



GYNESONICS ANNOUNCES PUBLICATION OF FINAL SONATA IDE PIVOTAL TRIAL RESULTS IN THE JOURNAL, *OBSTETRICS AND GYNECOLOGY*

Robust Outcomes Support the Potential of the Sonata System as a First-Line Treatment for Symptomatic Uterine Fibroids

Redwood City, CA – January 10, 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 SONATA IDE Pivotal Trial 12-month results in the January edition of *Obstetrics and Gynecology*, the official publication of the American College of Obstetricians and Gynecologists (ACOG).

The article, *Ultrasound-Guided Transcervical Ablation of Uterine Leiomyomas*, reports the final 12-month results from the SONATA Trial. Treatment of 147 enrolled patients was performed using the company’s Sonata system, a proprietary and innovative treatment device allowing incisionless transcervical radiofrequency energy ablation of uterine fibroids under intrauterine ultrasound control, at 22 outpatient clinical research sites, including 21 in the U.S. and one in Mexico. Highlights from the publication include the following final 12-month outcomes:

- 99% of patients were free from surgical reintervention for heavy menstrual bleeding
- 97% were satisfied with the treatment and would recommend it to family or friends
- 96% reported improved symptoms
- 95% had a reduction in menstrual bleeding
- 65% had at least a 50% reduction in menstrual bleeding

Additionally, the mean length of stay, including procedure time, was 2.5 ± 1.2 hours, and 50% of patients returned to normal activity the next day (mean 2.2 ± 2.2 days). There were no device-related adverse events.

“Uterine fibroids are a common problem that reduce the quality of life for women in the United States today. The SONATA pivotal clinical trial outcomes, along with the data from other published clinical outcome studies using the same technology, support offering sonography-guided transcervical uterine fibroid ablation as a treatment option to appropriate patients suffering from symptomatic uterine fibroids,” stated Scott Chudnoff, MD, MSc, FACOG, Chair, Department of OB/GYN at Stamford Health (Stamford, CT), a SONATA Trial investigator and lead author on the publication. He continued, “This transcervical, uterine sparing approach avoids some of the risks of other treatment options, with minimal disruption in our patients’ lives.”

Karen Talmadge, Ph.D., Chair of the Gynesonics Board of Directors, explained, “Publication of our pivotal clinical trial results in the prominent journal, *Obstetrics and Gynecology*, will help us raise awareness among gynecologists, the broader women’s healthcare community, and private insurers about the risk-benefit profile of treating symptomatic uterine fibroids in appropriate patients using the SONATA system. Publication in this excellent journal also supports the quality of the clinical trial design and the robustness of the one-year outcomes. Taken together, our current and future clinical trial publications are designed to strongly support the clinical value of the Sonata system, as we seek insurance coverage and begin commercialization.”

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, many of which cannot be treated with current operative hysteroscopy methods.

“It is exciting to have the final one-year results from the SONATA Pivotal IDE Trial published in *Obstetrics and Gynecology*,” said Christopher M. Owens, President and CEO of Gynesonics. “We are appreciative of the investigators and their commitment to advancing options in women’s healthcare by studying the outcomes of our technology for the treatment of symptomatic uterine fibroids in the SONATA Trial. This is an important milestone and it comes on the heels of our recently announced substantial equity financing. We will continue to invest in high quality clinical and health economic outcomes research to help ensure access to the Sonata treatment for women suffering from symptomatic uterine fibroids in the United States and globally.”

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 and the United States. Gynesonics is a privately held company with headquarters in Redwood City, CA. For more information, go to www.gynesonics.com.

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