# XIAPEX® (Collagenase Clostridium Histolyticum) Authorized in the European Union (EU) For Dupuytren’s Contracture

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"The availability of a treatment like XIAPEX® is an important step forward for patients with Dupuytren’s contracture,"

(BUSINESS WIRE)--XIAPEX® (collagenase clostridium histolyticum), a new non-surgical treatment option for Dupuytren’s contracture in adult patients with a palpable cord, has been granted marketing authorization by the European Commission and is expected to be available for use in some European markets later this year.1 Collagenase clostridium histolyticum is the first injectable treatment to be approved in the EU for the treatment of Dupuytren's contracture. Pfizer (NYSE:PFE) has the marketing rights to collagenase clostridium histolyticum in Europe, and Auxilium Pharmaceuticals, Inc. (NASDAQ: AUXL) has the rights in the rest of the world.

Dupuytren’s disease is a slowly progressive connective tissue disorder that can cause the affected finger to bend into the palm of the hand.2 It affects approximately 13 percent of the European population.3-6 The disease starts in the palm of the hand with the appearance of a number of small lumps (called nodules), made of cells that can produce collagen.2 As the disease progresses, excess collagen continues to build up and may eventually form into a rope-like cord under the skin.2 The cord extends from the palm into the finger and can gradually contract or bend the finger permanently toward the palm, known as Dupuytren’s contracture.2 Once contracture has occurred, the affected finger often impacts the ability to carry out everyday tasks.2

“The availability of a treatment like XIAPEX® is an important step forward for patients with Dupuytren’s contracture,” said Geno Germano, president and general manager, Specialty Care and Oncology, Pfizer Inc. “The EU approval of this treatment for Dupuytren’s contracture is a testament to Pfizer’s commitment to bringing innovative medicines to patients.”

“We welcome today's decision by the European Commission to approve a new, non-surgical alternative for European physicians to treat their patients with Dupuytren’s contracture,” said Armando Anido, chief executive officer and president of Auxilium.

The EU approval of collagenase clostridium histolyticum is based on results from two pivotal studies, Collagenase Option for Reduction of Dupuytren’s (CORD I and CORD II).7,8 Data from CORD I showed that 64 percent of cords that received injections of collagenase clostridium achieved a reduction in contracture of that joint to 5 degrees or less, approximately 30 days after the last injection, compared with 6.8 percent of those injected with placebo (P <0.001).7 In CORD II, which had this same primary endpoint as CORD I, statistically significantly more cords injected with collagenase than placebo achieved a reduction in contracture of that joint to 5 degrees or less, approximately 30 days after the last injection (44.4 percent vs 4.8 percent; P <0.001).8

“Dupuytren’s contracture can significantly impact a patient’s quality of life, as the affected finger often interferes with daily activities such as driving, washing one’s face or shaking hands. So a new alternative treatment for the condition is encouraging to those living with Dupuytren’s contracture across the EU,” said Dr. Jörg Witthaut, consultant hand surgeon from Schön Klinik Vogtareuth Handchirurgie, Vogtareuth, Germany.

Pfizer is working closely with the in-country medicines regulatory bodies across the EU to launch the new treatment and anticipates that healthcare professionals will be able to prescribe the treatment in some European markets later this year.

About Dupuytren’s Disease

Dupuytren’s disease is found more frequently in people of white northern European descent9 and the highest prevalence has been seen in northern Scotland, Iceland and Norway.10,11 The condition is more common in men who also tend to be more severely affected by Dupuytren’s disease than female patients.12

Dupuytren’s disease can affect up to 20 percent of men who are over 60 years of age, and 20 percent of women who are over 80 years of age.2 This means that as the population ages, so does the incidence of Dupuytren’s disease.13

Pfizer has the marketing rights to collagenase clostridium histolyticum in Europe, and Auxilium Pharmaceuticals, Inc. has the rights in the rest of the world. Collagenase clostridium histolyticum has been approved in the United States by the U.S. Food and Drug Administration (tradename in the US: XIAFLEX®) for treatment of adult patients with Dupuytren's contracture.14

About XIAPEX® (Collagenase clostridium histolyticum)

Collagenase clostridium histolyticum is a combination of two purified collagenases (collagenase is an enzyme capable of breaking down collagen), derived from the bacterium Clostridium histolyticum. It is the first pharmacological treatment to be developed for Dupuytren's contracture and may be an alternative to invasive and often complicated surgery for patients in the EU. Collagenase clostridium histolyticum is administered by local injection directly into the Dupuytren's cord – a procedure which can be carried out in an outpatient setting. It works by breaking down the structure of the cord and, 24 hours after injection, a finger extension procedure can be carried out as necessary to break the cord and allow extension of the finger. If contracture remains four weeks after treatment, another injection can be administered into the same cord, and the finger extension procedure can be carried out again. Injections and finger extension procedures may be administered up to three times per cord, at approximately four-week intervals.

