



## **IRRAS Provides Update on CE Mark Re-Certification of IRRAflow®**

- Company's Notified Body has requested clarifications and updates of certain previous older reports regarding IRRAflow device -
- US, other global markets, and worldwide regulatory submissions shall remain the main focus for the rest of the year -
- Previously communicated 2021 financial objectives remain -

Stockholm, April 24, 2019 – IRRAS AB (Nasdaq First North Premier: IRRAS), a commercial-stage medical technology company focused on developing and commercializing innovative solutions for neurocritical care, announced today that it received a response from G-MED, its designated European Notified Body, that requests clarifications and additional information regarding the company's CE Mark re-certification of IRRAflow Catheter.

G-MED has asked for additional technical clarifications and updates of certain previous older reports performed by the previous Swedish development partner. The requests are part of the routine review cycle and will be addressed by IRRAS in a timely manner.

"We finally received the feedback from G-MED after a lengthy period," said Kleanthis G. Xanthopoulos, Ph.D, President and CEO of IRRAS. "We believe that all of their comments are addressable. Having established a productive dialogue with the notified body, we now have a clear path forward, and we anticipate responding shortly to the list of questions. We will continue to work closely with the G-MED team to reintroduce this innovative medical device to the EU market, offering patients, neurosurgeons, and hospitals an effective, intelligent solution to treat intracranial bleeding. In the meantime, the launch of IRRAflow in the United States is on track since our 510(k) clearance last year, and our plans to open other global markets remain unchanged."

### **About IRRAS**

IRRAS AB (Nasdaq First North Premier: IRRAS) is a publicly-traded, commercial-stage medical technology company focused on developing and commercializing innovative solutions for brain surgery. The company's initial product, IRRAflow, is the world's first "irrigating ventricular drain." Its unique mechanism of action addresses the complications associated with the current methods of managing intracranial fluid by using a dual lumen catheter that combines active irrigation with ongoing fluid drainage. IRRAflow received FDA-clearance in July 2018.

Regularly during treatment, the IRRAflow catheter is automatically flushed to prevent common catheter occlusions from forming. Because IRRAflow is a completely closed system, it is designed to reduce the documented infection risk of these procedures. Additionally, IRRAflow incorporates

ICP monitoring and uses a proprietary software to regulate treatment based on desired pressure levels.

With its unique product portfolio, protected by property patents and patent applications, IRRAS is well positioned to establish a leadership position in the medical device market. IRRAS maintains its headquarters in Stockholm, Sweden, with corporate offices in Munich, Germany, and San Diego, California, USA. For more information, please visit [www.irras.com](http://www.irras.com).

IRRAS AB (publ) is listed on Nasdaq First North Premier. Wildeco is certified adviser of the company. Wildeco is reached at + 46 8 545 271 00 or at [info@wildeco.se](mailto:info@wildeco.se).

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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 April 24, 2019 at 08.00 a.m. (CET).