GYNESONICS RECEIVES FDA CLEARANCE TO MARKET NEXT GENERATION SONATA® SYSTEM 2.1

EARLY LAUNCH IN EUROPE CONTRIBUTES TO SIGNIFICANT PROCEDURAL GROWTH

Redwood City, CA – May 28, 2020 – Gynesonics, a women's healthcare company focused on the development of minimally-invasive solutions for symptomatic uterine fibroids, announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its next generation Sonata® System 2.1 for Transcervical Fibroid Ablation (TFA). The Sonata technology platform integrates the first and only intrauterine ultrasound system with a proprietary advanced radiofrequency ablation device, providing an incision-free, uterus-preserving, transcervical treatment for symptomatic uterine fibroids. This next generation system incorporates additional features developed through close collaboration with experienced physicians and validated with rigorous testing, to improve usability and streamline workflow.

Having implemented the advanced system in January at Spital Oberengadin – Schweiz (Samedan, Switzerland), Dr. Ladina Christoffel has performed TFA using Sonata 2.1 in several fibroid cases since the restart of elective procedures at the facility at the end of April. "The significant improvement to the controls on the Sonata RFA handpiece enables our team to perform TFA with increased confidence and improved efficiency," said Dr. Christoffel. "We implemented Sonata TFA in our fibroid treatment offering in view of the impressive published patient outcomes. Based upon our experience, it has now become a first-line fibroid treatment."

The new advances in Sonata 2.1 include a new integrated treatment device design that enables all procedure steps to be performed on the sterile field and in the palm of the physician's hand; a smaller more ergonomic radio-frequency ablation handpiece with improved controls; and importantly provides a superior graphical user interface with new enhanced SMART technology procedural cues. In addition, the new design significantly improves the manufacturability of the device.

"FDA clearance for our advanced Sonata System 2.1 is a noteworthy achievement. The feedback from European physicians on the improved system design and performance during the early 2020 launch in Europe is positive. This contributed to a significant increase in procedure volumes," explained Christopher Owens, President and CEO of Gynesonics. "We look forward to introducing the technology to the U.S. market and others around the globe. This highlights Gynesonics' commitment to consistently deliver breakthrough advances for women's health, while continuing to demonstrate our clinical significance through published peer-reviewed evidence."

Regarding his experience with Sonata 2.1 at the Universitätsklinikum, Erlangen, Germany, Dr. Thomas Hildebrandt said, "The technology advancements included in Sonata 2.1 has improved and streamlined the procedure for treating fibroids. This gives us great confidence in recommending Sonata as a treatment option to our indicated patients."

With an estimated volume of more than one million annual global fibroid procedures, Gynesonics projects a greater than $4 billion global market opportunity for its Sonata System for the treatment of uterine fibroids, including a market opportunity of more than $1 billion in the U.S. alone. Sonata is the only technology that can treat up to 80% of fibroid types transcervically.

About Sonata System

The Sonata System uses radiofrequency energy to ablate fibroids under real time intrauterine sonography guidance. The Sonata System, including the SMART Guide, enables the operator to target fibroids and optimize ablations within them. The 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, incision-free, uterus-preserving, transcervical 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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