



GYNESONICS ANNOUNCES FULL LAUNCH OF NEW SONATA 2 SYSTEM AT 48TH AAGL GLOBAL CONGRESS

2-year Outcomes Data from the SONATA IDE Pivotal Trial To Be Presented, Demonstrating Significant and Sustained Symptom Relief

REDWOOD CITY, Calif. - November 11, 2019 - Gynesonics, a women's healthcare company focused on the development of minimally-invasive solutions for symptomatic uterine fibroids, announced today the full launch of the Sonata[®] 2 System in the United States and Europe at the American Association of Gynecologic Laparoscopists (AAGL) Conference, in Vancouver, BC, Canada, from November 10-13. The Sonata System is the world's first and only transcervical fibroid ablation system that combines the first ever intrauterine ultrasound guidance with the proven benefits of targeted radiofrequency energy in an incisionless, uterus preserving procedure.

The Company also announced that it had completed the first patients treated with the new Sonata 2 System in the U.S. with now more than 1,000 patients treated globally.

The new Sonata 2 System features a next-generation intrauterine ultrasound probe that has improved performance and durability, providing higher resolution imaging for targeting of fibroids throughout the uterus. The new system also includes an improved graphic user interface that enhances workflow efficiency and the overall user experience.

The long-term 2-year Outcomes Data for the SONATA FDA IDE Pivotal Trial will be presented in a plenary session on Monday, November 11 at the AAGL conference. The data will reveal sustained symptom relief with patients showing a significant improvement in quality of life and reduction in severity of symptoms through two years, with a low rate of reintervention. These data were recently published in the Journal of Gynecologic Surgery.

The long-term efficacy of the Sonata System is further supported by the positive 5-year outcomes data reported in the VITALITY study published earlier this year in the Journal of Gynecologic Surgery. These long-term data follow the impressive early clinical results in the SONATA pivotal trial where 95% of patients had a reduction in their bleeding symptoms with a 97% patient satisfaction rate at 12 months. A growing body of clinical evidence substantiating the significant patient benefits and long-term efficacy of Sonata includes 24 peer-reviewed publications to date, with three-year results for the SONATA FDA IDE Pivotal Trial expected to be published in 2020.

Scott Chudnoff, M.D., MSc, FACOG, Chair of the Department of Obstetrics and Gynecology, Stamford (CT) Health, performed several procedures as a trial investigator in the SONATA FDA IDE pivotal trial and performed the first case with the Sonata 2 System in the U.S. "We have always been looking to give women options that go beyond removing her entire uterus to alleviate the many painful and challenging symptoms caused by fibroids," said Dr. Chudnoff. "Now with the use of the Sonata technology, we can

perform a same-day procedure that not only avoids a hysterectomy, but also eliminates having to make any incision at all, so this really is a game-changer for women who suffer with fibroids.”

Gregory Shifrin, M.D., FACOG, Surgery of Tomorrow, Brooklyn, N.Y., has also performed several commercial cases of the Sonata 2 System in the U.S. “I find the Sonata technology and technique to be straightforward in treating a wide range of fibroid types and sizes,” Dr. Shifrin said. “This is an exciting new incision-free uterus preserving treatment option for my patients who want to resolve their symptoms but prefer to avoid traditional surgery.”

Attendees of the conference are encouraged to visit the Gynesonics exhibit (number 819) and to attend the following scientific presentations:

NOVEMBER 11, 2019

Oral Presentation • Laparoscopy • Room 109-110 11:00 AM - C.E. Miller, M.D., Transcervical Radiofrequency Ablation of Symptomatic Uterine Fibroids: 2-Year Results of the Sonata Pivotal Trial.

Virtual Poster • Laparoscopy • Station N - Improvement in 24-Month Health-Related Quality of Life and Work Productivity after Ultrasound-guided Transcervical, Intrauterine Radiofrequency Ablation of Uterine Fibroids in the Sonata Pivotal IDE Trial.

Virtual Poster • Laparoscopy • Station E - Term Delivery in an Infertile Patient after Transcervical Radiofrequency Fibroid Ablation and Assisted Reproductive Technology.

Virtual Poster • Basic Sci/Research/Edu • Station G - 12-Month Outcomes of the US Patient Cohort in the Sonata Pivotal IDE Trial of Transcervical Ablation of Uterine Fibroids.

NOVEMBER 12, 2019

Oral Presentation • Laparoscopy • Room 205-207 2:00 PM - D. Delvadia, D.O., The INSPIRE Comparative Cost Study: One-Year Medical Resource Utilization, and Payer Cost Analysis Associated with Hysterectomy and Myomectomy Compared to Sonography-Guided Transcervical Ablation for the Treatment of Uterine Fibroids.

Sponsored Educational Symposium • Room 212 5:30 PM - C.E. Miller, M.D.; K. Roy, M.D. & S. Chudnoff, M.D., Robotic-Assisted Hysterectomy is STILL Hysterectomy: It’s Time for Incisionless Transcervical Fibroid Ablation with the Sonata System.

Christopher M. Owens, Gynesonics President and CEO, noted that the global launch of the Sonata 2 System is initially focused on the U.S. and Europe. In the U.S., the Company has its first sales representatives in the field engaging gynecologists and establishing its first U.S. treatment centers. He also commented on the excitement of having the excellent 2-year long-term clinical outcomes data presented at the AAGL Congress, as the company continues to support the publication of additional clinical and health economic evidence supporting the technology.

“Based on the published evidence showing durable relief of symptoms and high rates of patient satisfaction, we believe Sonata is truly a breakthrough solution for physicians and patients,” Owens said. “The promising clinical results provided with the Sonata platform are rapidly gaining strong interest throughout the physician community as an innovative new treatment option for patients suffering from symptomatic uterine fibroids.”

About Sonata System

The new Sonata[®] 2 System, the next generation of Gynesonics’ technology platform, uses radiofrequency energy to ablate fibroids under intrauterine sonography guidance. The Sonata 2 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 new Sonata 2 System for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids. The Sonata 2 System is CE marked for distribution in the European Economic Area and FDA cleared for sale in 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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