NEWS RELEASE

Women Treated with Hologic's NovaSure® Endometrial Ablation System in New Study Reported Higher Amenorrhea Rates than Those Treated with Minerva

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NovaSure patients in study also used fewer pads and tampons, reported better menstrual-related quality of life and alleviation of PMS symptoms as compared to Minerva patients

MARLBOROUGH, Mass., April 19, 2018 /**PRNewswire**/ -- Hologic, Inc. (Nasdaq: HOLX) announced today that in a new study, women treated with NovaSure® endometrial ablation reported a higher one-year amenorrhea (absence of menstruation) rate, better quality of life (QoL) post-procedure, and greater satisfaction than women treated with Minerva endometrial ablation.1 The full study results are published in the peer-reviewed International Journal of Women's Health, available at **https://www.dovepress.com/**.

The multi-center, IRB-approved retrospective case control study surveyed 189 pre-menopausal women who underwent endometrial ablation in accordance with FDA-approved use of either the NovaSure or Minerva device (97 NovaSure and 92 Minerva).1 The primary efficacy outcome was the percentage of patients experiencing amenorrhea post-ablation; the mean follow-up was 11.3 months (range 137 – 532 days). Secondary efficacy outcomes were change in abnormal uterine bleeding (AUB) symptom severity from baseline, the percentage of patients requiring secondary intervention (medical or surgical) for refractory AUB, and patient satisfaction level.1 The primary safety-related outcome was the incidence of perioperative adverse events, which included, among others, pain, fever, nausea, vomiting, vaginal bleeding, and vaginosis.1

Study Results

- The subject-reported amenorrhea rate was 52% higher in NovaSure patients than in Minerva patients (64%

and 42%, respectively; p=0.004).1

- Bleeding reduction in women with AUB was comparable with both endometrial ablation systems (97% and 92%, respectively; p=0.2039).1
- Mean days per cycle with any reported bleeding were comparably reduced in both groups, from 9.0 - 9.5 days to 4.8 – 5.5 days.1
- Diminished bleeding after ablation was reflected in the overall reduction in self-reported sanitary products used in both the NovaSure and Minerva groups (78% and 61%, respectively; p=0.049).1
- The post-ablation incidence of menstrual pain reported was lower in the NovaSure group versus the Minerva group (21% and 41%, respectively; p=0.003).1
- After NovaSure ablation, 85% of women who initially experienced Pre-Menstrual Syndrome (PMS) reported improvement vs. 68% in the Minerva group (p=0.019).1
- Endometrial ablation lowered the impact of menstrual bleeding on subject QoL in both NovaSure and Minerva groups. The average postoperative impact score was improved (lower) in NovaSure versus Minerva subjects (0.3 points and 0.7 points, respectively; p=0.012).1
- 94% of NovaSure patients reported some level of satisfaction with clinical outcomes versus 78% of Minerva patients (p=0.003). Additionally, a larger proportion of NovaSure patients said they would "definitely recommend the procedure to a friend" compared to Minerva patients (92% and 78%, respectively; p=0.013).1
- The primary safety-related outcome was the incidence of perioperative AEs; 5 Minerva patients and 10 NovaSure patients (p=0.284) experienced postoperative adverse events, including, pain, fever, nausea, vomiting, vaginal bleeding, acute renal failure, urinary tract infection and vaginosis, with onsets occurring within 14 days after ablation.1
- A total of 5 additional gynecologic procedures were performed in 4 NovaSure subjects and 4 procedures in 3 Minerva subjects ($p > 0.05$).1
- Categorical variables were assessed with Fisher's Exact test. Continuous variables were compared by Student's t-test; p-values <.05 indicated statistically significant differences.1

NovaSure Pivotal Study Information

The pivotal study supporting FDA approval of the NovaSure system on September 28, 2001 was a randomized, prospective, multi-center clinical study, in which the NovaSure system was compared to a control arm of wire loop resection plus rollerball endometrial ablation (hysteroscopic endometrial ablation). A total of 265 patients were enrolled in the study, with 175 being randomized into the NovaSure study arm. The NovaSure study arm reported 1-year success rates of 77.7% and 1-year amenorrhea rates of 36%. Patient success was based on a reduction in a menstrual diary score from ≥ 150 pre-treatment to ≤ 75 at one-year post-treatment, using a validated menstrual dairy scoring system developed by Higham.11 Patient satisfaction was assessed by administering Quality of Life (SF-12 Questionnaire) and Menstrual Impact questionnaires prior to treatment and at 3, 6 and 12 months post-

treatment, with 92.8% of NovaSure patients reporting being satisfied or very satisfied with the procedure after 1 year.

For more information on the NovaSure procedure, visit **www.NovaSure.com**, and for its full product labeling, visit **www.NovaSure.com/hcp/resources/ifus**.

About Abnormal Uterine Bleeding (AUB)

Abnormal uterine bleeding (AUB), or menorrhagia, affects up to 30% of premenopausal women,2 and negatively impacts quality of life (QoL).3 Medical treatment of AUB is often effective, but associated costs and potential adverse effects (AEs) of long-term treatments restrict patient adherence.4 Hysterectomy, while a decisive treatment for AUB if other treatments fail, is an aggressive approach that carries risk of serious short-term and long-term AEs, as well as an increased risk of cardiovascular disease.5–7 Endometrial ablation is an effective, less-invasive surgical option for treating AUB, using either resectoscopy or newer second-generation techniques that deliver high-dose energy to uniformly destroy the entire uterine lining.8–10

About Hologic

Hologic, Inc. is an innovative medical technology company primarily focused on improving women's health and well-being through early detection and treatment. For more information on Hologic, visit **www.hologic.com**.

Important Safety Information

NovaSure® endometrial ablation is for premenopausal women with heavy periods due to benign causes who are finished childbearing. Pregnancy following the NovaSure procedure can be dangerous. The NovaSure procedure is not for those who have or suspect uterine cancer; have an active genital, urinary or pelvic infection; or an IUD. NovaSure endometrial ablation is not a sterilization procedure. Rare but serious risks include, but are not limited to, thermal injury, perforation and infection. Temporary side effects may include cramping, nausea, vomiting, discharge and spotting. Inform patients to contact you if they experience a possible side effect related to use of this product. For detailed benefit and risk information, please consult the IFU.

Forward-Looking Statements

This news release may contain forward-looking information that involves risks and uncertainties, including statements about the use of Hologic products. There can be no assurance these products will achieve the benefits described herein or that such benefits will be replicated in any particular manner with respect to an individual patient, as the actual effect of the use of the products can only be determined on a case-by-case basis. In addition, there can be no assurance that these products will be commercially successful or achieve any expected level of sales. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein to reflect any change in expectations or any change in events, conditions or circumstances on which any such data or statements are based.

This information is not intended as a product solicitation or promotion where such activities are prohibited. For specific information on what products are available for sale in a particular country, please contact a local Hologic sales representative or write to **womenshealth@hologic.com**.

Media Contact:

Jane Mazur
508.263.8764 (direct)
585.355.5978 (mobile)
jane.mazur@hologic.com

Investor Contact:

Michael Watts
858.410.8588
michael.watts@hologic.com

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