



## Endo Announces Issuance of Vasostrict® Patent

June 28, 2016

DUBLIN, June 28, 2016 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) (TSX: ENL) today announced that one of its operating companies, Par Pharmaceutical, has been issued a new patent by the U.S. Patent and Trademark Office (PTO) relating to Vasostrict® (vasopressin injection, USP) 20 units/mL. The PTO has issued to Par U.S. Patent No. 9,375,478, which has an expiration date of January 30, 2035. Patent No. 9,375,478 has been submitted to the U.S. Food and Drug Administration's (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, and will have a submission date of June 28, 2016.

This Orange Book listing requires any Abbreviated New Drug Application (ANDA) applicant seeking FDA approval for a generic version of Vasostrict® prior to expiration of the patent to notify Par of its ANDA filing before it can obtain FDA approval. Any ANDA filer whose application was not received prior to submission of the new patent information would be subject to a 30-month stay of marketing approval by the FDA upon the initiation of Hatch-Waxman litigation by Par against the ANDA filer.

Par's Vasostrict® is the first and only vasopressin injection, USP, product approved by the FDA. Vasostrict® is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. Under the FDA's unapproved drugs initiative, Par invested significant time and resources to demonstrate the safety and efficacy of its reformulated and improved Vasostrict® product and to obtain FDA approval. Par continues to invest in its sterile injectables manufacturing facility and has proven to be a reliable supplier of high-quality, high-purity products.

### Important Information About Vasostrict® (vasopressin injection, USP)

Vasostrict® is contraindicated in patients with known allergy or hypersensitivity to 8-L-arginine vasopressin or chlorobutanol. Use in patients with impaired cardiac response may worsen cardiac output. The most common adverse reactions include decreased cardiac output, bradycardia, tachyarrhythmias, hyponatremia and ischemia. These highlights do not include all the information needed to use Vasostrict® safely and effectively. For full prescribing information, visit [www.parsterileproducts.com](http://www.parsterileproducts.com)

### 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](http://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. 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), 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 does not assume 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 laws.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/endo-announces-issuance-of-vasostrict-patent-300291415.html>

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