

[Print Page](#)[Close Window](#)**Auxilium Announces U.S. Food and Drug Administration Approval for XIAFLEX(TM) for the Treatment of Dupuytren's Contracture****Auxilium to Host Conference Call and Webcast on Wednesday, February 3 at 8:30 a.m. Eastern Time**

MALVERN, Pa., Feb 03, 2010 /PRNewswire via COMTEX/ -- Auxilium Pharmaceuticals, Inc. (Nasdaq: AUXL), a specialty biopharmaceutical company, just announced that it has received marketing approval from the U.S. Food and Drug Administration (FDA) for XIAFLEX(TM) (collagenase clostridium histolyticum), a novel, first-in-class, orphan-designated, biologic, for the treatment of adult Dupuytren's contracture patients with a palpable cord. The Company expects to begin shipping XIAFLEX to its distribution partners in early March in advance of a launch planned for late March.

To view the multimedia assets associated with this release, please click: <http://multivu.prnewswire.com/mnr/auxilium/41254/>

"We believe the approval of XIAFLEX represents a major breakthrough for patients suffering from the debilitating effects of Dupuytren's contracture," said Armando Anido, Chief Executive Officer and President of Auxilium. "XIAFLEX is the only FDA-approved nonsurgical medical treatment for Dupuytren's contracture. I want to thank the employees of Auxilium and all of the clinical investigators who worked so hard to make this breakthrough a reality."

The Company will market and sell XIAFLEX in the United States through a team of approximately 100 field sales managers and representatives, reimbursement specialists and managed market account directors. In addition, a staff of 11 highly trained medical science liaisons will provide medical support for XIAFLEX. The Company has established a distribution network that will allow health care providers to access XIAFLEX through specialty distributors and specialty pharmacies or in the institutional setting after they have undergone training on XIAFLEX and its administration. For information and questions on XIAFLEX, patients and physicians can contact Auxilium at 1-877-XIAFLEX.

"With the safety and effectiveness of XIAFLEX demonstrated across multiple clinical trials, physicians can now use XIAFLEX to treat any symptomatic cords in patients with Dupuytren's contracture," said Larry Hurst, M.D., study investigator and Professor and Chair, Department of Orthopaedics at SUNY Stony Brook. "I believe that XIAFLEX, as a new nonsurgical treatment, could potentially become the standard of care for Dupuytren's contracture."

FDA has required a risk evaluation and mitigation strategy (REMS) program for XIAFLEX, which consists of a communication plan and a medication guide. This REMS is designed to (1) evaluate and mitigate known and potential risks and serious adverse events; (2) to inform healthcare providers about how to properly inject XIAFLEX and perform finger extension procedures; and, (3) to inform patients about the serious risks associated with XIAFLEX. Auxilium plans to market XIAFLEX to physicians who are experienced in injection procedures of the hand and treatment of Dupuytren's contracture and will only provide access to XIAFLEX after physicians have attested to completion of a training program. The training program is available as video or written manual and demonstrates proper use and administration of XIAFLEX, as well as an overview of both identified and potential risks with XIAFLEX.

XIAFLEX's product insert is available via our website at [www.XIAFLEX.com](http://www.XIAFLEX.com).

XIAFLEX is a prescription medicine used to treat adults with Dupuytren's contracture when a "cord" can be felt. Over time, the thickening of this cord in your hand can cause one or more fingers to bend toward your palm, so that you cannot straighten them. XIAFLEX should be injected into the cord by a healthcare provider who is experienced in injection procedures of the hand and treating people with Dupuytren's contracture. XIAFLEX helps "break" the cord that is causing the finger to be bent.

**IMPORTANT SAFETY INFORMATION**

XIAFLEX can cause serious side effects, including:

- **Tendon or ligament damage.** Receiving an injection of XIAFLEX may cause damage to a tendon or ligament in your hand and cause it to break or weaken. This could require surgery to fix the damaged tendon or ligament. Call your healthcare provider right away if you have trouble bending your injected finger (towards the wrist) after the swelling goes down or you have problems using your treated hand after your follow-up visit.
- **Nerve injury or other serious injury of the hand.** Call your healthcare provider if you get numbness, tingling, or increased pain in your treated finger or hand after your injection or after your follow-up visit.
- **Allergic Reactions.** Allergic reactions can happen in people who have received an injection of XIAFLEX because it contains foreign proteins. Call your healthcare provider right away if you have any of these symptoms of an allergic reaction after an injection of XIAFLEX: hives; swollen face; breathing trouble; or chest pain.

Before receiving XIAFLEX, tell your healthcare provider if you have had an allergic reaction to a previous XIAFLEX injection, or have a bleeding problem or any other medical conditions. Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Be sure to tell them if you use blood thinners such as aspirin, clopidogrel (Plavix(R)), prasugrel hydrochloride (Effient(R)), or warfarin sodium (Coumadin(R)).

Common side effects with XIAFLEX include: swelling of the injection site or the hand, bleeding or bruising at the injection site; and pain or tenderness of the injection site or the hand, swelling of the lymph nodes (glands) in the elbow or underarm, itching, breaks in the skin, redness or warmth of the skin, and pain in the underarm.

Please see **Full Prescribing Information** and **Medication Guide**.

**Conference Call**

Auxilium will hold a conference call February 3 at 8:30 a.m. ET, to discuss the U.S. approval of XIAFLEX for the treatment of Dupuytren's contracture and other related topics. The conference call will be simultaneously web cast on Auxilium's web site and archived for future review until March 3, 2010.

