Abbott Receives FDA Approval For New Heart Rhythm Devices Featuring Bluetooth Connectivity And Continuous Remote Monitoring

- Next-generation Gallant™ implantable cardioverter defibrillator family of devices offers Bluetooth® capability for a more meaningful connection between patients and their doctors

- Gallant ICD and CRT-D devices feature a patient-preferred design without compromising on battery longevity and compatibility with magnetic resonance imaging (MRI)

ABBOTT PARK, Ill., July 6, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the U.S. Food and Drug Administration (FDA) has approved the company's next-generation Gallant™ implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) devices. The devices bring new benefits to patients with heart rhythm disorders, including a patient-preferred design without compromising battery longevity and MRI compatibility. In addition, the new devices offer Bluetooth technology and a new patient smartphone app for improved remote monitoring, allowing for increased patient/physician engagement and streamlined communications.

It is estimated that as many as 6.1 million people inthe United States battle cardiac arrhythmias, or abnormal heart rhythms,[1] and ICDs are used to help reduce the risks of life-threatening arrhythmias. For patients with heart failure or in situations when the heart's chambers beat out of sync, CRT-Ds can be used to restore the heart's natural pattern of beating.

"We are focused on developing and delivering life-changing technologies that impact patient care in a meaningful way," said Randel Woodgrift, senior vice president, Cardiac Rhythm Management, Abbott. "The Gallant devices are the latest example of how Abbott is driving innovation to meet changing healthcare needs and helping to improve connectivity and engagement between patients and their doctors."

The new Gallant system pairs with Abbott's secure myMerlinPulse™, an iOS- and Android™- compatible mobile smartphone app that helps streamline communication between doctors and their patients. The app provides people with access to data, device performance, and transmission history, which helps them take an active role in their healthcare. Through the myMerlinPulse app, physicians can continuously monitor their patients remotely allowing for identification of asymptomatic episodes as well as patient-triggered transmissions, which can lead to earlier intervention and reduce clinical burden.

"The ability for patients to stay connected to their doctors via their implanted device and a smartphone app has the potential to change how healthcare providers and patients communicate with each other," said Raffaele Corbisiero, M.D., FACC, director of electrophysiology and pacing at Deborah Heart and Lung Center, Browns Mills, N.J. "The FDA's approval of Abbott's Gallant devices enables doctors to provide a more collaborative approach to treatment plans and the increased bond between a patient and provider will lead to better outcomes for all."

The Gallant system received CE Mark for use across Europe earlier this year.

For important safety information, please visit abbott.com.

Note: Bluetooth is a registered trademark of Bluetooth SIG, Inc. iOS is a trademark of Cisco Technology, Inc. Android is a trademark of Google LLC.

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 107,000 colleagues serve people in more than 160 countries.

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[1] Centers for Disease Control and Prevent, Atrial Fibrillation. https://www.cdc.gov/heartdisease/atrial_fibrillation.htm. Accessed June 3, 2020.

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