Further details and product information will be available in the European Public Assessment Report on the web site of the European Medicines Agency at www.emea.europa.eu.

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difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com.

About Auxilium

Auxilium Pharmaceuticals, Inc. is a specialty biopharmaceutical company with a focus on developing and marketing products to predominantly specialist audiences, such as urologists, endocrinologists, certain targeted primary care physicians, hand surgeons, subsets of orthopedic, general, and plastic surgeons who focus on the hand, and rheumatologists. Auxilium markets XIAFLEX® (collagenase clostridium histolyticum) in the U.S., for the treatment of adult Dupuytren's contracture patients with a palpable cord and Testim® 1 percent, a topical testosterone gel, for the treatment of hypogonadism. Auxilium has two projects in clinical development. XIAFLEX is in phase III 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 also has options to all indications using XIAFLEX for non-topical formulations. For additional information, visit http://www.auxilium.com.

Pfizer Safe Harbor Statement

The information contained in this release is as of February 28, 2011. 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 that involves substantial risks and uncertainties regarding XIAPEX®, including its potential benefits and the timing of the launch of XIAPEX® for the treatment of Dupuytren’s contracture in the EU. Such risks and uncertainties include, among other things, when the in-country regulatory authorities across the EU will authorize the launch of XIAPEX® in their respective countries. A further list and description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 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 release.

Auxilium Safe Harbor Statement

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 timing of the launch of XIAPEX for the treatment of Dupuytren's contracture in Europe; Pfizer's ability to commercialize XIAPEX® for Dupuytren's contracture in the EU; the potential benefits and effectiveness of XIAFLEX for Dupuytren's contracture; the number of people suffering from Dupuytren's contracture; and products in development for Frozen Shoulder syndrome, overactive bladder, pain, hormone replacement and urologic disease; and all other statements containing projections, statements of future performance or expectations, or statements of plans or objectives for future operations (including statements of assumption underlying or relating to any of the foregoing). You can identify these statements by the fact that they use 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, 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, 2009 and in Auxilium's Quarterly Report on Form 10-Q for the period ended September 30, 2010 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 "Investor Relations -- 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”, which were provided by Pfizer for inclusion in this release.

References:


1.
Note to the members of the standing committee on medicinal products for human use/standing committee on veterinary medicinal products: Adoption of COMMISSION IMPLEMENTING DECISION granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Xiapex - collagenase clostridium histolyticum", a medicinal product for human use. 28 February 2011. Available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002048/smc

2.
NHS Choices. Dupuytren’s contracture. Accessed 19 January 2011. Available at http://www.nhs.uk/Conditions/Dupuytrens-contracture/Pages/Introduction.aspx.

3.
Attali P, Ink O, Pelletier G, et al. Dupuytren’s contracture, alcohol consumption, and chronic liver disease. Arch Intern Med 1987; 147(6): 1065-1067.

4.
Bergenudd H, Lindgarde F, Nilsson BE. Prevalence of Dupuytren’s contracture and its correlation with degenerative changes of the hands and feet and with criteria of general health. J Hand Surg [Br] 1993; 18(2): 254-257.

5.
Godtfredsen NS, Lucht H, Prescott E, Sorensen TI, Gronbaek M. A prospective study linked both alcohol and tobacco to Dupuytren’s disease. J Clin Epidemiol 2004; 57(8): 858-863.

6.
Finsen V, Dalen H, Nesheim J. The prevalence of Dupuytren’s disease among 2 different ethnic groups in northern Norway. J Hand Surg [Am] 2002; 27(1): 115-117.

7.

Hurst LC, Badalamente MA, Hentz VR et al. Injectable collagenase clostridium histolyticum for Dupuytren’s contracture (CORD I). NEJM 2003; 361: 968-79.

8.
Gilpin D, et al. Injectable Collagenase Clostridium Histolyticum: A New Nonsurgical Treatment for Dupuytren’s Contracture. J Hand Surg 2010; 35(12): 2027-2038.

9.
Townley WA, et al. Dupuytren’s contracture unfolded. BMJ 2006; 332: 397-400.

10.
Hart MG and Hooper G. Clinical associations of Dupuytren’s disease. Postgrad Med J 2005; 81: 425-428.

11.
Trojian TH, Chu SM. Dupuytren’s disease: diagnosis and treatment. Am Fam Physician 2007; 76: 86-9.

12.
Gudmundsson KG, et al. Epidemiology of Dupuytren’s disease: clinical, serological, and social assessment. The Reykjavik Study. J Clin Epidemiology 2000; 53: 291-6.

13.
Bayat A and McGrouther DA. Management of Dupuytren’s disease – clear advice for an elusive condition. Ann R Coll Surg Engl 2006; 88: 3-8.

14.
U.S. Food and Drug Administration. FDA Approves Xiaflex for Debilitating Hand Condition. 2 February 2010. Accessed 19 January 2011. Available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm199736.htm.

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