June 1, 2016

Repros Provides Update on EU Submission of Enclomiphene for the Treatment of Secondary Hypogonadism and 3 Month Interim Results for Enclomiphene Study in Obese Secondary Hypogonadal Men

- *EU submission on track with anticipated registration decision expected Fall 2017*
  - *UK designated as rapporteur and France as co-rapporteur for the centralized review of the enclomiphene marketing application*
- *3 month interim assessment of testosterone levels in obese men participating in Phase 2 diet and exercise study show statistically significant increases in testosterone in the active arms versus the placebo arm*

THE WOODLANDS, Texas, June 01, 2016 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc.® (Nasdaq:RPRX) today announced that it remains on track for submission of a European centralized marketing authorization application (MAA) for enclomiphene for the treatment of secondary hypogonadism. To that end, the European Medicines Agency (EMA) has assigned France and the UK as rapporteurs for the application review. The Company expects to submit the application in Fall 2016. As part of the review process, the Company is scheduled to meet with British and French medical reviewers in June 2016.

Secondary hypogonadism is recognized in Europe. The epidemiology of the disorder, based on published evidence from the European Male Aging Study (EMAS), has been well reported and the Company believes that it is well understood amongst key European thought leaders.

US Development of Enclomiphene in the Treatment of Secondary Hypogonadism

The US FDA currently approves testosterone therapies for the treatment of "Classical Hypogonadism". The FDA defines this disorder as essentially a condition in which the testes are no longer functional (other than for old age) and/or the pituitary is defective. As required by the FDA, in order for any drug to be approved for treating men with secondary hypogonadism, a clinical benefit other than increasing testosterone must be determined in well controlled clinical studies. To that end, the Company is conducting the ongoing Phase 2 diet and exercise study evaluating numerous endpoints which could be deemed as clinically beneficial. There are two active arms dosing men with 12.5 and 25 mg of enclomiphene and one placebo group.

During the first six month phase of the study, men are provided a commercially available prepared diet along with enrollment in a health club with a personal trainer. Subjects are asked to attend the health club at least three times per week. At the end of the six month period the subjects will be assessed for changes in a variety of biochemical markers as well as anatomical markers such as waist circumference, lean body mass and BMI. Quality of life will also be assessed. The six month data should be available in Fall 2016.

During the second six month phase, men will continue treatment with enclomiphene or placebo but will no longer be provided the commercial diet. Exercise with the assigned trainer will continue during this period. A second assessment for changes previously monitored will be made and reported.

In the last three months of the study, the subjects will no longer receive treatment but will stay enrolled in the health club, though, without a trainer.

After three months of treatment, all groups lost weight. However, the weight loss exhibited in the placebo group did not yield increased levels of testosterone. The placebo group had an average testosterone level of 221 ng/dL at baseline. After three months of diet and exercise the average testosterone level dropped to 214 ng/dL. For the active arms, the mean baseline testosterone increased from 212 ng/dL to 399 ng/dL. The difference between the active and placebo group was highly significant, $p < 0.0001$. Metabolic function was not assessed at the three month time point.

The Company plans to report metabolic and anatomical effects, including change in lean body mass, after the six month assessment.

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, the potential marketing opportunities that could follow such authorization, the timing and nature of the results of clinical studies, and possible future interactions with the FDA. 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, that additional 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.

CONTACT: Investor Relations:

Thomas Hoffmann

The Trout Group

(646) 378-2931

thoffmann@troutgroup.com

Primary Logo

Source: Repros Therapeutics Inc.