



## Endo Pharmaceuticals Announces XIAFLEX® for Dupuytren's Contracture Formal Pricing in Japan; Commercial Launch Set for September 16, 2015

August 31, 2015

-- First Commercial Sale Triggers \$20 Million Milestone Payment to Endo --

DUBLIN, Aug. 31, 2015 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) (TSX: ENL) today announced that XIAFLEX® (collagenase clostridium histolyticum) for the treatment of Dupuytren's contracture has been listed on the Japanese National Health Insurance (NHI) drug price standard. As a result, Endo partner Asahi Kasei Pharma expects to commercially launch the product in Japan on September 16, 2015. Under the terms of the partnership agreement, Endo will receive a \$20 million milestone payment upon the first commercial sale of XIAFLEX® in Japan.

"We are pleased with the continued and productive collaboration with Asahi Kasei Pharma and excited about their launch of XIAFLEX® as the first, effective non-surgical treatment option available in Japan for patients suffering from the debilitating effects of Dupuytren's contracture," said Rajiv De Silva, President and CEO of Endo. "This milestone marks an important next step in the expansion of XIAFLEX® to a global patient population."

In March 2011, Asahi Kasei Pharma received rights to develop and market XIAFLEX® in Japan through an agreement with Auxilium Pharmaceuticals, which was subsequently acquired by Endo in January 2015. Under the agreement, Asahi Kasei Pharma was granted the exclusive right to commercialize XIAFLEX® for the treatment of Dupuytren's contracture and Peyronie's disease in Japan upon receipt of applicable regulatory approvals. Asahi Kasei Pharma is also responsible for clinical development and regulatory activities for XIAFLEX® and has a right of first negotiation to obtain exclusive rights to commercialize other XIAFLEX® pipeline indications in Japan. Endo is eligible to receive up to \$217 million in remaining potential milestone payments and up to \$210 million in connection with the achievement of aggregate annual net sales thresholds. In addition, Asahi Kasei Pharma will provide tiered payments based on net sales of XIAFLEX®. Asahi Kasei Pharma obtained approval in Japan for the manufacture and marketing of XIAFLEX® for Dupuytren's contracture in July 2015.

### About Dupuytren's Contracture (DC)

DC is a progressive condition affecting the hand, specifically the layer of tissue just under the skin of the palm and fingers. While this layer of tissue normally contains collagen, in patients with DC there is an increase in the amount of collagen produced. Abnormal collagen build-up results in nodule and cord formation that worsens over time. Eventually, rope-like collagen cords may form, thicken and shorten, causing the fingers to be drawn in toward the palm. This thickening and shortening of the Dupuytren's cord can reduce the finger's range of motion (how much a person can move or straighten them). Once the Dupuytren's collagen cord can be felt, it is referred to as a "palpable cord."

### About XIAFLEX®

XIAFLEX® (collagenase clostridium histolyticum, or CCH) is a biologic approved in the U.S., EU, Canada, Australia and Japan for the treatment of adult Dupuytren's contracture (DC) patients with a palpable cord and in the U.S. for the treatment of adult men with Peyronie's disease (PD) with a palpable plaque and penile curvature deformity of at least 30 degrees at the start of therapy. XIAFLEX® consists of a combination of two subtypes of collagenase, derived from *Clostridium histolyticum*. Together, the collagenase sub-types are thought to work synergistically to break the bonds of the triple helix collagen structure. XIAFLEX® has been granted Orphan status in the U.S. by the FDA for DC and PD and is currently in clinical development for several other potential indications including cellulite and adhesive capsulitis / Frozen Shoulder Syndrome. Since 2010, it is estimated that more than 60,000 Dupuytren's contracture patients have been treated with XIAFLEX®.<sup>1</sup>

### About Endo International plc

Endo International plc is a global specialty pharmaceutical company focused on improving patients' lives while creating shareholder value. Endo develops, manufactures, markets and distributes quality branded pharmaceutical and generic pharmaceutical products as well as over-the-counter medications through its operating companies. Endo has global headquarters in Dublin, Ireland, and U.S. headquarters in Malvern, PA. Learn more at [www.endo.com](http://www.endo.com).

### Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements," including but not limited to the statements by Mr. De Silva, as well as statements regarding the safety, efficacy, market and product potential, and other statements regarding XIAFLEX®. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Endo's expectations and projections. Risks and uncertainties include, among other things, general industry and pharmaceutical market conditions; technological advances and patents attained by competitors; challenges inherent in the research and development process; challenges related to new product marketing, such as the unpredictability or market acceptance for new pharmaceutical products and new indications for such products; and governmental laws and regulations affecting domestic and foreign operations. Endo expressly disclaims any intent or obligation to update these forward-looking statements except as required by law. Additional information concerning these and other risks can be found in press releases issued by Endo, as well as in Endo's public filings with the U.S. Securities and Exchange Commission and Canadian securities regulators, including the discussion under the heading "Risk Factors" in Endo's Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q. Copies of Endo's press releases and additional information about Endo are available at [www.endo.com](http://www.endo.com).

XIAFLEX is a registered trademark of Endo Global Ventures.

<sup>1</sup> Data on file. Specialty pharmacy vial per patient analysis. April 2015. Auxilium Pharmaceuticals, Inc.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/endo-pharmaceuticals-announces-xiaflex->

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SOURCE Endo International plc

Endo International plc: Investors/Media: Keri P. Mattox, (484) 216-7912 Investors: Jonathan Neely, (484) 216-6645 Media: Heather Zoumas-Lubeski, (484) 216-6829