



May 18, 2016

## **Repros Reports Positive Clinical Data for Oral Proellex® in Women With Severe Menstrual Bleeding Due to Uterine Fibroids**

- 1 *Primary endpoint of induction of amenorrhea met for the pooled oral doses compared to placebo,  $p=0.0004$*
- 1 *Proellex®-treated subjects reported a median 100% (mean 95%) reduction in diary reports of menstrual bleeding product usage (PBAC)*
- 1 *Statistically significant reduction in fibroid size from baseline achieved for the combined active arms compared to increase in fibroid volume in placebo arm,  $p=0.0007$*

THE WOODLANDS, Texas, May 18, 2016 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc.® (Nasdaq:RPRX) today reported that oral administration of Proellex® at doses of both 6 and 12 mg achieved significant reduction in excessive menstrual bleeding, the key symptom of uterine fibroids.

Normal blood loss in a menstrual cycle is approximately 35 mL. Women experiencing blood loss of > 80 mL are considered to suffer from menorrhagia or excessive menstrual bleeding. In this Phase 2b study, 12, 17 and 14 women with confirmed uterine fibroids were enrolled in the 6mg, 12mg and Placebo arms, respectively. One subject dosed at 6mg and one Placebo-treated subject were discontinued as they did not meet entry criteria, and thus were not eligible for efficacy analysis. At baseline, the mean amount of blood lost for one menstrual cycle was 177 mL, 251 mL and 260 mL for each arm, respectively. The blood loss ranged from a low of 82 mL to a high of 769 mL. Blood loss was determined by collecting all sanitary products used from an individual and then an alkaline hematin assay was performed to estimate the actual amount of blood collected in the pads.

When a sufficient concentration of Proellex® is achieved in circulation, amenorrhea (cessation of menses) is achieved. At the end of the first course of treatment (18 weeks LOCF), 79% of Proellex®-treated subjects became amenorrheic with no evidence of a dose effect. Two (17%) subjects treated with Placebo had amenorrhea at the end of course 1. The p-value for this comparison is 0.0004. Treatment effect was rapid with 78% of Proellex®-treated subjects became amenorrheic in the first 6 weeks of treatment. Bleeding diaries consistently report a statistically significant difference in the number of days of bleeding and bleeding intensity between those treated with Proellex® and Placebo.

Bleeding was also evaluated by PBAC (Pictorial Blood Assessment Chart). Subjects tallied sanitary product usage and stain size as guided by the chart. Proellex®-treated subjects reported a median 100% reduction (mean 95% reduction) in PBAC scores while Placebo-treated subjects reported a median 62% reduction, further supporting the treatment effect associated with bleeding ( $p=0.0001$ ).

Along with changes in menstrual patterns, fibroids measured by MRI were reduced in volume in the Proellex®-treated arms by 28% while the Placebo group showed continued increase in size, 3%,  $p=0.0007$ .

The drug was generally well tolerated. Women in the drug arms continued to exhibit levels of estradiol consistent with bone preservation.

After the first 18 week treatment period, the women were withdrawn from drug to allow for menses. The women in the study are currently being treated with the second course of treatment for another 18 weeks. The study treatment assignment remains blinded to the subjects, physicians and those managing the study and data. The results of the second course of treatment should be reported within the next 5 months.

The Company believes Proellex® suggests a significant advantage over GnRH agonists and antagonists in the treatment of uterine fibroids. Once both the vaginal and oral studies complete both 18 week courses of treatment the Company plans to request an end of Phase 2 meeting with the FDA to jointly discuss plans for Phase 3.

### **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 ongoing and future clinical studies and the timing and results thereof, the Company's plans to communicate with the FDA, possible submission of one or more NDAs and the commercial potential of Proellex®, 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](http://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](mailto:thoffmann@troutgroup.com)

 Primary Logo

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