IRRAS Provides Update on FDA 510(k) Application of IRRA*flow*™

- Requests for certain technical clarifications and labeling definition -
- Financial targets remain unchanged -

San Diego, CA, USA, Munich, Germany and Stockholm, Sweden March 12, 2018 – IRRAS AB (NASDAQ Stockholm: IRRAS), a commercial-stage medical technology company focused on designing, developing, and commercializing innovative solutions for various brain pathologies, announced that it received a response from the U.S. Food and Drug Administration (FDA) regarding the company's 510(k) application for the approval of IRRA*flow*™, a CE-marked, fully integrated, closed-circuit medical device system that enables intelligent intracranial fluid management as well as accurate, real-time monitoring of intracranial pressure.

The FDA has asked for technical clarifications and updates of certain reports primarily relating to IRRAS' third party contractors' biocompatibility and sterility testing and software. Recommendations and clarifications of the proposed labeling have also been provided. The requests by the FDA are not unusual for a complex, software-driven surgical device like IRRA*flow*™ and will be addressed by IRRAS in a timely manner.

"The feedback from the FDA is both appreciated and addressable, and we believe this communication brings us closer to the approval of IRRA*flow*™ in the United States," said Kleanthis G. Xanthopoulos, Ph.D, President and CEO of IRRAS. "With the completion of our dialog on labeling and the technical clarifications with the FDA, we anticipate a potential launch of IRRA*flow*™ in the U.S. in the second half of 2018. We are working closely with the FDA to bring this innovative medical device to the U.S. market, offering patients, neurosurgeons, and hospitals an effective, intelligent solution to treat intracranial bleedings."

About IRRA*flow*™

IRRAS has developed and commercialized a revolutionary intelligent brain fluid management device stemming from its core IRRA*flow*™ technology that addresses the complications associated with the occurrence of intracranial bleedings. Currently available devices do not address the complications that lead to death because they do not prevent occlusion (or blockage) in the catheter during treatment and they do not accurately monitor intracranial pressure (ICP). IRRAS' products provide a transformative solution for stroke and hematoma patients with less invasiveness and more efficacy, through the integration of aspiration, targeted infusion and intracranial pressure monitoring in a single robust device.

About IRRAS AB

IRRAS (NASDAQ Stockholm: IRRAS), is a publicly-traded, commercial-stage medical technology company focused on designing, developing and commercializing innovative solutions for various brain pathologies, with a goal of dramatically improving patient outcomes, reducing patient-time in the intensive care unit and medical ward, and providing significant health economic benefits to hospitals and healthcare providers. The Company's initial product focus is on intracranial fluid management solutions that utilize its proprietary platform technology, IRRA*flow*™, which is a CE-marked, fully integrated, closed-circuit medical device system that enables intelligent intracranial fluid management as well as accurate, real-time monitoring of intracranial pressure.

With its unique product portfolio, protected by key intellectual property patents and patent applications, IRRAS is well-positioned to improve patient outcomes and establish a leadership position in the medical device market. IRRAS maintains its headquarters in Sweden with corporate offices in Germany and San Diego, CA, USA. For more information, please visit www.irras.com.

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This document is considered information that IRRAS is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure, through the agency of the contact person above, on March 12, 2018 at 08.00 a.m. (CET).