Gynesonics yesterday released 12 month results from the FDA investigational device exemption pivotal trial of its Sonata system intended for diagnostic intrauterine imaging and the transcervical treatment of symptomatic uterine fibroids.

Results from the trial were published in the journal *Obstetrics and Gynecology*, the Redwood City, Calif.-based company said.

The company’s flagship Sonata System is a uterus preserving, incision-free uterine fibroid treatment designed to treat fibroids transcervically with radiofrequency energy. The system combines both an intrauterine ultrasound system with a proprietary radiofrequency ablation device, Gynesonics added.

“It is exciting to have the final one-year results from the Sonata Pivotal IDE Trial published in *Obstetrics and Gynecology*. 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,” prez & CEO Christopher Owens said in prepared remarks.

In the 147-patient Sonata trial, investigators explored the use of the Sonata system at 21 outpatient sites in the U.S. and a single site in Mexico.

Data from the trial indicated that 99% of patients in the trial required no surgical reinterventions for heavy menstrual bleeding, with 97% reporting satisfaction with the treatment, the company said. Symptom improvement was reported by 96% of patients, with 95% reporting a reduction in menstrual bleeding. A total of 65% of patients in the trial reported at least a 50% reduction in menstrual bleeding.

The mean length of stay for patients, including procedure time, was reported as 2.5±1.2 hours, with 50% of patients returning to normal activity the next day. No device-related
adverse events were reported, Gynesonics said.

“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. This transcervical, uterine sparing approach avoids some of the risks of other treatment options, with minimal disruption in our patients’ lives,” study lead author Dr. Scott Chudnoff of Stamford Health said in a prepared statement.

“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,” board chair Karen Talmadge said in a press release.

Earlier this month, Gynesonics said that it closed a $75 million equity financing round to support its Sonata system.

The post Gynesonics touts 1-year pivotal IDE Sonata trial data appeared first on MassDevice.