ZOLL Receives Shonin Approval from Japan to Market Intravascular Temperature Management Technology

The Associated Press

CHELMSFORD, Mass.--(BUSINESS WIRE)--Feb 6, 2013--ZOLL Medical Corporation, a manufacturer of medical devices and related software solutions, has received Shonin approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) to enter the Japanese market with its Intravascular Temperature Management (IVTM ™) technology—the first intravascular temperature management system to receive Shonin approval in Japan.

ZOLL Thermogard XP (Photo: Business Wire) ZOLL's IVTM solution will be marketed and sold by Asahi Kasei ZOLL Medical (AZM), a ZOLL company established in August 2012 to pursue the regulatory approval, sale, and marketing of ZOLL products in Japan.

ZOLL's IVTM technology was approved in Japan for fever control in neurologically injured patients. The intravascular system offers superior temperature control when compared to other cooling methods. Fever is commonly found in both neurologically injured and neurosurgical patients and is associated with poor outcomes. 1 Specifically, moderate fever has been reported to almost double patient mortality, while extremely high fever can triple mortality. 2 Management of the body's core temperature is key to proper neurological function, especially for patients in neurointensive care.

ZOLL's IVTM system provides cooling and warming through a balloon catheter inserted into the venous system. This provides better control of the core body temperature over surface methods by directly cooling or warming the patient's blood as it flows through the body. This catheter is connected to the Thermogard XP ® console, which circulates cold saline solution inside the catheter. Since the saline flows only within the catheter, no fluid is infused into the patient. ZOLL offers a variety of triple-lumen catheters with placement options to handle specific patient challenges. The ZOLL IVTM system is efficient, precise, and easy to use, and frees up clinical staff to attend to other patient needs.

"We are very excited to begin commercialization of IVTM in Japan and to continue to offer innovative technologies and devices for critical care to this high-growth market," said James Palazzolo, President of ZOLL Sunnyvale (Calif.) operations. "We are now preparing for a clinical trial for therapeutic hypothermia following cardiopulmonary resuscitation, a treatment having a Class 1 recommendation 3 from both the American Heart Association (AHA) and the Japan Resuscitation Council (JRC).

Other ZOLL products sold in Japan: The AED Plus ® —an automated external

defibrillator (AED) that incorporates ZOLL's real-time CPR feedback technology, Real CPR Help ®, which assists rescuers in delivering high-quality CPR to sudden cardiac arrest victims. The AED Plus is the only AED with CPR feedback capability available in the Japanese market. The AutoPulse ® Non-invasive Cardiac Support Pump —a unique mechanical CPR system that employs a load-distributing band to provide consistent, uninterrupted, high-quality chest compressions. Pocket CPR ® —an easy-to-use portable device that uses Real CPR Help to provide real-time audible and visual feedback on the depth and rate of chest compressions, guiding rescuers to meet current guidelines. About ZOLL Medical Corporation ZOLL Medical Corporation, an Asahi Kasei Group company, develops and markets medical devices and software solutions that help advance emergency care and save lives, while increasing clinical and operational efficiencies. With products for defibrillation and monitoring, circulation and CPR feedback, data management, fluid resuscitation, and therapeutic temperature management, ZOLL provides a comprehensive set of technologies that help clinicians, EMS and fire professionals, and lay rescuers treat victims needing resuscitation and critical care. For more information, visit www.zoll.com.

About Asahi Kasei The Asahi Kasei Group is a diversified group of companies led by holding company Asahi Kasei Corp., with operations in the chemicals and fibers, homes and construction materials, electronics, and health care business sectors. Its health care operations include devices and systems for critical care, dialysis, therapeutic apheresis, transfusion, and manufacture of biotherapeutics, as well as pharmaceuticals, diagnostic reagents, and nutritional products. With more than 25,000 employees around the world, the Asahi Kasei Group serves customers in more than 100 countries. For more information, visit www.asahi-kasei.co.jp/asahi/en/.

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1 Diringer MN, et al. Crit Care Med (2004) 32, 2:559–564.

2 Diringer MN, et al. Crit Care Med (2004) 32, 7:1489–1495.

3 2010 AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care and JRC 2010 Guidelines. Class I: Procedure/treatment should be performed/administered, Class IIa: It is reasonable to perform procedure/administer treatment, Class IIb: Procedure/treatment may be considered, Class III: Procedure/treatment should not be performed/administered since it is not helpful and may be harmful.

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