# GYNESONICS ANNOUNCES EARLY COMPLETION OF ENROLLMENT IN THE SONATA FDA CLINCIAL TRIAL FOR INCISION FREE TREATMENT OF SYMPTOMATIC UTERINE FIBROIDS

## *Company Expects to Submit Trial Results to FDA in Fourth Quarter of 2017*

Redwood City, CA – October 18, 2016 - Gynesonics, a women's healthcare company focused on the development of advanced incision-free solutions for treatment of benign uterine conditions, today announced the completion of enrollment in the SONATA Investigational Device Exemption (IDE) clinical trial, the pivotal trial of the Sonata® System, an incision-free, transcervical treatment for uterine fibroids that preserves the uterus. The clinical trial design was approved by the U.S Food and Drug Administration (FDA) in support of the Company's effort to achieve regulatory clearance for the Sonata System in the U.S.

The SONATA trial is a prospective, longitudinal, multi-center study evaluating the safety and effectiveness of the Company's investigational Sonata system in the treatment of women with heavy menstrual bleeding symptoms due to fibroids. A total of 147 patients were enrolled at 22 centers in the U.S. and Mexico. The pivotal trial's primary endpoints include the reduction of bleeding and incidence of surgical reintervention, both at 12 months after completion of the procedure.

Gynesonics pioneered the sonography-guided, uterus preserving, incision-free, transcervical treatment for symptomatic fibroids. The Sonata procedure involves the transcervical delivery of a single integrated handpiece combining intrauterine sonography guidance with radiofrequency ablation. Gynesonics is the only company in the world with an intrauterine ultrasound imaging and guidance technology platform.

"We are pleased to have completed the patient enrollment in the SONATA pivotal trial ahead of schedule," said Christopher M. Owens, President and CEO of Gynesonics. "There is a significant unmet need for an incision free, uterus-preserving option for the treatment of symptomatic uterine fibroids. We are optimistic and eager to fulfill the requirements of the trial with the goal of demonstrating the value of the Sonata system as a new option for women worldwide. We are already completing the required patient follow-up to support FDA clearance of the Sonata System."

Gynesonics expects to complete the required follow up and submit the results to FDA in a 510(k) submission during the fourth quarter of 2017.

**About Sonata System**

The Sonata System, the next generation of Gynesonics' fibroid treatment platform (the previous generation referred to as VizAblate), uses radiofrequency energy to ablate fibroids under intrauterine sonography guidance. The Sonata System, including the SMART Targeting Guide, enables the operator to target and ablate fibroids. 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 advanced incision-free solutions for treatment of benign uterine conditions. 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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