

Auxilium Pharmaceuticals, Inc. Announces Initiation Of XIAFLEX(TM) Phase IIb Study For Peyronie's Disease

Main Category: Urology / Nephrology

Also Included In: Erectile Dysfunction / Premature Ejaculation

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Auxilium Pharmaceuticals, Inc. (NASDAQ: AUXL), a specialty biopharmaceutical company, today announced that the first patients have been dosed in the Company's U.S. phase IIb trial of XIAFLEX(TM) for the treatment of Peyronie's disease. Peyronie's disease is the development of a collagen plaque, or scar tissue, on the shaft of the penis that hardens and reduces flexibility, causing the penis to bend or arc during erection resulting in psychological distress and pain for the patient and often interfering with or preventing intercourse.

"We believe XIAFLEX is a company-transforming product for Auxilium and the excitement surrounding this trial in the urological community that treats Peyronie's patients has been resounding. Additionally, the response from potential patients has been highly encouraging, and as a result, we believe we will complete enrollment in this study in the first quarter of 2009," said Armando Anido, Chief Executive Officer and President of Auxilium. "We are extremely pleased to achieve this important development milestone in Peyronie's disease, a potential second indication for XIAFLEX, and we look forward to having the results of the trial by the end of 2009."

The Phase IIb study is a randomized, double-blind, placebo-controlled study that is designed to assess the safety and efficacy of XIAFLEX, when administered two times a week every six weeks for up to three treatment cycles (2 x 3), in subjects with Peyronie's disease. The study will involve at least 120 patients at approximately 11 sites throughout the U.S., and patients will be monitored for 36 weeks following the first injection.

The trial is also designed to validate a proprietary Peyronie's Patient Reported Outcome (PRO) questionnaire, which will measure several domains of patients' sexual quality of life, over a 36 week period. The four domains measured by the PRO are penile pain, Peyronie's disease bother, intercourse discomfort and intercourse constraint.

"We are encouraged by earlier Phase II clinical trials in Peyronie's disease which demonstrated a reduction in penile curvature with XIAFLEX," said Dr. Tony DelConte, Auxilium's Chief Medical Officer. "Our team, in conjunction with outside experts, has spent a significant amount of time and effort to develop the Peyronie's PRO questionnaire and we are eager to validate its use for our Phase III protocols where it is intended to be the primary endpoint."

To qualify for the study, patients must be able to maintain a rigid erection and have a penile contracture between 30 and 90 degrees. Patients will be stratified by the degree of penile curvature (i.e. 30 degrees to 60 degrees versus 60 degrees) and then randomized into 4 treatment groups to receive either XIAFLEX or placebo with or without modeling of the penile plaque. Modeling refers to massaging of the plaque after the second injection of a treatment series and is intended to maximize the enzymatic effect of the XIAFLEX injection in the plaque. Patients will be randomized in a 3:1 ratio of XIAFLEX to placebo and a 1:1 ratio to receive penile plaque modeling or no modeling.

About Peyronie's Disease

Peyronie's disease is the development of collagen plaque, or scar tissue, on the shaft of the penis that hardens and reduces flexibility, thus causing pain and forcing the penis to bend or arc during erection. This often can prevent intercourse. In addition to difficulty with sexual intercourse, Peyronie's disease may also be associated with emotional distress, loss of self-esteem and depression. In certain populations, the estimated number of men affected by Peyronie's Disease may be as high as 9 percent in men over 60 years of age and 3 percent in men over 30.(1)

(1) L.A. Levine "Peyronie's Disease: A Guide to Clinical Management."
Humana Press: 10-17, 2007.

About Auxilium

Auxilium Pharmaceuticals, Inc. is a specialty biopharmaceutical company with a focus on developing and marketing to urologists, endocrinologists, orthopedists and select primary care physicians. Auxilium markets Testim(R) 1%, a topical testosterone gel, for the treatment of hypogonadism through its approximately 190-person sales and marketing team. Auxilium has five projects in clinical development. XIAFLEX(TM) (clostridial collagenase for injection), formerly referred to as AA4500, is in phase III of development for the treatment of Dupuytren's contracture and is in phase II of development for the treatment of Peyronie's disease and Frozen Shoulder syndrome (Adhesive Capsulitis). Auxilium's transmucosal film product candidate for the treatment of overactive bladder (AA4010) is in phase I of development. The Company is currently seeking a partner to further develop this product candidate. Auxilium also has one pain product using its transmucosal film delivery system in phase I of development. Auxilium has rights to seven additional pain products and products for hormone replacement and urologic disease using its transmucosal film delivery system. Auxilium also has options to all indications using XIAFLEX for non-topical formulations. For additional information, visit <http://www.auxilium.com>.

Safe Harbor Statement Under The Private Securities Litigation Reform Act Of 1995

This release contains "forward-looking-statements" within the meaning of The Private Securities Litigation Reform Act of 1995, including statements regarding XIAFLEX as a company-transforming product; the timing of completion of enrollment of patients in the phase IIb trial for XIAFLEX for the treatment of Peyronie's disease; the timing of release of

results from the phase IIb trial for XIAFLEX for the treatment of Peyronie's disease; the ability to use data from the phase IIb study to further validate the Patient Reported Outcome questionnaire as a tool to be used as the primary efficacy endpoint in phase III studies for XIAFLEX for the treatment of Peyronie's disease; the interpretation of data from earlier phase II clinical trials for Peyronie's disease; the number of men affected by Peyronie's disease; and products in development for Dupuytren's contracture, Frozen Shoulder syndrome, overactive bladder, pain, hormone replacement and urologic disease. All statements other than statements of historical facts contained in this release, including but not limited to, statements regarding future expectations, plans and prospects for the Company, statements regarding forward-looking financial information and other statements containing the words "believe," "appears," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," and similar expressions, as they relate to the Company, constitute forward-looking statements. Actual results may differ materially from those reflected in these forward-looking statements due to various factors, including further evaluation of clinical data, results of clinical trials, the performance of third-party service providers, decisions by regulatory authorities regarding whether or when to proceed to the next phase of clinical trials, general financial, economic, regulatory and political conditions affecting the biotechnology and pharmaceutical industries and those discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2007 under the heading "Risk Factors", which is on file with the Securities and Exchange Commission (the "SEC") and may be accessed electronically by means of the SEC's home page on the Internet at <http://www.sec.gov> or by means of the Company's home page on the Internet at <http://www.auxilium.com> under the heading "Investor Relations -- SEC Filings." There may be additional risks that the Company does not presently know or that the Company currently believes are immaterial which could also cause actual results to differ from those contained in forward-looking statements. Given these risks and uncertainties, any or all of the forward-looking statements contained in this release may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements.

In addition, forward-looking statements provide the Company's expectations, plans or forecasts of future events and views as of the date

of this release. The Company anticipates that subsequent events and developments will cause the Company's assessments to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's assessments as of any date subsequent to the date of this release.

<http://www.medicalnewstoday.com/articles/122335.php>