# IRADIMED CORPORATION Provides Regulatory Update

Provides regulatory update on the status of its MRI compatible IV infusion pump

WINTER SPRINGS, Fla., June 09, 2016 — IRADIMED CORPORATION (NASDAQ:IRMD)

CURRENT NEWS

IRADIMED CORPORATION has received the FDA's written response to our appeal of their determination that our 510(k) application for the MRidium 3860+ MRI compatible IV infusion pump was not substantially equivalent to its predicate device. The FDA has now reinstated the subject 510(k) and we have been granted another 180 days to make certain specified changes to several messages displayed by the infusion pump. Specifically, changes to messages the infusion pump displays to clarify whether the Dose Error Reduction System (DERS) is active or inactive and to better describe the over and under range indications. Further, the FDA's response also stated that no additional human factors usability testing is required.

ACTION PLAN

The Company intends to revise the messages identified by the FDA, consistent with the agency's explicit recommendations, and submit the required additional information within the 180 day period as prescribed in the FDA's response.

"We are very pleased with this outcome and now have a clear path to fully resolving this matter. In the coming weeks, we will begin taking the necessary steps of revising the specific messages identified by the agency and revalidate the pump's software. We anticipate completing this process well before the end of the 180 day period. We are also very pleased with FDA's conclusion that no additional human factors usability testing is required," said Roger Susi, President and Chief Executive Officer.

BACKGROUND

In September 2014 we were required by the FDA to stop selling our MRI compatible infusion pump systems and submit a new 510(k) application because of the addition of the DERS feature. In response we halted domestic shipments of our infusion pumps and the DERS feature. In November 2014 we filed the requested 510(k) and in December 2014, with the FDA's consent, we resumed shipping the infusion pump product without the DERS feature. In January 2015, again with the FDA's consent, we resumed shipping the infusion pump with the DERS feature. In March 2016, we received a letter stating that our infusion pump was not substantially equivalent to its predicate device. Their finding was based upon a lack of human factors data supportive of certain aspects of exiting the DERS feature. The FDA stated that we may resubmit a new 510(k) application with data showing our infusion pump is substantially equivalent to similar devices in the market. In April 2016, we appealed the FDA's determination to a higher level within the agency and on May 2, 2016, met with the agency to discuss the appeal. While the FDA's response to our appeal did not withdraw their

consent to our continued marketing of the infusion pump with the DERS system, we cannot guarantee that the FDA will not change its position on allowing the continued marketing of our MRI compatible infusion pump systems with DERS.

**About IRADIMED CORPORATION**

IRADIMED CORPORATION is the only known provider of non-magnetic intravenous (IV) infusion pump systems that are specifically designed to be safe for use during magnetic resonance imaging (MRI) procedures. We were the first to develop an infusion delivery system that largely eliminates many of the dangers and problems present during MRI procedures. Standard infusion pumps contain magnetic and electronic components which can create radio frequency (RF) interference and are dangerous to operate in the presence of the powerful magnet that drives an MRI system. Our patented MRidium MRI compatible IV infusion pump system has been designed with a non-magnetic ultrasonic motor, uniquely-designed non-ferrous parts and other special features in order to safely and predictably deliver anesthesia and other IV fluids during various MRI procedures. Our pump solution provides a seamless approach that enables accurate, safe and dependable fluid delivery before, during and after an MRI scan, which is important to critically-ill patients who cannot be removed from their vital medications, and children and infants who must generally be sedated in order to remain immobile during an MRI scan.

MRidium is a trademark of IRADIMED CORPORATION.

For more information please visit www.iradimed.com.

**Forward-Looking Statements**

This press release contains forward-looking statements as defined in the Private Securities Litigation Act of 1995, particularly statements regarding our expectations, beliefs, plans, intentions, future operations, financial condition and prospects, and business strategies. These statements relate to future events or our future financial performance or condition and involve unknown risks, uncertainties and other factors that could cause our actual results, level of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. The risks and uncertainties referred to above include, but are not limited to, risks associated with the Company’s ability to receive clearance of its 510(k) submission, additional actions by or requests from the FDA (including a request to cease domestic distribution of products) and unanticipated costs or delays associated with resolution of these matters; our reliance on a single product; unexpected costs, expenses and diversion of management attention resulting from the FDA warning letter; potential disruptions in our limited supply chain for our products; a reduction in international distribution as we focus on fulfilling orders from our U.S. backlog; actions of the FDA or other regulatory bodies that could delay, limit or suspend product development, manufacturing or sales; the effect of recalls, patient adverse events or deaths on our

business; difficulties or delays in the development, production, manufacturing and marketing of new or existing products and services; changes in laws and regulations or in the interpretation or application of laws or regulations.

Further information on these and other factors that could affect the Company's financial results is included in filings we make with the Securities and Exchange Commission from time to time. All forward-looking statements are based on information available to us on the date hereof, and we assume no obligation to update forward-looking statements.

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