Abbott Announces CE Mark And First Use Of The World's First Smartphone Compatible Insertable Cardiac Monitor

-The new Confirm Rx™ ICM automatically captures vital cardiac information and relays data to physicians via the myMerlin™ mobile app enabling remote monitoring of irregular heart rhythms

ABBOTT PARK, Ill., May 8, 2017 /PRNewswire/ -- Abbott (NYSE: ABT) today announced CE Mark and first use of the new Confirm Rx™ Insertable Cardiac Monitor (ICM), the world's first smartphone compatible ICM that will help physicians identify difficult to detect cardiac arrhythmias, including atrial fibrillation (AF), to help guide therapy. Since CE Mark approval, adoption of the device has been strong and implants have occurred in 10 countries across Europe. The Confirm Rx ICM is designed to continuously monitor a patient's heart rhythm and proactively transmit information via the myMerlin™ mobile app, allowing physicians to follow their patients remotely and accurately diagnose arrhythmias.

With the launch of the Confirm Rx ICM in European CE Mark countries, Abbott has established a new paradigm in the connectivity of cardiac devices by incorporating wireless technology, which allows the ICM to communicate directly and securely to the app downloaded onto a patient's smartphone. Traditional remote monitoring has required bulky handheld or bedside transmitters, which limit patient mobility. The new interactive myMerlin mobile app replaces these passive transmitters and empowers patients to participate in their own care.

In addition to patient convenience, the device is slimmer than currently available ICMs. The Confirm Rx ICM also offers intuitive one-touch indication-based programming, and remote monitoring via the Merlin.net™ Patient Care Network, making the technology convenient for clinicians involved in procedure and follow up.

"The Confirm Rx ICM device will be an important tool for diagnosing patients with suspected arrhythmias, such as those who have experienced fainting or palpitations," said Georg Nölker, M.D., head of electrophysiology at the Herz-und Diabeteszentrum NRW, Ruhr-University of Bad Oeynhausen, Germany. Dr. Nölker was one of the first physicians to implant the Confirm Rx ICM after it received CE Mark. "The simple insertion procedure and small device size make this technology convenient for both patients and providers. Patients can record symptoms directly on their smartphone without the need for a bedside transmitter or separate activator."

Christopher Piorkowski, M.D., head of the Department of Electrophysiology at the University of Dresden Heart Center in Dresden, Germany, and one of the first implanters, added: "The Confirm Rx ICM will be particularly useful in monitoring for atrial fibrillation in my patients with paroxysmal AF, following AF ablation and with stroke of an unknown cause. It allows an objective way to quantify AF events to guide treatment decisions. The smartphone compatibility engages patients and allows better compliance to remote monitoring through a simple and intuitive user interface. This allows clinic staff to reduce follow-up burden and focus on reviewing transmitted data for AF."

The myMerlin mobile app, available in over 35 languages, makes it easy for patients to stay connected to their physicians. Patients can record their symptoms on their own smartphone and specify events such as fainting or if they experience a fast heart rate. Patients can also confirm their data was transmitted to their physician and get automatic alerts when they have missed a scheduled transmission, saving the clinic from having to follow up with the patient. The device also offers secure transmission of patient data. Recently, Abbott's Merlin.net Patient Care Network received one of the medical device industry's first Service Organization Control certifications (SOC2 certification), further confirming the safety and security of the company's remote monitoring network.

"Incorporating wireless technology directly into our devices enhances the quality of remote monitoring and patient compliance," said Mark D. Carlson, M.D., chief medical officer of Abbott's cardiac arrhythmias and neuromodulation businesses. "The Confirm Rx ICM addresses a broad range of indications, such as syncope, palpitations and atrial fibrillation. The technology has been designed with robust data privacy and security measures to ensure peace of mind for both patients and providers."

Currently the Confirm Rx ICM is available in select countries inEurope, with full European release expected during the second quarter of 2017. The device is currently under review by the U.S. Food and Drug Administration. The estimated 2017 worldwide insertable cardiac monitor market is approximately $800 million and is growing by more than $100 million a year.

About Abbott:
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