



GYNESONICS ANNOUNCES FIVE-YEAR PATIENT OUTCOMES WITH THE SONATA SYSTEM PUBLISHED IN *JOURNAL OF GYNECOLOGIC SURGERY*

*VITALITY Study Demonstrates the Long-Term Durability of Patient Outcomes
In Treating Symptomatic Uterine Fibroids*

Redwood City, CA – March 5, 2019 - Gynesonics, a women’s healthcare company and the developer of the Sonata[®] system for the treatment of uterine fibroids (also known as leiomyomas) today announced the publication of the VITALITY study in the *Journal of Gynecologic Surgery*.

The article, “Long-Term Clinical Outcomes of Transcervical Radiofrequency Ablation of Uterine Fibroids: The VITALITY Study,” reports the retrospective long-term clinical outcomes from FAST-EU trial patients enrolled at the site in Monterrey, Mexico. The patients were treated with the Sonata system providing incisionless transcervical radiofrequency energy ablation of uterine fibroids under intrauterine ultrasound guidance. The mean follow-up period for the patients enrolled was 5.4 years.

Highlights from the publication include:

- No surgical reinterventions in the first 3.4 years
- Annualized surgical reintervention rate per year of 2.2%
- 11.8% cumulative reintervention rate through 5.4 years average follow up
- 37 point mean improvement in Symptom Severity Score at follow up
- 49 point mean improvement in Health-Related Quality of Life at follow up

“We are pleased to follow our patients treated with Sonata out to more than 5 years,” explained Jose Gerardo Garza-Leal, MD, Universidad Autonoma de Nuevo Leon, Monterrey, Mexico. “We have evaluated many new fibroid treatment innovations in our facility and are especially impressed with the patient results achieved with Sonata over this extended time frame. Such lasting results are even more impressive considering the low risk and quick recovery our patients experienced with the Sonata procedure, especially when compared to other fibroid treatment alternatives.”

The Sonata (Sonography-Guided Transcervical Fibroid Ablation) system is intended for the diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding. The system combines a novel integrated technology -- the first and only intrauterine ultrasound system -- with a proprietary

radiofrequency ablation device. This novel technology platform provides transcervical access to a wide range of fibroid types, most of which cannot be treated with current operative hysteroscopy methods.

“We are appreciative of the commitment by Dr. Garza-Leal to investigate the long-term effects of Sonata on his patients. These exciting results from the VITALITY study, along with the data recently published from our Pivotal IDE Trial and other published studies, are compelling and support the clinical application of Sonata for the treatment of symptomatic fibroids,” said Christopher M. Owens, President and CEO of Gynesonics. “The long term sustained clinical outcomes reported in VITALITY are important to the physician community, especially when considering adoption of a breakthrough technology like the Sonata system.”

About 70-80 percent of women in the U.S. and Europe will develop uterine fibroids by age 50, with a significant proportion of the fibroids causing symptoms. These symptoms can impair physical function and greatly reduce quality of life. The National Institutes of Health estimate 200,000 hysterectomies are performed in the U.S. each year specifically to address symptomatic uterine fibroids. With an estimated volume of more than 1 million annual global uterine fibroid procedures, Gynesonics projects a \$3 billion-\$4 billion global market opportunity for its Sonata system, including a market opportunity of more than \$1 billion in the U.S. alone.

About Sonata System

The Sonata system, the next generation of Gynesonics’ technology platform (the previous generation referred to as VizAblate), uses radiofrequency energy to ablate fibroids under intrauterine sonography guidance. The Sonata system, including the SMART Guide, enables the operator to target fibroids and optimize ablations within them. Sonata system’s design provides a straightforward, transcervical access for a uterus preserving, incision-free fibroid treatment. This intrauterine approach is designed to treat a wide range of fibroid types while avoiding the peritoneal cavity.

For Indication and Safety Information, or to learn more about the Sonata system, visit gynesonics.com/sonata-system.

About Gynesonics

Gynesonics is a women’s healthcare company focused on advancing women’s health, by developing minimally invasive, transcervical, uterus-preserving, incision-free technologies for diagnostic and therapeutic applications. Gynesonics has developed the Sonata system for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids. The Sonata system is CE marked. Sonata is approved for sale in the European Union, the United States, Australia, New Zealand, Hong Kong, Singapore and Malaysia. Gynesonics is a privately held company with headquarters in Redwood City, CA. For more information, go to www.gynesonics.com.

CONTACT:

Chris Owens, Gynesonics President and CEO

+1.650.216.3860

www.gynesonics.com