Auxilium Pharmaceuticals, Inc. Announces Initiation of XIAFLEX® Phase III Studies for Peyronie's Disease

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MALVERN, Pa., Oct. 11 /PRNewswire/ -- Auxilium Pharmaceuticals, Inc. (Nasdaq: AUXL [1]), a specialty biopharmaceutical company, today announced that the first subject has been dosed in the global phase III program of XIAFLEX® for the treatment of Peyronie's disease. Peyronie's disease is the development of scar tissue on the penis that can cause the penis to curve during erection, often interfering with or preventing intercourse and resulting in psychological distress or bother for the patient.

"Peyronie's disease is a devastating disease that is estimated to affect approximately 5% of adult men and, therefore, we are pleased to be moving forward into the phase III development of XIAFLEX," said Armando Anido, Chief Executive Officer and President of Auxilium. "We believe that there is significant unmet medical need for a nonsurgical alternative for Peyronie's disease, and we have been encouraged by the enthusiasm that we have perceived among the urology community and their prospective patients for participating in our phase III program. We anticipate completing enrollment for the double-blind studies in the first quarter of 2011 and reporting top-line results in first half of 2012."

Our late stage global development plan for XIAFLEX will consist of four clinical studies and will be known by the acronym IMPRESS – The Investigation for Maximal Peyronie's Reduction Efficacy and Safety Studies. There will be two randomized, double-blind, placebo-controlled phase III studies, which are expected to enroll at least 600 patients at approximately 70 sites in the U.S. and Australia, with a 2:1 ratio of XIAFLEX to placebo. There also will be one open label study, which is expected to enroll at least 250 patients, at approximately 30 sites in the U.S., EU and New Zealand, and one pharmacokinetic study, which should enroll approximately 16 pat
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