Endo Pharmaceuticals Announces the Launch of NATESTO™ (testosterone nasal gel), the First and Only Nasal Gel for Testosterone Replacement Therapy

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Commercial launch expands Endo's growing branded pharmaceutical men's health portfolio

DUBLIN, March 16, 2015 /PRNewswire/ -- Endo Pharmaceuticals Inc., a subsidiary of Endo International plc (NASDAQ: ENDP) (TSX: ENL), announced today the commercial availability of NATESTO™ (testosterone nasal gel), the first and only nasal gel for testosterone replacement therapy in adult males diagnosed with hypogonadism.

NATESTO™ was approved by the U.S. Food and Drug Administration (FDA) in May 2014 for replacement therapy in adult men with conditions associated with deficiency or absence of endogenous testosterone, including primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired). NATESTO™ reduces the risk of transference via intranasal application.

"The launch of NATESTO™ further expands Endo's branded portfolio of men's health treatment offerings and highlights our continuing commitment to ensuring that patients living with hypogonadism have access to high quality medicines," said Rajiv De Silva, President and CEO of Endo. "With testosterone gels, implantable testosterone pellets, a long-acting injectable, and now an intranasal gel, Endo offers healthcare professionals a broad range of delivery options to appropriately raise testosterone levels that help meet the individual needs of men living with hypogonadism."

In 2014, Endo acquired the rights to NATESTO™ in the U.S. and Mexico from Trimel BioPharma SRL, a wholly-owned subsidiary of Trimel Pharmaceuticals Corporation (TSX: TRL), for $25 million plus additional payments upon the achievement of certain regulatory and sales milestones. Endo will collaborate with Trimel on all regulatory and clinical development activities regarding NATESTO™.

About NATESTO™ (testosterone) Nasal Gel

NATESTO™ is an androgen indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone including:

- Primary hypogonadism (congenital or acquired)
- Hypogonadotropic hypogonadism (congenital or acquired)

Limitations of Use

- Safety and efficacy of NATESTO™ in males less than 18 years old have not been established

Dosage

NATESTO™ for intranasal use is available as a metered-dose pump. One pump actuation delivers 5.5 mg of testosterone. The recommended dose of NATESTO™ is 11 mg of testosterone (two pump actuations, one per nostril), applied intranasally three times daily for a total daily dose of 33 mg.

Contraindications

- Men with carcinoma of the breast or known or suspected prostate cancer
- Pregnant or breast-feeding women. Testosterone may cause fetal harm.

Warnings and Precautions

- Nasal adverse reactions: nasal signs and symptoms should be monitored. NATESTO™ is not recommended for use in patients with chronic nasal conditions or alterations in nasal anatomy
- Monitor patients with benign prostatic hyperplasia (BPH) for worsening of signs and symptoms of BPH
- Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients using testosterone products. Evaluate patients with signs or symptoms consistent with DVT or PE
- Women and children should not use Natesto™
- Exogenous administration of androgens may lead to azoospermia
- Edema with or without congestive heart failure (CHF) may be a complication in patients with preexisting cardiac, renal, or hepatic disease
- Sleep apnea may occur in those with risk factors
- Monitor serum testosterone, prostate-specific antigen (PSA), hemoglobin, hematocrit, liver function tests, and lipid concentrations periodically

Adverse Reactions

The most common adverse reactions (incidence >/=3%) to NATESTO™ observed in clinical trials were an increase in prostate specific antigen (PSA), headache, rhinorrhea, epistaxis, nasal discomfort, nasopharyngitis, bronchitis, upper respiratory tract infection, sinusitis and nasal scab.

Click here for full prescribing Information for NATESTO or visit www.endo.com/File%20Library/Products/Prescribing%20Information/Natesto_prescribing_information.html.

About Endo International plc

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

About Endo Pharmaceuticals Inc.

Endo Pharmaceuticals Inc. is focused on developing and delivering high-value branded pharmaceutical products that meet the unmet needs of patients. Endo Pharmaceuticals is an operating company of Endo International plc (NASDAQ: ENDP) (TSX: ENL), a global specialty healthcare company focused on improving patients' lives while creating shareholder value. Learn more at www.endo.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation. Statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may," "look forward," "intend," "guidance," "future" or similar expressions are forward-looking statements. Because these statements reflect Endo's current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties. Although Endo believes that these forward-looking statements and information are based upon reasonable assumptions and expectations, readers should not place undue reliance on them, or any other forward-looking statements or information in this news release. Investors should note that many factors, as more fully described in the documents filed by Endo with securities regulators in the United States and Canada including under the caption "Risk Factors" in Endo's Form 10-K, and Endo's Form 10-Q and Form 8-K filings, as applicable, with the Securities and Exchange Commission and by Endo with securities regulators in Canada on the System for Electronic Document Analysis and Retrieval ("SEDAR") and as otherwise enumerated herein or therein, could affect Endo's future financial results and could cause Endo's actual results to differ materially from those expressed in forward-looking statements contained in Endo's Annual Report on Form 10-K. The forward-looking statements in this press release are qualified by these risk factors. These are factors that, individually or in the aggregate, could cause Endo's actual results to differ materially from expected and historical results. Endo assumes any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities law.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/endo-pharmaceuticals-announces-the-launch-of-natesto-testosterone-nasal-gel-the-first-and-only-nasal-gel-for-testosterone-replacement-therapy-300050447.html

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