



GYNESONICS ANNOUNCES ANOTHER PEER-REVIEWED PUBLICATION AND PRESENTATION OF SIGNIFICANT INTERNATIONAL CLINICAL EXPERIENCE WITH VIZABLATE TECHNOLOGY FOR SYMPTOMATIC UTERINE FIBROIDS

***FAST-EU Trial 6 Month Results Published in Gynecological Surgery;
12 Month Results presented at 43rd Annual AAGL Meeting***

REDWOOD CITY, CA – December 9, 2014 – Gynesonics, Inc., a women’s healthcare company focused on the development of minimally invasive solutions for symptomatic uterine fibroids, today announced the recent publication and presentation of results from the *Symptom Effectiveness Study of VizAblate® Intrauterine Ultrasound-Guided Radiofrequency Ablation (IUUSgRFA) in the Ablation of Uterine Fibroids (FAST-EU)*. Fifty patients were treated at seven centers across The Netherlands, the UK and Mexico.

“Transcervical, intrauterine ultrasound-guided radiofrequency ablation of uterine fibroids with the VizAblate System: three and six month endpoint results from the FAST-EU study” was published online on November 28 by *Gynecological Surgery*, the official journal of the European Society for Gynaecological Surgery (ESGE). Marlies Bongers, MD, PhD, of Maxima Medisch Centrum, Veldhoven, The Netherlands, is the lead author of the paper. “We were impressed with the 69% average reduction in perfused fibroid volume seen at three months in study subjects,” commented Dr. Bongers. “This, along with the 61% mean reduction in bleeding at 6 months, with a median return to normal activity of 4 days indicates the tremendous potential of the VizAblate technology as a treatment for heavy menstrual bleeding associated with fibroids”

Additionally, there were four separate abstracts regarding the 12-Month FAST-EU outcomes that were accepted for presentation at the 43rd annual meeting of the American Association of Gynecologic Laparoscopists (AAGL) in Vancouver, Canada, from November 17-19. These presentations and presenters were: “12 Month Reduction of Fibroid Perfused and Total Volume” by Sebastiaan Veersema, MD, PhD, Nieuwegein, The Netherlands; “Menstrual Blood Loss Reduction at 12 Months” by Rik Quartero, MD, PhD, Enschede, The Netherlands; “Fibroid Symptom Reduction, Health Related Quality of Life Improvement and Patient Satisfaction” by JG Garza-Leal, MD, Monterrey Mexico; and “12 Month Safety, Reintervention and Pregnancy Outcomes” by David Toub, MD, MBA, Medical Director of Gynesonics.

Dr. Quartero noted “The continued reduction in fibroid volume with the VizAblate system through 12 months, with a median 76% reduction, is significant. Also, as physicians, we are particularly focused with relief of heavy menstrual bleeding. The 73% median reduction in menstrual blood loss at 12 months for this challenging patient group is very encouraging. This was achieved with an outstanding safety profile.”

“The six-month data publication and presentations of the 12-month FAST-EU trial results are important milestones for our company,” noted Christopher Owens, President and CEO. “The significant FAST-EU patient outcomes have clearly demonstrated the potential of the VizAblate technology in the treatment of heavy menstrual bleeding associated with uterine fibroids. The impressive outcomes, both in terms of fibroid volume reduction as well as diminution of bleeding symptoms, demonstrated sustained and continued improvement from 6 months to 12 months. In addition, 83% of FAST-EU subjects were either very satisfied or satisfied with their treatment at 12 months. We are thankful to our dedicated investigators who contributed to the FAST-EU study and who also presented and published this important data.”

In October, Gynesonics announced FDA approval of the SONATA IDE pivotal trial for the latest generation of the VizAblate system, the only medical device to integrate ultrasound imaging with radiofrequency ablation in a single, handheld device for the incision-free, transcervical treatment of fibroids. This latest generation system has CE Mark and is approved for sale in the European Union. The VizAblate System offers a distinct alternative to power morcellation and other major surgical and radiological approaches to the treatment of fibroids

According to the medical literature, in the United States, about 70-80 percent of women in the US will develop uterine fibroids by age 50. In addition, approximately 200,000 hysterectomies are performed in the United States each year because of symptomatic fibroids, according to the *New England Journal of Medicine*.

About VizAblate:

VizAblate uses radiofrequency energy to ablate fibroids under intrauterine sonography guidance. The VizAblate device and software allows users to visually target specific fibroids and optimize ablations within them.

VizAblate's unique transcervical access is straight-forward, is associated with short procedure times, requires minimal in-procedure assistance, and is incision-free. Treatment with the VizAblate System is confined to the uterus; the device does not violate the uterine serosa or peritoneal cavity and is a distinct alternative to power morcellation procedures.

The Next Generation VizAblate System Features:

- **First and only intrauterine ultrasound probe** for identification and SMART targeting of fibroids
- The only system to integrate imaging guidance and therapy into a **single handheld delivery system**
- Designed as an **incision-free, uterus-preserving** alternative to hysterectomy and myomectomy for symptomatic fibroids
- A transcervical approach developed to completely **avoid the peritoneal cavity and tissue morcellation**, minimize BMI-related access issues and avoid the need for general anesthesia
- Designed to treat a wider range of fibroids, including **larger/deeper fibroids**, that are not accessible with hysteroscopy
- Proprietary radiofrequency delivery system, scalable to provide **predictable ablations of varying sizes**
- Innovative **SMART Targeting Guide** automates treatment parameters, while minimizing the risk of thermal injury to adjacent viscera
- Incision-free in-situ fibroid treatment device developed to **reduce procedural complexity, risk and morbidity** compared to surgical excision and removal

About Gynesonics

Gynesonics is a women's healthcare company focused on minimally invasive solutions for symptomatic uterine fibroids. Gynesonics has developed the VizAblate® System for the transcervical treatment of symptomatic uterine fibroids under intrauterine ultrasound guidance. VizAblate has received CE Mark approval for commercial sale in the European Union. VizAblate is not available for sale in the United States. Gynesonics is a privately held company with headquarters in Redwood City, CA.

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