Pfizer and Auxilium Announce Commencement of European Regulatory Review of XIAFLEXTM for the Treatment of Dupuytren's Contracture

Wednesday, January 20, 2010 - 08:30pm

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) and Auxilium Pharmaceuticals, Inc. (NASDAQ: AUXL) today announced that Pfizer received notification from the European Medicines Agency that the Marketing Authorization Application (MAA) for XIAFLEX™ (collagenase clostridium histolyticum), a novel, first-in-class, biologic for the treatment of Dupuytren's contracture (a condition resulting in the contracture of the fingers into the palm), has completed the validation phase successfully. As a result, the scientific/technical review procedure commenced on 21 January 2010.

"We are pleased to partner with Auxilium to bring forward what potentially could be the first approved pharmaceutical treatment option for patients suffering with Dupuytren's contracture, a condition which can significantly impact patients' ability to perform everyday tasks with their hands and therefore impacts quality of life," said Michael Berelowitz, M.D., senior vice president, Clinical Development and Medical Affairs, Pfizer Specialty Care Business Unit. "XIAFLEX, if approved, will be an important addition to the Specialty Care Business Unit's portfolio of medicines in Europe designed to offer true clinical value to patients and healthcare providers who need them."

Armando Anido, Chief Executive Officer and President of Auxilium said, "We believe that commencement of the regulatory review procedure is a notable milestone in our effort to bring the first approved minimally-invasive, nonsurgical treatment option to Dupuytren's contracture patients in Europe. We look forward to working with our partner Pfizer as the EU regulatory review process for the product moves forward."

Based on the completion of the validation phase and today’s confirmation from the European Medicines Agency of the start of the regulatory review procedure, Auxilium will receive a $15 million milestone payment from Pfizer.

Under the terms of the strategic alliance agreement between Pfizer and Auxilium, Pfizer will receive exclusive rights to commercialize XIAFLEX in the 27 member countries of the European Union (EU) and 19 other European and Eurasian countries. In addition, Pfizer will be primarily responsible for regulatory activities for XIAFLEX in these countries.

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, 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. Most cases of Dupuytren's contracture occur in patients older than 50 years and a hereditary component exists in approximately 40% of patients.

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 palm 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 and about half of patients have bilateral disease. There are currently no drugs approved by the U.S. Food and Drug Administration or in the European Union for the treatment of Dupuytren's contracture, which is treated primarily by an open surgical procedure.

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® 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™ (collagenase clostridium histolyticum), formerly referred to as AA4500, has completed phase III clinical trials for the treatment of Dupuytren’s contracture, and the biologics license application is under review at the FDA for the treatment of Dupuytren’s contracture. The compound

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) is in phase I of development. Auxilium also has one pain product (fentanyl) using its transmucosal film delivery system in phase I of development. Auxilium has rights to additional pain products and products for hormone replacement and urologic disease using its transmucosal film delivery system. The Company is currently seeking a partner to further develop these transmucosal film product candidates. Auxilium also has options to all indications using XIAFLEX for non-topical formulations. For additional information, visit http://www.auxilium.com.

About Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world’s best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world’s leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com

Wyeth is now a wholly owned subsidiary of Pfizer Inc. The merger of local Wyeth and Pfizer entities may be pending in various jurisdictions and is subject to completion of various local legal and regulatory obligations.

More information is available at www.pfizer.com.

AUXILIUM SAFE HARBOR STATEMENT

This release contains "forward-looking-statements" within the meaning of The Private Securities Litigation Reform Act of 1995, including statements regarding the value of XIAFLEX, if approved, to Pfizer’s Specialty Care Business Unit’s portfolio; working with Pfizer to secure the approval of XIAFLEX in the EU; Auxilium’s receipt of a $15 million milestone payment from Pfizer; 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 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.

Auxilium disclaims responsibility for statements above in “About Pfizer Inc.: Working together for a healthier world™”, which were provided by Pfizer for inclusion in this press

release.

PFIZER SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

The information contained in this release is as of January 21, 2010. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a product candidate, XIAFLEX, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, whether and when the European Medicines Agency will approve the applications that have been filed with it for XIAFLEX as well as its decisions regarding labeling and other matters that could affect the availability or commercial potential of XIAFLEX; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and in its reports on Form 10-Q and Form 8-K.

Pfizer disclaims responsibility for statements above in "About Auxilium," which were provided by Auxilium for inclusion in this press release.

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Pfizer: Gwen Fisher (Media) O: 484-865-5160 C: 215-407-1548Gwen.Fisher@pfizer.com or Fanny La Monica (European Media) +39.06.33182452Fanny.LaMonica@pfizer.com or Suzanne Harnett (Investors) 212-733-8009Suzanne.Harnett@pfizer.com or Auxilium:

James E. Fickenscher/CFO Auxilium Pharmaceuticals, Inc. (484) 321-5900jfickenscher@auxilium.com or William Q. Sargent Jr./ VP IR (484) 321-5926wsargent@auxilium.com