Endo announces launch of Authorized Generic of FORTESTA® Gel

September 8, 2014

First and only generic 2% topical testosterone gel
Product launched by Qualitest is now available

DUBLIN, Sept. 8, 2014 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) (TSX: ENL) announced today that it has introduced the first and only generic 2% topical testosterone gel, an authorized generic of FORTESTA® Gel (testosterone gel) CIII. FORTESTA Gel and its Authorized Generic version are the first and only 2% testosterone gels approved by the U.S. Food and Drug Administration to treat adult males diagnosed with hypogonadism. The Authorized Generic product, distributed by Qualitest and promoted by Endo Pharmaceuticals Inc., has product inventory which has shipped and is now available.

"We believe the launch of the Authorized Generic of 2% FORTESTA Gel will help expand access to this important therapy for men who are diagnosed with hypogonadism," said Rajiv De Silva, President and CEO of Endo. "In addition, we expect this launch will create the opportunity to maximize the value of our FORTESTA franchise while also enhancing the commercial partnership opportunities between our branded and generics business segments."

Qualitest is responsible for the distribution of the Authorized Generic, while Endo Pharmaceuticals is responsible for the promotion. Endo Pharmaceuticals continues to be responsible for the distribution and promotion of 2% FORTESTA Gel.

Important Safety Information

What are FORTESTA® (testosterone) Gel and Testosterone Gel?

FORTESTA® Gel and Testosterone Gel are prescription medications that contain testosterone. They are used to treat adult males who have low or no testosterone. Your healthcare provider will test your blood before you start taking and while you are taking FORTESTA® Gel or Testosterone Gel.

It is not known if FORTESTA® Gel and Testosterone Gel are safe or effective in children younger than 18 years old. Improper use of FORTESTA® Gel and Testosterone Gel may affect bone growth in children.

FORTESTA® Gel and Testosterone Gel are controlled substances (CIII) because they contain testosterone that can be a target for people who abuse prescription medicines. Keep your FORTESTA® Gel or Testosterone Gel in a safe place to protect it. Never give FORTESTA® Gel or Testosterone Gel to anyone else, even if they have the same symptoms you have. Selling or giving away this medicine may harm others and is against the law.

FORTESTA® Gel and Testosterone Gel are not meant for use in women.

What is the most important information I should know about FORTESTA® Gel and Testosterone Gel?

- FORTESTA® Gel and Testosterone Gel can transfer from your body to others. This can happen if other people come into contact with the area where the FORTESTA® Gel or Testosterone Gel was applied.
- Signs of puberty that are not expected (for example, pubic hair) have happened in young children who were accidentally exposed to testosterone through contact with men using topical testosterone products like FORTESTA® Gel and Testosterone Gel.
    - **Women and children should avoid contact with the unwashed or unclothed areas where FORTESTA® Gel or Testosterone Gel have been applied. If a woman or child makes contact with the FORTESTA® Gel or Testosterone Gel application area, that area on the woman or child should be washed well with soap and water right away.**
    - **To lower the risk of transfer of FORTESTA® Gel or Testosterone Gel from your body to others, you should:** Apply FORTESTA® gel or Testosterone Gel **only** to the front and inside area of your thighs that will be covered by clothing and wash your hands **right away** with soap and water after applying FORTESTA® Gel or Testosterone Gel. After the gel has dried, **cover the application area with clothing** and keep the area covered until you have washed the application area well or have showered.
    - If you expect another person to have skin-to-skin contact with your thighs, first **wash the application area well with soap and water.**
- **Stop using FORTESTA® Gel or Testosterone Gel and call your healthcare provider right away if you see any signs and symptoms in a child or a woman that may have occurred through accidental exposure to FORTESTA® Gel or Testosterone Gel.**
- **Do not use FORTESTA® Gel or Testosterone Gel if you** have breast cancer, have or might have prostate cancer, are pregnant, may become pregnant, or are breastfeeding.
    - FORTESTA® Gel and Testosterone Gel may harm your unborn or breastfeeding baby. Women who are, or who may become pregnant should avoid contact with the area of skin where FORTESTA® Gel or Testosterone Gel have been applied.
- Your doctor may check your testosterone, prostate specific antigen (PSA), blood count, liver function, cholesterol, and

blood calcium levels while taking FORTESTA® Gel or Testosterone Gel.

Other possible serious side effects include:

- **If you already have enlargement of your prostate gland your signs and symptoms can get worse** while using FORTESTA® Gel or Testosterone Gel
- **Possible increased risk of prostate cancer**
- **In large doses FORTESTA® Gel and Testosterone Gel may lower your sperm count**
- **Swelling of your ankles, feet, or body, with or without heart failure. This may cause serious problems for people who have heart, kidney or liver disease**
- **Enlarged or painful breasts**
- **Have problems breathing while you sleep (sleep apnea)**
- **Increased red blood cell count**
- **Blood clots in the legs or lungs.** This can include pain, swelling or redness of
- your legs, difficulty breathing, or chest pain.
- FORTESTA® Gel and Testosterone Gel may cause an increase in blood calcium levels in some patients with cancer
- FORTESTA® Gel and Testosterone Gel are flammable until dry. Let FORTESTA® Gel and Testosterone Gel dry before smoking or going near an open flame
- **Call your healthcare provider right away if you have any of the serious side effects listed above**

Tell your HCP about all of your medications, especially insulin, medicines that decrease blood clotting, and corticosteroids.

The most common side effects of FORTESTA® Gel and Testosterone Gel include skin redness or irritation where FORTESTA® Gel or Testosterone Gel applied, increased prostate specific antigen (PSA) (a test used to screen for prostate cancer), and abnormal dreams.

Please see the accompanying full Prescribing Information, including the Medication Guide for patients.

Please see full Prescribing Information, including Boxed Warning for FORTESTA® Gel

Please see full Prescribing Information, including Boxed Warning for Testosterone Gel

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 U.S. headquarters in Malvern, PA. 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, 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.

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