Endo Acquires Rights to Natesto™ Testosterone Nasal Gel

November 24, 2014

FDA-approved product further expands Endo's Branded Pharmaceutical Men's Health portfolio

DUBLIN, Nov. 24, 2014 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) (TSX: ENL), announced today the acquisition of rights to Natesto™ (testosterone nasal gel), the first and only testosterone nasal gel for replacement therapy in adult males diagnosed with hypogonadism, from Trimel BioPharma SRL, a wholly-owned subsidiary of Trimel Pharmaceuticals Corporation (TSX: TRL). Natesto™ was approved by the U.S. Food and Drug Administration (FDA) in May of 2014.

Under the terms of the agreement Trimel will receive an upfront payment of $25 million and could receive additional payments upon the achievement of certain regulatory and sales milestones. Additionally, Trimel will be responsible for the manufacture and supply of Natesto™ and Endo will pay a tiered supply price for the product. Endo expects the transaction to close in early 2015.

"We are pleased to acquire the rights to Natesto™ to further enhance our branded pharmaceutical portfolio and look forward to leveraging our commercial expertise in the areas of men's health and urology to support this highly differentiated product," said Rajiv De Silva, President and CEO of Endo. "Natesto™ offers a unique intranasal delivery system which will expand options for appropriate patients seeking testosterone replacement therapy and we are focused on getting Natesto™ to market as expeditiously as possible."

Under the terms of the agreement, Endo receives sole and exclusive commercial rights to the Natesto™ product in the US and Mexico. In addition, Endo will collaborate on all regulatory and clinical development activities in coordination with Trimel.

About Natesto™ (testosterone) Nasal Gel

Indications and Usage

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.

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 and device products through its operating companies. Endo has global headquarters in Dublin, Ireland, and US headquarters in Malvern, PA. Learn more at www.endo.com.

About Trimel

Trimel is a specialty pharmaceutical company involved in the sale, distribution, and development of products with a focus in men's health, women's health, and respiratory medicine. NATESTO™, a product utilizing Trimel's licensed nasal gel technology, has been approved for sale inthe United States by the FDA and is licensed to an affiliate of Endo International plc for commercialization. For more information, please visit www.trimelpharmaceuticals.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, Form 10-Q and Form 8-K filings with the Securities and Exchange Commission and with securities regulators in Canada on 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 no 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-acquires-rights-to-natesto-testosterone-nasal-gel-300000129.html

SOURCE Endo International plc

Investors/Media: Blaine Davis, +353-1-268-2001, (484) 216-7158; Investors: Jonathan Neely, (484) 216-6645; Media: Heather Zoumas-Lubeski, (484) 216-6829