American Medical Systems Enrolls First Patient in Embrace, a 522 Post Market Surveillance Study for the Elevate™ Anterior and Apical Prolapse System

June 9, 2014

Largest AMS study-to-date will further evaluate the safety and efficacy of this important option for the treatment of pelvic organ prolapse

MINNEAPOLIS, June 9, 2014 /PRNewswire/ -- American Medical Systems Inc. (AMS), an Endo International plc (Nasdaq: ENDP) (TSX: ENL) subsidiary and leading provider of medical technologies for pelvic health, today announced that the first patient has been enrolled in Embrace™, AMS's 522 post market surveillance study for the Elevate™ Anterior and Apical Prolapse Repair System. The FDA has required post market surveillance studies be conducted by all manufacturers for transvaginal mesh products currently on the market, to determine the risks compared to the benefits of this approach to treating prolapse.

Dr. Eric Sokol, Co-Chief, Urogynecology and Pelvic Reconstructive Surgery at Stanford University School of Medicine, is the principal investigator for the Embrace study. The study is designed as a large multi-center cohort-controlled study that compares Elevate Anterior and Apical Prolapse Repair System with a native tissue repair control group. "Pelvic organ prolapse is often complex. Multiple treatment options are needed to address the exact nature and complexity of the prolapse and there are particular circumstances when the placement of transvaginal mesh may be beneficial and appropriate. The Embrace study will provide valuable information to clinicians and patients about the role of mesh for the treatment of female pelvic organ prolapse," said Dr. Sokol.

The first patient enrolled in the study was by Dr. Michael Ingber from the Center for Specialized Women's Health, Division of Garden State Urology in New Jersey. The first patient procedure completed in the study was performed by Dr. Richard Bercik of Yale Gynecological Oncology in New Haven, Conn.

The Embrace Study is one of the largest clinical trials ever performed by American Medical Systems, and the largest to date involving the Elevate Anterior and Apical Prolapse Repair System.

It is anticipated that there will be 494 patients enrolled in the Embrace study at approximately 40 sites throughout the United States. Concurrently, AMS plans another 522 post market surveillance study, Harmony™, for the Elevate™ Posterior and Apical Prolapse Repair System, which is expected to also enroll 494 patients at 40 participating sites. Each study will take approximately 2 years to enroll and 3 years to follow for a total duration of 5 years, making these studies significantly longer than other mesh clinical trials of similar design.

"These studies demonstrate the commitment of AMS to provide medical evidence that further validates the safety and efficacy of our products," said Camille Farhat, president of American Medical Systems. "As a global leader in Women's Health, we will continue to invest in the science that supports these therapies and maintain our support of robust physician training as well as patient education that encourages conversations about the risks and benefits of these treatments."

As with all mesh surgical procedures, there are risks and potential complications that may occur. Please consult a physician before considering surgery

More information on the Elevate™ Anterior and Apical Prolapse System is available at www.amselevate.com

About the Elevate™ Anterior and Apical Prolapse System

The Elevate Anterior & Apical Repair System is a surgical mesh kit intended for the transvaginal surgical treatment of women with anterior wall prolapse and vaginal apical prolapse. The Elevate Anterior & Apical System is contraindicated in infants, children, pregnant women, or women planning future pregnancies. Elevate Anterior System should not be implanted in the presence of: active or latent infections, cancers of the vagina, cervix, or uterus or in patients who have received radiation the area of treatment or in direct contact with bowel or visceral organs, including the urinary bladder.

Although rare, some of the known risks of surgical procedures for the treatment of pelvic organ prolapse include the following: adhesion formation, mild to severe bleeding (hematoma, perforation of vessels), constipation, complete failure of the procedure resulting in recurrent pelvic organ prolapse, dyspareunia, de novo prolapse of an untreated compartment, fecal incontinence, foreign body reaction, infection, graft erosion, graft extrusion, graft migration, nerve damage, obstruction of the ureter, pain, perforation of: bladder, bowel, ureter, urethra, and other pelvic structures, urinary tract infection, vaginal contracture, voiding dysfunction, and wound dehiscence.

About Prolapse

Pelvic organ prolapse is a condition in which the tissues that hold the pelvic organs in place become weak or stretched, resulting in the displacement (prolapse) of the pelvic organs from their normal position. Common causes of pelvic organ prolapse include: pregnancy childbirth, obesity, and genetics.[1] One in two women may experience pelvic organ proplape in their lifetime.[1] Women may experience stress and a decreased quality of life as a result of pelvic organ prolapse (POP) and symptoms may limit daily activities and related decisions.[2,3] In addition, POP can affect work performance and can have a major impact on sexual activity.[2,3] One study found that women with prolapse endure their symptoms for years, delaying conversations with doctors because they are reluctant to discuss this subject.[4]

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.

1. Jelovsek JE, Maher C, Barber MD. Pelvic organ prolapse. Lancet. 2007;369(9566):1027-38.

2. Kuncharapu I, Majeroni BA, Johnson DW. Pelvic organ prolapse. Am Fam Physician. 2010;81(9):1111-7.

3. Margalith I, Gillon G, Gordon D. Urinary incontinence in women under 65: quality of life, stress related to incontinence and patterns of seeking health care. Quality of life research Oct 2004 v. 13(8) pp. 1381-90.

4. Mouritsen L, Larsen JP. Symptoms, bother and POPQ in women referred with pelvic organ prolapse. Int Urogynecol J. 2003 v. 14 p. 122-127.

SOURCE American Medical Systems

Investors/Media: Blaine Davis, +353-1-669-6635, (484) 216-7158, Investors: Jonathan Neely, (484) 216-6645, Media: Brian O'Donnell, (484) 216-6726