IRRAS Receives Renewed CE Mark for the IRRA*flow* Catheter

Approval completes the IRRAflow system's CE Mark requirements and permits product's relaunch in European Union

Stockholm, Sweden, December 19, 2019 – IRRAS, a global healthcare company with a comprehensive portfolio of innovative products for neurocritical care, announced today that it received CE Mark approval for its IRRA*flow*® catheter. This CE Mark complements the two CE Marks previously obtained for the IRRA*flow* system's tube set with digital pump and control unit, and allows IRRAS to once again commercially market the IRRA*flow* system in the European Union. The complete IRRAflow CNS System received approval for CE Mark today and will be ready for commercial launch in the EU.

IRRA*flow,* the company's initial commercial product, is a transformative medical device system that combines controlled irrigation with ongoing fluid drainage to better manage patients with intracranial bleedings. In April 2018, IRRAS received an updated ISO 13485:2016 certificate and updated CE Mark approvals for both the control unit and tube set with digital pump in the IRRA*flow* system, both of which are Class II products. The proprietary IRRA*flow* catheter, however, is a Class III product, and required more time to review.

"We are pleased to receive the final CE Mark for IRRA*flow* in Europe, which is a strategically important geography for IRRAS," said Kleanthis G. Xanthopoulos, Ph.D., President and CEO of IRRAS. "With this approval, we can now ramp up our marketing and sales efforts for the initiation of product sales in the key EU market."

"In my previous patient treatment experience with IRRA*flow*, I found the system's combination of irrigation and drainage to be a valuable tool in treating my critically ill patients with

intracranial bleeding and brain infections," said Dr. Behnam Rezai Jahromi, Neurosurgeon from Helsinki University Hospital in Helsinki, Finland. "Innovation in neurocritical care has been limited through the years, and I look forward to studying the potential impact of IRRA*flow* more closely in the future."

"Over the past year, we have seen many successful case outcomes and significant customer interest across a variety of neurosurgery procedures with IRRA*flow,* therefore, we are thrilled to be able to continue our expansion to Europe," said Will Martin, IRRAS' Chief Commercial Officer. Based on this early experience, we are confident that IRRA*flow* will continue to significantly improve patient outcomes and result in sustained sales growth."

About IRRAS

IRRAS AB is a global healthcare company focused on delivering innovative medical technologies to our customers and their patients. IRRAS designs, develops and commercializes products that improve patient outcomes and decrease the overall cost of care by addressing complications associated with current treatment methods in neurocritical care. IRRAS markets and sells its products to hospitals worldwide through its direct sales organizations in the U.S. and select European countries and a network of distribution partners in other markets.

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.

IRRAS AB (publ) is listed on Nasdaq First North Premier Growth Market (ticker: IRRAS). Redeye AB is certified adviser of the company with email certifiedadviser@redeye.se or phone +46 8 121 576 90.

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