July 17, 2017

Repros Announces Proellex® Development Program Will Remain on Partial Clinical Hold by the FDA

- ***Repros Assessing Uterine Fibroid and Endometriosis Development Program with Vaginal Drug Delivery Treatment***

- ***Expects to Receive European Patent that Relates to Selective Progesterone Modulators***

THE WOODLANDS, Texas, July 17, 2017 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc.®, (Nasdaq:RPRX) dedicated to treating male and female reproductive disorders, today announced that it received preliminary feedback from the FDA on the Company's clinical development program for Proellex®, its oral delivery mechanism for telapristone acetate. The Proellex® program will remain on partial clinical hold, and based upon the FDA's review of all the existing liver function safety data, the FDA has indicated that the Company will be required to compile a large pre-approval safety data base to support future development.

Larry Dillaha, MD, Chief Executive Officer of Repros, said, "We are appreciative of the preliminary feedback received from the FDA and expect further clarification from the FDA in the coming weeks on our Proellex® development program. Our discussions with the FDA, and their guidance that a large safety data base will be required to continue the development of Proellex®, indicate that a much larger clinical trial, with associated time and cost requirements, would be necessary."

In light of the FDA guidance, the Company is assessing increasing its focus on its uterine fibroid and endometriosis development program utilizing a vaginal drug delivery program for telapristone acetate, a selective progesterone modulator (SPRM). Dr. Dillaha commented, "We are encouraged by our clinical studies with our vaginal drug delivery program, which may provide the potential opportunity to differentiate our treatment from other orally-dosed compounds in development or on the market to treat uterine fibroids. Clinical work done to date suggests that vaginal delivery of telapristone acetate has the potential to yield good efficacy with significantly lower systemic blood levels. Furthermore, we intend to leverage drug delivery technology that could offer dosing less frequently than once per day."

Additionally, Repros has received notice that on August 2, 2017 it will be granted a European patent relating to the use of SPRMs, in particular Telapristone Acetate (Proellex®) or Ulipristal Acetate, with an Off Drug Interval (ODI) for the treatment of estrogen-dependent hyperproliferative uterine conditions, such as uterine fibroids and endometriosis. The European patent is related to the Company's recently granted U.S. Patent number 9,616,074, announced by the Company in April 2017.

Finally, as previously announced, the Company submitted to the European Medicines Agency (EMA) a marketing authorization application (MAA) for enclomiphene in the treatment of secondary hypogonadism in Europe in September of 2016. As part of the ongoing review process, the Company expects to file responses to the EMA in the third quarter of 2017.

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 relating to the Company's pipeline and plans for growth; ongoing and future clinical studies and the timing and results thereof; the Company's plans to communicate with and submit further information to the FDA; possible submission of one or more NDAs; the commercial potential of vaginally delivered telapristone acetate; the fact that the EMA may not ultimately grant the marketing authorization, on the expected timeline or at all; the fact that the marketing authorization, if granted, may have significant limitations on use and that even if the marketing authorization is ultimately granted, the Company may not be able to successfully commercialize the product candidate; 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.

CONTACT: Investor Relations:

Joe Schepers

jschepers@reprosrx.com

770-558-5517


Primary Logo

Source: Repros Therapeutics Inc.