GYNESONICS RECEIVES FDA APPROVAL TO COMMENCE A PIVOTAL IDE CLINICAL TRIAL FOR THE NEWLY-DESIGNED VIZABLATE® SYSTEM

Distinct Alternative to Surgery, Radiological Approaches and Power Morcellation, for the Treatment of Symptomatic Uterine Fibroids

REDWOOD CITY, CA – October 22, 2014 – Gynesonics, Inc., a women's healthcare company focused on the development of minimally invasive solutions for symptomatic uterine fibroids, today announced it has received approval from the U.S. Food and Drug Administration (FDA) of an investigational device exemption (IDE) for the pivotal trial, Sonography Guided Transcervical Ablation of Uterine Fibroids (SONATA Trial), of its newly-designed VizAblate® System. The system is designed to provide women with a transcervical, incision-free, outpatient option to invasive surgical procedures such as hysterectomy for the relief of symptomatic uterine fibroids.

"We are pleased to have FDA approval to begin this pivotal trial thus validating the pre-clinical testing profile and clinical trial design for VizAblate," said Diane King, Vice President of Regulatory, Clinical and Quality Systems for Gynesonics. "Initiation of this study will begin in Q4 this year and will be conducted at up to 22 clinical sites with 147 patients, and upon favorable conclusion will allow the company to complete a 510k application for VizAblate with the FDA."

The SONATA trial will investigate the safety and effectiveness of VizAblate in treating heavy menstrual bleeding associated with symptomatic uterine fibroids.

"Receiving FDA IDE approval of the SONATA trial is a significant strategic milestone for Gynesonics," said Chris Owens, President and Chief Executive Officer. "We are excited by the positive outcomes with VizAblate in the FAST-EU clinical trial, as well as the level of interest displayed by leading gynecologists throughout the U.S. to participate in the SONATA US IDE trial. We will continue to collaborate with all parties to make this breakthrough technology available to physicians and to the millions of women suffering from symptomatic fibroids in the United States and around the globe. Our VizAblate System is designed to offer gynecologists a new approach to the management of symptomatic uterine fibroids; for patients VizAblate may offer a much needed, precisely targeted therapy without the need for surgery."

The Company has also recently received CE Mark approval to market the new system in the European Union. In June, Gynesonics announced the successful treatment of the first patient in Europe using the new VizAblate System, the only medical device to integrate ultrasound imaging with radiofrequency ablation in a single, handheld device for the incisionless, transcervical treatment of fibroids. The VizAblate System offers a distinct alternative to power morcellation and other major surgical and radiological approaches for 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 accurate 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.

CONTACT:
Chris Owens
Gynesonics President and CEO
650.216.3860
www.gynesonics.com