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Repros Announces Initiation of Formal Approval Process by the European Medicines Agency

THE WOODLANDS, Texas, March 15, 2016 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc.® (Nasdaq:RPRX) today announced that it has formally activated the process for obtaining marketing authorization for enclomiphene in the treatment of secondary hypogonadism by the European Medicines Agency (EMA).

Repros is seeking the enclomiphene marketing authorization for Europe through a central filing which is valid in all European Union and European Economic Area countries, i.e. 31 countries in total. The centralized procedure allows for a pan-EU review of the data, led by the Rapporteur's and Co-Rapporteur's assessment teams, and is governed by set timelines; therefore the review time is well defined. Based on these timelines, the Company believes authorization to market enclomiphene in the EU can be obtained by the fourth quarter of 2017. Importantly, EU approval would open potential marketing opportunities for enclomiphene to numerous non-US territories.

The EMA already recognizes secondary hypogonadism as a discrete disorder that requires medical intervention. This medical need is confirmed by Professor Fred Wu, Professor of Medicine and Endocrinology, University of Manchester and Principal Investigator in the European Male Aging Study who stated: "One of the most disabling but less recognized problems in obese men is low testosterone (secondary hypogonadism). With the increasing fattening of our society, there is a great need for effective medical treatment of secondary hypogonadism. Drugs, such as enclomiphene, that raise testosterone production in obese men, could be invaluable as part of the management of diabetic and obese patients."

Dr. John Dean, St. Peter's Andrology Centre and past President of the International Society for Sexual Medicine, commented: "The majority of men with secondary hypogonadism, the most prevalent form of hypogonadism, are poorly served. In addition, for many men receiving existing T replacement there can be a counterproductive reduction in fertility. For these reasons the approval of enclomiphene has the potential to represent a substantial step forward in the management of this area of high, and increasing, medical need. Fortunately, the EMA appears to recognize secondary hypogonadism as a disorder requiring medical intervention."

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 possibility of obtaining marketing authorization from the EMA, the timeframe for such process, and the potential marketing opportunities that could follow such authorization. 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 the EMA may not ultimately grant the marketing authorization, on the expected timeline or at all, the risk that the marketing authorization, if granted, may have significant limitations on use, that even if the marketing authorization is ultimately granted, 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.

CONTACT:

Investor Relations:

Thomas Hoffmann

The Trout Group

(646) 378-2931

thoffmann@troutgroup.com


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