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# Repros Provides Six Month Interim Results for Enclomiphene Study in Obese Secondary Hypogonadal Men

- *Six month interim assessment of testosterone (T) levels shows statistically and clinically significant increases in total T (p = 0.0017) and free T (p = 0.0020) superior to placebo*
- *Effects of diet and exercise and enclomiphene treatment are additive*
  - *Diet and exercise alone increased mean total T (263.9 ng/dL to 368.2 ng/dL, p = 0.0055) and mean free T (55.6 pg/mL to 57.1 pg/mL, p = 0.0802)*
  - *Enclomiphene treatment combined with diet and exercise increased mean total T (277.3 ng/dL to 780.9 ng/dL, p < 0.0001) and free T (56.3 pg/mL to 140.1 pg/mL, p = 0.0001)*
- *Enclomiphene treatment combined with diet and exercise increases lean body mass over baseline; higher weight loss in placebo group*

THE WOODLANDS, Texas, Aug. 15, 2016 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc.® (Nasdaq:RPRX) today provided a six month update on results from Repros' ongoing 15 month study of secondary hypogonadal men in which diet and exercise alone is compared to diet and exercise in combination with enclomiphene treatment. There are two active arms, one dosing men with 12.5 mg of enclomiphene and the other with 25 mg, and one placebo group.

During the recently completed first six month phase of the study, all subjects were provided a commercially available prepared diet along with enrollment in a health club with a personal trainer. In this first phase subjects were asked to attend the health club at least three times per week. All subjects have been assessed for changes in a variety of biochemical markers as well as anatomical markers such as lean body mass and BMI. Changes in responses to three different quality of life questionnaires were also assessed.

During the second six month phase, men will continue their current 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.

Using LC/MS/MS assessments for total T and free T, it was determined diet and exercise alone increased total T from a mean of 264 ng/dL (SD 67) at baseline to 368 ng/dL (SD 116), p = 0.0055, at 6 months but only raised free T from 55.6 pg/mL (SD 18.7) to 57.1 pg/mL (SD 18.2), p = 0.0802.

On the other hand, the 12.5 and 25 mg doses of enclomiphene achieved levels of both total T and free T beyond levels reached without the addition of diet and exercise in previous studies. Again using LC/MS/MS assessments, the 12.5 mg group exhibited an increase in mean morning T from 298 ng/dL (SD 89) to 723 ng/dL (SD 205), p = 0.0002, at six months, while mean morning T for the 25 mg group increased from 255 ng/dL (SD 64) to 864 ng/dL (SD 425), p = 0.0082. Free T by equilibrium method also increased significantly from 62.8 pg/mL (SD 24.1) to 129 pg/mL (SD 47.3), p = 0.0048, for the 12.5 mg group and from 49.0 pg/mL (SD 16.2) to 154 pg/mL (SD 86.2), p = 0.0313, for the 25 mg group. Treatment with enclomiphene produced statistically significantly higher increases in total T (p = 0.0017) and free T (p = 0.0020).

A standard antibody-based assay also showed significant increases for total T in enclomiphene-treated subjects. Eighty-eight percent (88%) of subjects treated with enclomiphene had a T level in the normal range after six months of treatment while only 23% of placebo-treated subjects were able to normalize T with diet and exercise alone. At all time points, the antibody-based method yielded lower T levels than the LC/MS/MS technique.

Men in all three groups lost weight over the six month evaluation period. Men in the placebo group lost more weight as determined by mean (SD) BMI, 38.1 (2.6) to 33.7 (3.9) at six months compared to 35.5 (3.0) to 33.5 (3.6) for 12.5 mg and 37.4 (3.6) to 35.0 (4.8) for 25 mg. This finding was statistically significant, p < 0.05.

Interestingly, subjects treated with enclomiphene showed a statistically significant increase in mean (SD) lean body mass, 1.4 kg (3.0), while the placebo group showed a decrease in lean body mass, 0.3 kg (2.7). This difference between treatment

group responses approached borderline statistical significance, p=0.1078.

All groups showed statistically significant improvement in all metabolic parameters tested. However, there was no difference noted between groups.

In terms of the secondary objective of the development of a patient reported outcome (PRO), some encouragement has come from the patient questionnaires incorporated into the protocol. The DISF-SR, a sexual function questionnaire, showed numerical improvement in the drug arm over placebo in the orgasm domain; the IWQOL-LITE, an obesity related questionnaire, showed numerical improvement in the work domain; and the SF-36, a general health questionnaire, showed similar improvement in both the emotional and physical domains. The Company plans to use this data to further research the use of a PRO in this indication.

**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 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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