



GYNESONICS ANNOUNCES RESULTS FROM PIVOTAL IDE TRIAL FOR INCISION FREE TREATMENT FOR UTERINE FIBROIDS

Results highlight robust Sonata System design and its potential to become a standard of care for fibroid treatment

Redwood City, CA – January 9, 2018 - Gynesonics, a women’s healthcare company focused on the development of minimally invasive solutions for symptomatic uterine fibroids, today announced the results from their pivotal IDE trial for the Sonata® system for the incision-free treatment of uterine fibroids. These results were recently submitted to FDA as a part of the 510(k) application supporting the clearance of the Sonata system in the U.S.

The Sonography-Guided Transcervical Fibroid Ablation (SONATA) trial is a prospective, longitudinal, multicenter trial evaluating the safety and effectiveness of the company’s investigational Sonata system in the treatment of women with fibroid related heavy menstrual bleeding (HMB). A total of 147 patients were enrolled at 22 centers in the U.S. and Mexico. The FDA specified co-primary endpoints were reduction of bleeding and freedom from surgical reintervention due to HMB, both at 12-month follow-up.

The highlights of the 12-month clinical outcomes include;

- 99% of trial patients were free from surgical reintervention for HMB
- 94% of patients had a reduction in bleeding, with 64% of patients achieving a $\geq 50\%$ reduction in bleeding
- 97% of patients were satisfied with the procedure and would likely recommend it to friends
- Most patients returned to normal activity the day after the procedure

Scott Chudnoff, Chief of OB/GYN at Stamford Hospital, Stamford CT a principal investigator in the SONATA trial, stated, “The actual results achieved in the SONATA trial far exceed the required thresholds established by the FDA for the co-primary end points of reduction in menstrual bleeding and freedom from surgical reintervention for bleeding. These results, along with the impressive levels of patient satisfaction and rapid return to normal activity achieved, clearly demonstrate the potential for Sonata as a first line treatment for symptomatic fibroids.”

“In light of the recent controversies in gynecologic surgery which are impacting access for women to existing minimally invasive fibroid treatment options, it is important that new innovations be made available. Sonata provides our patients with an incision-free transcervical treatment for most types and sizes of fibroids.” stated Charles E. Miller, MD, a SONATA investigator and recent past president of the American Association of Gynecologic Laparoscopists (AAGL). “The impressive patient outcomes achieved with the Sonata system demonstrate its potential to cause a paradigm shift away from more invasive surgical procedures in addressing this significant quality of life issue for women.”

“While these impressive results achieved with Sonata in this pivotal trial are an important milestone for women and physicians, it is the consistency of the clinical effect of our technology achieved when compared alongside the previously published FAST-EU trial that is truly noteworthy.” Chris Owens, President and CEO stated. “Considering these two prospective, multicenter trials were comprised of several disparate patient populations across two continents, and performed by a broad range of physician operators

across various healthcare delivery systems and clinical settings, the consistency of these results is remarkable. The reproducible results highlight the robustness of the Sonata platform design and its potential to become a new standard of care for fibroid treatment.”

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 avoid the peritoneal cavity.

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 the transcervical treatment of symptomatic uterine fibroids under intrauterine sonography guidance. The Sonata system is CE Marked and approved for sale in the European Union. Sonata system 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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