



IRRAS Announces FDA Clearance of New 510(K) Filing to Expand the Time of Use of IRRAf^{low}®

Stockholm, November 21, 2019 – IRRAS, a global healthcare company with a comprehensive portfolio of innovative products for neurocritical care, announced today that the US FDA has cleared a new 510(K) for IRRAf^{low}. The application provided the FDA with supporting data demonstrating that extending the time of use of the product is safe and has the potential to be beneficial for patients.

IRRAf^{low} 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. IRRAf^{low} incorporates intracranial pressure or ICP monitoring and uses a proprietary software to regulate treatment based on desired pressure levels. IRRAS received initial clearance from the US FDA for IRRAf^{low} in July 2018.

"We are very pleased to have received this new clearance from the FDA. The extended time of use will further enhance the usability of the transformative IRRAf^{low} product for the benefit of neurocritical care patients. We are equally very pleased to continue to build a very good relationship with the FDA that has acted in an expeditious matter to award us this new 510(K) clearance" said Kleanthis G. Xanthopoulos, Ph.D., Chief Executive Officer of IRRAS.

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 currently markets and sells its IRRAf^{low} and Hummingbird product lines 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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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 November 21, 2019 at 8:30 p.m. (CET).