Abbott Receives CE Mark For Its Groundbreaking Assert-IQ™ Insertable Cardiac Monitor, Expanding Availability Of Long-Term Monitoring For Irregular Heart Rhythms

- Assert-IQ offers the world's longest battery life‡ for a Bluetooth® enabled ICM
- A new addition to Abbott's portfolio of connected health devices, the Assert-IQ ICM helps doctors monitor people's heart rhythms remotely for up to six years
- Having pioneered the world's first Bluetooth enabled ICM, Abbott is demonstrating its leadership in innovative, connected health technologies with the introduction of Assert-IQ ICM

ABBOTT PARK, Ill., Mar. 25, 2024 — Abbott today announced it has received CE Mark in Europe for its Assert-IQ™ insertable cardiac monitor (ICM), offering physicians a new option for diagnostic evaluation and long-term monitoring of people experiencing abnormal heartbeats. Assert-IQ ICM is a new addition to Abbott's growing portfolio of connected health devices. It can detect even hard-to-spot irregularities with heartbeats and help physicians determine the best treatment course.

More than 33.5 million people globally have atrial fibrillation,[1] the most common heart arrhythmia, and its prevalence is expected to increase over the next 30 years.[2] Arrhythmias, or irregular heartbeats, can be fleeting, making them difficult to diagnose. Now, with a minimally invasive procedure, physicians can insert the small, thin Assert-IQ ICM under the skin of the chest to monitor a person's heart continuously and detect arrhythmias, which can lead to symptoms such as fainting and shortness of breath. After insertion, people can go about their daily lives while the ICM continuously monitors their heart.

Using Bluetooth technology, Abbott's Assert-IQ ICM is designed to connect to a transmitter —usually the person's own cell phone — where it checks heart rhythms every 20 seconds, transmitting important findings in virtually real time to their clinic's portal. Assert-IQ offers the world's longest battery life‡ for a Bluetooth enabled ICM.

While many commercially available ICMs monitor a person's heart rhythm for a few years, Assert-IQ has two options, one with a battery life of at least three years and another with at least six years. The three-year option may be preferred for more traditional monitoring, such as diagnosing fainting or heart palpitations, or detections of abnormal heart rhythms, while the six-year option is designed for longer-term monitoring for those at risk of developing arrhythmias. Both options have advanced algorithms available to detect irregular heartbeats and provide clinically actionable data. Improved algorithms in Assert-IQ ICM reduce the data burden and increase the accuracy of the device, ultimately improving physician workflow and efficiency.

"As the prevalence of abnormal heart rhythms rise, physicians increasingly rely on ICM technology to diagnosis various heart conditions," said Leonard Ganz, M.D., divisional vice president of medical affairs and chief medical officer of Abbott's cardiac rhythm management business. "Introducing Assert-IQ in Europe will expand access to transformative benefits of long-term monitoring and more clinically relevant information, and allow care providers to make clinical decisions faster and with more precision."

Having pioneered the introduction of the world's first Bluetooth®-enabled ICM, Abbott is leading innovation once more in arrhythmia management with Assert-IQ ICM. The latest device provides consistent monitoring for abnormal heart rhythms while offering tools designed to improve data management and workflow.

"Assert-IQ is the next generation of implantable cardiac monitors, providing physicians with actionable data and new patient insights," said Professor Paolo Della Bella, M.D., head of the arrhythmia department at IRCCS San Raffaele Scientific Institute in Italy. "The real-time data, advanced algorithms and diagnostic accuracy empower physicians to deliver more personalized and effective care. For those with abnormal heart rhythms, Assert-IQ ICM provides peace of mind and the freedom to live their lives with confidence."

For important safety information on Assert-IQ ICM, visit: https://bit.ly/3OoJMjE

About Abbott:
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals, and branded generic medicines. Our 114,000 colleagues serve people in more than 160 countries.

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[1] Chugh SS, Havmoeller R, Narayanan K, et al. Worldwide Epidemiology of Atrial Fibrillation: a Global Burden of Disease 2010 Study. Circulation. 2014;129(8):837-847. doi:10.1161/CIRCULATIONAHA.113.005119

[2] Lippi G, Sanchis-Gomar F, Cervellin G. Global epidemiology of atrial fibrillation: An increasing epidemic and public health challenge [published correction appears in Int J Stroke. 2020 Jan 28;:1747493020905964]. Int J Stroke. 2021;16(2):217-221. doi:10.1177/1747493019897870

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications for Use: The Assert-IQ™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms that may be cardiac-related such as: dizziness, palpitations, chest pain, syncope, and shortness of

breath, as well as patients who are at risk for cardiac arrhythmias such as bradycardia, tachycardia, and sinus pauses. The Assert-IQ ICM is also indicated for patients who have been previously diagnosed with atrial fibrillation (AF) or who are susceptible to developing AF. The Assert-IQ ICM is intended to be inserted subcutaneously in the left pectoral region, also described as the left anterior chest wall. The Assert-IQ ICM has not been specifically tested for pediatric use.

Intended Use: The Assert-IQ ICM is intended to help physicians and clinicians monitor, diagnose and document the heart rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms by detecting arrhythmias and transmitting data for review.

Contraindications: There are no known contraindications for the insertion of the Assert-IQ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

Potential Adverse Events: Possible adverse events (in alphabetical order) associated with the device, include the following: allergic reaction, bleeding, chronic nerve damage, erosion, excessive fibrotic tissue growth, extrusion, formation of hematomas or cysts, infection, keloid formation and migration.

Refer to the User's Manual for detailed indications for use, contraindications, warnings, precautions and potential adverse events.

An Abbott mobile transmitter is available for patients without their own compatible mobile device.

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