Top-Line Data Show the Investigational TOPAS™ System Improves Fecal Incontinence in Women

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Results unveiled yesterday at the International Society of University Colon & Rectal Surgeon (ISUCRS) Congress demonstrate significant reductions in incontinence episodes

MINNEAPOLIS, Sept. 8, 2014 /PRNewswire/ -- American Medical Systems Inc. (AMS), a subsidiary of Endo International plc (Nasdaq: ENDP) (TSX: ENL) and leading provider of medical technologies for pelvic health, today announced positive top-line results from its TRANSFORM study. The results show that over a 12 month period, 69% of women suffering from fecal incontinence who were implanted with the TOPAS™ System experienced at least a 50% reduction in weekly incontinence episodes and experienced a durable, consistent effect across the study period. The results were presented yesterday in Cape Town, South Africa at the International Society of University Colon & Rectal Surgeon (ISUCRS) Congress.

The TOPAS™ System is an innovative, minimally-invasive approach to treating fecal incontinence, also known as accidental bowel leakage, or ABL. It uses a permanent mesh implant that is designed to restore and maintain anatomic support of the pelvic floor muscles. TOPAS™ is in development for women with ABL who have failed conservative therapy, which includes dietary changes, anti-diarrheal medications or bulking agents and pelvic floor muscle training. This is an investigational device whose efficacy and safety are not yet approved by the U.S. Food and Drug Administration (FDA).

"We are very excited and encouraged by the data shown in TRANSFORM and the potential future treatment option for women suffering from ABL," said Steve Blum, General Manager, Women's Health at American Medical Systems. "TOPAS represents the next milestone for AMS in bringing innovative new options to market for patients with pelvic health conditions. AMS is committed to Women's Health and furthering science that addresses unmet medical needs for women worldwide."

In the United States, about 11 million women over age 20 experience ABL.[1,2] It affects half of nursing home residents and is the second leading reason for nursing home placement among the elderly.[3] Nearly one in five women over age 45 experience ABL at least once a year.[4] ABL can occur when the position of the pelvic floor muscles have changed due to damage that may occur during childbirth, injury, aging, straining or pelvic floor weakness.

Due to the complexity of ABL, there is no standard treatment that fits all patients. In addition, treatments often place an additional burden on patients so newer and effective options are needed. Sustained improvements in bowel control with the TOPAS™ System exhibited in the TRANSFORM study suggest a promising outlook for a valuable therapeutic option for ABL.

About TRANSFORM

The TRANSFORM study is a prospective, open-label, single-arm study involving 152 women implanted with the TOPAS™ system at 14 centers in the United States. The primary endpoint was treatment success, which was defined as reduction in number of fecal incontinence episodes of 50% or more from baseline in 50% of patients. These episodes were assessed at baseline and then at 3, 6 and 12 months post-operatively. The participants included women ages 18 or older (average age, 59) who experienced symptoms for at least six months and failed at least two types of conservative therapy, including diet, medication or biofeedback.

Overall, 69% of women experienced at least a 50% reduction in fecal incontinence episodes, exceeding the study's primary efficacy endpoint. Fecal incontinence episodes were reduced from a median weekly frequency of 9 episodes and 5 incontinence days at baseline, to 2.5 episodes and 2 incontinence days per week at 3, 6, and 12 months. In addition, patients reported an improvement in quality of life as indicated by validated questionnaires.

A total of 71 patients experienced 113 procedure and/or device (treatment-related) adverse events, 97% of which were managed without therapy or through non-surgical treatment. The most commonly observed complications (>5%) were pain (primary buttock, pelvic or groin pain) and incision site infection. There were no erosions, extrusions, organ perforations, bowel obstructions, or device revisions and no unanticipated adverse device effects observed in this study.

"Currently, there is no standard treatment that is suitable for all women suffering from ABL," said Dee Fenner, M.D., Professor of Obstetrics and Gynecology University of Michigan and a primary investigator. "These new findings suggest that TOPAS has the potential to be a safe, effective and minimally invasive approach to managing ABL in women where more conservative measures have failed. It takes about 30 minutes to implant and requires a minimal hospital stay."

About The TOPAS™ System

The TOPAS™ System is an implantable device intended to treat women with fecal incontinence (also referred to as accidental bowel leakage) who have failed more conservative therapies. The device is currently contraindicated for use in pregnant patients, patients with pre-existing conditions that pose an unacceptable surgical risk, patients with known sensitivity or allergy to polypropylene mesh products, and patients who are unwilling to abstain from receptive anal intercourse. Surgical revision or removal of the TOPAS device may involve multiple surgeries. Complete removal of the mesh may not be possible and may not result in complete resolution of the symptoms or complications.

Some of the most common risks (>5.0% incidence) include, but are not limited to: pain/discomfort in the buttock, groin and pelvic region, and incision site infection. Potential severe risks associated with this procedure may include, but are not limited to: perforation of the bowel, infection resulting in sepsis, allergic/hypersensitivity or other immune reaction, deep vein thrombosis, or erosion of the mesh through the rectum. Although rare, some mesh-related adverse events (e.g. mesh erosion/extrusion, mesh infection) may involve surgical intervention.

About American Medical Systems

American Medical Systems (AMS), headquartered in Minnetonka, MN, is a diversified supplier of medical device technology to treat incontinence, sexual dysfunction, benign prostatic hyperplasia (BPH) and other pelvic disorders. AMS is focused on improving access and outcomes with the goal of restoring patient quality of life. AMS 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.

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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SOURCE American Medical Systems

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