Conference call details:

Date: Wednesday, February 3, 2010  
 Time: 8:30 a.m. ET  
 Dial-in (U.S.): 866-202-1971  
 Dial-in (International): 617-213-8842  
 Web cast: <http://www.auxilium.com>  
 Passcode: Auxilium

To access an audio replay of the call:

Access number (U.S.): 888-286-8010  
 Access number (International): 617-801-6888  
 Replay Passcode #: 90800506

### About Dupuytren's Contracture

Dupuytren's contracture is a condition that affects the connective tissue that lies beneath the skin in the palm. The disease is progressive in nature. Typically, skin pits then nodules develop in the palm as collagen deposits accumulate. As the disease progresses, the collagen deposits form a cord that stretches from the palm of the hand to the base of the finger. Once this cord develops, the patient's fingers contract and the function of the hand is impaired. Currently, surgery is the only effective treatment. The incidence of Dupuytren's disease, inclusive of pits, nodules and cords, is highest in Caucasians, historically those of Northern European descent, with a global prevalence of three to six percent of the Caucasian population. (1) Most cases of Dupuytren's contracture occur in patients older than 50 years. (2)

The most frequently affected parts of the hand associated with Dupuytren's contracture are the joints called the Metacarpal Phalangeal Joint, or MP joint, which is the joint closest to the thumb of the hand and the Proximal Intra-Phalangeal Joint, or the PIP joint, which is the middle joint in the finger. The little finger and ring finger are most frequently involved. XIAFLEX is the only drug approved by the U.S. Food and Drug Administration for treatment of Dupuytren's contracture, which has historically been treated primarily by an open surgical procedure.

(1) Hurst, L. C. et al., Injectable Collagenase Clostridium Histolyticum for Dupuytren's Contracture, New England Journal of Medicine, (2009; 361:968-979)

(2) Badalamente, M. A., Hurst, L. C. et al., Collagen as a Clinical Target: Nonoperative Treatment of Dupuytren's Disease, The Journal of Hand Surgery, (2002; 27A:788-798)

### About Auxilium

Auxilium Pharmaceuticals, Inc. is a specialty pharmaceutical company with a focus on developing and marketing to urologists, endocrinologists, orthopedists and select primary care physicians. Auxilium will market XIAFLEX(TM) (collagenase clostridium histolyticum) for the treatment of adult Dupuytren's contracture patients with a palpable cord and markets Testim(R) 1%, a topical testosterone gel, for the treatment of hypogonadism. Auxilium has four projects in clinical development. XIAFLEX is in phase IIb of development for the treatment of Peyronie's disease and is in phase II of development for treatment of Frozen Shoulder syndrome (Adhesive Capsulitis). Auxilium's transmucosal film product candidate for the treatment of overactive bladder (AA4010) and its fentanyl pain product using its transmucosal delivery system are in phase I of development. The Company is currently seeking a partner to further develop these product candidates. Auxilium has rights to 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 the date on which the Company will ship XIAFLEX for the treatment of Dupuytren's to its distribution partners; the timing of launch of XIAFLEX; the number of field sales managers and representatives, reimbursement specialists and managed market account directors, and medical science liaisons supporting XIAFLEX; the distribution network for XIAFLEX; the design of the risk evaluation and mitigation strategy for XIAFLEX; the access to XIAFLEX by only physicians who are experienced in the injection procedures of the hand and treatment of Dupuytren's contracture after they had attested to completion of a training program; the number of patients with Dupuytren's contracture; products in development for Peyronie's disease, Frozen Shoulder syndrome, overactive bladder, pain, hormone replacement and urologic disease; and all other statements containing projections, statements of future performance or expectations, our beliefs or statements of plans or objectives for future operations (including statements of assumption underlying or relating to any of the foregoing). Forward-looking statements can generally be identified by words such as "believe," "appears," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," and other words and terms of similar meaning in connection with any discussion of projections, future performance or expectations, beliefs, plans or objectives for future operations (including statements of assumption underlying or relating to any of the foregoing). 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, decisions by regulatory authorities as to whether

and when to approve drug applications, and general financial, economic, regulatory and political conditions affecting the biotechnology and pharmaceutical industries and those discussed in Auxilium's Annual Report on Form 10-K for the year ended December 31, 2008, in Auxilium's Quarterly Report on Form 10-Q for the period ended June 30, 2009 and in Auxilium's Quarterly Report on Form 10-Q for the period ended September 30, 2009 under the heading "Risk Factors", which are 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 Auxilium's home page on the Internet at <http://www.Auxilium.com> under the heading "For Investors -- SEC Filings." There may be additional risks that Auxilium does not presently know or that Auxilium currently believes are immaterial which could also cause actual results to differ from those contained in the forward-looking statements. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements.

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

For More Information:  
James E. Fickenscher  
Chief Financial Officer  
Auxilium Pharmaceuticals, Inc.  
1-484-321-5900  
[jfickenscher@auxilium.com](mailto:jfickenscher@auxilium.com)

William Q. Sargent Jr.  
Vice-President  
Investor Relations and Corporate  
Communications  
1-484-321-5900  
[wsargent@auxilium.com](mailto:wsargent@auxilium.com)

SOURCE Auxilium Pharmaceuticals, Inc.