Abbott Secures FDA Approval For MRI-Compatibility For The Company's Ellipse™ ICD

- FDA approval of MR-conditional labeling for the Ellipse™ ICD family adds another patient-centric benefit to a device designed to optimize the treatment of abnormally fast heart rhythms

ABBOTT PARK, Ill., Sept. 22, 2017 /PRNewswire/ -- Abbott (NYSE: ABT) today announced U.S. Food and Drug Administration (FDA) approval for magnetic resonance (MR)-conditional labeling for one of Abbott's most widely-used implantable cardioverter defibrillators (ICD) and associated high voltage leads. The approval of MR-conditional labeling for the Ellipse™ ICD with the Tendril MRI pacing lead and Durata and Optisure high voltage leads adds another patient-centric benefit to the device and will help further improve access for patients suffering from abnormally fast heart rhythms who need an ICD and who may need an MRI scan in the future.

When electrical signals in the lower chamber of the heart fire erratically, the heart can beat abnormally fast – a condition known as *ventricular tachycardia or tachyarrhythmia* – which in turn leaves the heart unable to pump blood effectively. In addition to symptoms such as light-headedness, chest pains and shortness of breath, over time the condition can lead to a potentially life-threatening arrhythmia, heart failure, stroke or cardiac arrest. Abbott's ICD devices can monitor for and detect abnormally fast heart rhythms and deliver electricity to the heart to restore the heart's natural rhythm.

The new MR-conditional labeling for the Ellipse ICD allows patients to undergo an MRI scan if needed. In addition, patients previously implanted with an Ellipse device and Durata or Optisure leads can now undergo MRI scans.

"When you consider the number of patients each year who rely on the lifesaving treatment delivered by an ICD device, it is critical to continually innovate to provide new benefits to people battling complex arrhythmias and other cardiac conditions," said Mark Carlson, M.D., chief medical officer for Abbott's Cardiac Arrhythmias and Heart Failure division. "By expanding our portfolio of MRI compatible devices, we're adding another benefit onto an ICD device that was designed hand-in-hand with physicians to optimize therapy for patients."

The smaller shape and size of Ellipse ICD helps improve patient comfort once implanted and Abbott engineered the device with features designed to optimize ICD therapy and improve patient safety. The features, known as Abbott's TailoredTherapy™ approach, include:

- **DeFT Response™ Technology:** Allows physicians to adapt how therapy is delivered by the Ellipse ICD to ensure each patient receives therapy based on their unique need. The feature also helps ensure successful therapy delivery without the need to deliver an initial shock at the time of implant.
- **SecureSense™**: Abbott's SecureSense algorithm offers an additional level of protection for patients by providing proper sensing within the heart even in the presence of external interference (known as "*lead noise*") to safeguard against unnecessary therapy being delivered to the patient.
- **DynamicTx™**: With Abbott's DynamicTx algorithm, physicians can be confident that their patient's devices are consistently evaluating the condition of the lead and adapting the path of the electrical impulse to deliver appropriate therapy.

As a further benefit, all therapy and other data captured by the Ellipse ICD can be directly, securely and wirelessly sent to a patient's physician through the Merlin.net™ Patient Care Network. This communication allows physicians to remotely monitor their patient's therapy and assess any need for intervention.

The latest labeling ensuring Abbott's Ellipse ICD is MRI ready follows approval earlier this year of Abbott's Assurity MRI pacemaker and prior MR-conditional labeling approvals in Europe, allowing Abbott to further build its portfolio of MRI ready products. The company continues to work with regulatory agencies around the world to secure approval for MR-conditional labeling for additional commonly-implanted pacemakers, implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices.

ABOUT ICD TECHNOLOGY
An ICD is an advanced high voltage implantable device that treats potentially lethal, abnormally fast heart rhythms, which often lead to sudden cardiac death. Each year, more 300,000 ICDs are implanted worldwide.

A lead is a thin insulated wire that is placed through the vein as part of a pacemaker or ICD implantation procedure. The tip of the lead is attached to the heart tissue, and the other end connects to the ICD. A lead carries electrical impulses from the ICD to the heart and transmits information from the heart back to the implanted device.

Some ICDs are referred to as "MR-conditional" or "MRI ready." This means that they are designed to allow patients to safely undergo an MRI scan under certain conditions. By having an ICD implanted that allows MRI scans, patients have access to an imaging modality that offers important information and highly detailed images to medical professionals when making a patient diagnosis.

For more information about Abbott's focus on cardiac rhythm management, visitwww.sjm.com/en/patients/arrhythmias.

About Abbott:
At Abbott, we're committed to helping people live their best possible life through the power of health. For more than 125 years,

we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 94,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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