



Endo Announces Extension Of U.S. Rights For Voltaren® Gel

December 14, 2015

Grants Exclusive License to Commercialize Branded Product and any Future Authorized Generic Until 2023

Voltaren® Gel is the Most Prescribed FDA-Approved Topical NSAID for the Relief of Osteoarthritis Pain

DUBLIN, Dec. 14, 2015 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) (TSX: ENL) today announced the extension of its exclusive U.S. marketing rights for the currently marketed prescription medicine Voltaren® Gel (diclofenac sodium topical gel) 1% as well as for the product's Authorized Generic, should Endo opt to commercially launch it in the future. Endo, through an indirect wholly owned subsidiary, has entered into a licensing agreement with Sandoz Inc. and Novartis AG through June 30, 2023.

"We are very proud of Voltaren® Gel's market leading position and are therefore very pleased to extend our marketing rights and continue this successful commercialization," said Rajiv De Silva, President and CEO of Endo. "Endo has a long-standing commitment to supporting the pain community. With this agreement, we can now continue to provide Voltaren® Gel as an important product in our innovative pain product portfolio."

Under the terms of the seven-year agreement, Endo will make additional payments so long as there is no entry of a generic competitor product and the same minimum sales royalties and tiered, double-digit royalties on net sales of Voltaren® Gel in the U.S. as the current licensing agreement. Sandoz will continue to supply the product to Endo.

Endo will provide more detail regarding the anticipated financial impact of this license extension on its future performance when the Company provides full 2016 financial guidance.

About Osteoarthritis

Osteoarthritis (OA) is a chronic condition that occurs more frequently as people get older and can break down joints' protective cartilage causing damage and pain. OA pain develops slowly and can gradually worsen over time.

About Voltaren® Gel

Voltaren® Gel is a non-steroidal anti-inflammatory drug (NSAID) used for the relief of joint pain of osteoarthritis in the knees, ankles, feet, elbows, wrists, and hands. Voltaren® Gel has not been studied for use on the spine, hip, or shoulder. Voltaren® Gel received regulatory approval in October 2007 from the U.S. Food and Drug Administration. Voltaren® Gel provides 1% diclofenac sodium in a topical gel formulation. According to IMS (Health NPA, 2009-2015), Voltaren® Gel is the most prescribed non-steroidal anti-inflammatory (NSAID) medication indicated for the pain of osteoarthritis in joints amenable to topical treatment, such as the knees and those of the hands.

Important Safety Information About Voltaren® Gel

NSAID medicines, like Voltaren® Gel, may increase the chance of a heart attack or stroke that can lead to death. This chance increases:

- with longer use of NSAID medicines
- in people who have heart disease

NSAID medicines, like Voltaren® Gel, should never be used right before or after a heart surgery called a "coronary artery bypass graft (CABG)."

NSAID medicines, like Voltaren® Gel, can cause ulcers and bleeding in the stomach and intestines at any time during treatment.

- Ulcers and bleeding can happen without warning symptoms and may cause death
- The chance of a person getting an ulcer or bleeding increases with older age

NSAID medicines should only be used:

- at the lowest dose possible for your treatment
- for the shortest time needed

Do not use Voltaren® Gel if you are allergic to diclofenac (the active ingredient in Voltaren® Gel) or if you have had asthma, hives, or other allergic-type reactions after taking aspirin or other NSAIDs.

Tell your healthcare provider:

- if you have a history of ulcers or bleeding in the stomach or intestines, or kidney or liver problems, or heart failure
- about all of your medical conditions
- about all of the medicines you take. NSAIDs and some other medicines can interact with each other and cause serious side effects
- if you are pregnant or breastfeeding. Voltaren® Gel should not be used late in pregnancy

NSAIDs, including Voltaren® Gel, can lead to high blood pressure or worsening of high blood pressure, which may add to the increased risk of heart attack and stroke.

Possible serious side effects include life-threatening skin and allergic reactions.

Get emergency help right away if you have any of the following symptoms: shortness of breath or trouble breathing, chest pain, weakness in one side of your body, slurred speech, or swelling of the face or throat. **Stop using Voltaren® Gel and call your healthcare provider right away if you have:** skin rash or fever with blisters.

Do not use Voltaren® Gel on the same skin site that was treated with other topical products, such as sunscreens, cosmetics, lotions, moisturizers, or insect repellents.

Other information about NSAIDs:

- Aspirin, which is an NSAID, can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines

You should not use Voltaren® Gel with oral NSAIDs.

The most common side effects reported in studies using Voltaren® Gel were application site reactions, including dermatitis (reported in 7% of treated patients).

Use Voltaren® Gel exactly as prescribed by your healthcare provider.

- Apply Voltaren® Gel to clean, dry skin that does not have any cuts, infections, or rashes
- Avoid exposing skin where you apply Voltaren® Gel to sunlight and artificial light, such as tanning booths
- Do not get Voltaren® Gel in your eyes, nose, and mouth

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For additional information about Voltaren® Gel, please see the full prescribing information at <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=60045fc6-f0d9-4f67-ba91-c3b317596437>, including the Medication Guide.

About Endo International plc

Endo International plc (NASDAQ: ENDP) (TSX: ENL) is a global specialty pharmaceutical company focused on improving patients' lives while creating shareholder value. Endo develops, manufactures, markets and distributes quality branded 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.

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, including the statements by Mr. De Silva and other statements regarding market and product potential. 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 the Securities and Exchange Commission ("SEC") and with securities regulators in Canada on the System for Electronic Document Analysis and Retrieval ("SEDAR"), including under the caption "Risk Factors" in Endo's Form 10-K, Form 10-Q and Form 8-K filings, 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 this communication. The forward-looking statements in this press release are qualified by these risk factors. 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 laws.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/endo-announces-extension-of-us-rights-for-voltaren-gel-300192178.html>

SOURCE Endo International plc

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