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Repros Announces Submission of MAA to the European Medicines Agency for Enclomiphene in the Treatment of Secondary Hypogonadism

- | *UK designated as rapporteur and France as co-rapporteur*
- | *Average time to approval 13 - 16 months*

THE WOODLANDS, Texas, Sept. 12, 2016 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc.® (Nasdaq:RPRX) today announced that, as anticipated, it has activated the process for obtaining a marketing authorization (MAA) for enclomiphene in the treatment of secondary hypogonadism in Europe.

The MAA has been submitted today to the European Medicines Agency (EMA) by Renable Pharma Limited, the U.K. subsidiary of Repros.

The typical time from submission to authorization of a medicinal product through the centralized procedure is 13-16 months and culminates in one authorization being obtained which is valid in all European Union and European Economic Area countries, i.e. 31 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 that establish a well-defined review time.

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 (EMAS), 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. Michael Wyllie, Independent Director of Repros, commented: "The submission for approval by the EMA represents a key milestone toward the commercialization of enclomiphene. Not only is the MAA timeline definable, but obtaining authorization would potentially allow access to a considerable patient population, with the EU adult male population being 165% of that in the US. The data from Professor Wu's EMAS study indicates that the prevalence of secondary hypogonadism is significantly greater than the occurrence of primary hypogonadism."

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 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>.

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