but are not limited to, those relating to the timing and nature of the results of clinical studies and the impact of such results. Such statements are based on current expectations that involve a number of known and unknown risks, uncertainties and other factors that may cause actual events to be materially different from those expressed or implied by such forward-looking statements, including risks that additional phases of clinical studies may not be successfully undertaken or completed, that the FDA may not ultimately approve the product candidate, the risk that any marketing approvals, if granted, may have significant limitations on use, that even if an NDA is approved, the Company may not be able to successfully commercialize the product candidate, risks relating to the Company's ability to protect its intellectual property rights and such other risks as are identified in the Company's most recent Annual Report on Form 10-K and in any subsequent quarterly reports on Form 10-Q. These documents are available on request from Repros Therapeutics or at www.sec.gov. Repros disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

For more information, please visit the Company's website at <http://www.reprosrx.com>.

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