Press Release

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Cardiac Rhythm Management

First Implants of Lumax 540 Series

BIOTRONIK Announces First Implants of Lumax 540 Series - the Only Cardiac Devices with Long-Lasting Therapies and Home Monitoring® Technology for Improved Patient Care.

BERLIN, Germany, April 9, 2008 - After receiving CE Mark approval last week, BIOTRONIK GmbH & Co. KG, the pioneer in wireless remote monitoring technology for patients with cardiac devices, announced today the world's first implantations of the new Lumax 540 implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) devices in 11 hospitals in seven countries.

The new Lumax 540 platform is part of BIOTRONIK´s most technologically advanced tachycardia product portfolio, providing extended therapy options- for individualized patient device programming as well as BIOTRONIK Home Monitoring® technology for wireless remote monitoring of patient's cardiovascular status. A comprehensive set of diagnostic capabilities are further technical advancements included on the Lumax 540 devices to help physicians identify clinically relevant atrial fibrillation and early detection of worsening heart failure status.

Due to the advantage of developing its own industry-leading batteries and years of engineering research, BIOTRONIK has achieved longevity for the Lumax 540 platform which extends the life of the devices up to 10 years. "Patients could benefit from this extended battery longevity due to the need for fewer device replacements over time, thereby improving quality of life and at the same time helping to reduce healthcare costs", commented Marlou Janssen, Vice President Global Marketing and Sales, Cardiac Rhythm Management, BIOTRONIK. "In fact, we are so confident in the advantages of our new battery technology, BIOTRONIK will further extend our warranty for our Lumax 540 ICDs."

Professor Dr. Josep Brugada Terradellas, Hospital Clínic i Provincial de Barcelona, Barcelona, Spain, President of the European Heart Rhythm Association, implanted one of the first Lumax 540 HF-T and emphasized, "the future focus of heart failure therapy is to shift our effort toward preventing the patient from deteriorating rather than treating advanced disease states. Lumax 540 provides the technology that takes the first step in this direction. Furthermore, the device provides the state-of-the-art therapy that modern implant clinics require."

In response to the increasing number of implanted cardiac devices, technologies which ease complex programming, enable remote monitoring and simplify patient follow-up have become increasingly important. Therefore, Lumax 540 series was specifically designed to improve effective tachyarrhythmia programming and facilitate patient follow-

up with an innovative set of functionalities that help physicians efficiently automate the in-office follow-up of patients with BIOTRONIK devices.
Furthermore, in combination with BIOTRONIK Home Monitoring® technology, the new Lumax 540 platform sets the standard for remote monitoring of patients with cardiac devices. This exclusive technology enables continuous automatic daily data transmissions of the patient's cardiovascular status and clinically significant events to the physician from anywhere in the world using an antenna integrated in the Lumax 540 devices and the mobile telephone network.

"Lumax 540 gives me the opportunity to continuously check my patients using the wireless BIOTRONIK Home Monitoring solutions, said Professor Dr. Werner Jung, Schwarzwald-Baar Klinikum, Villingen-Schwenningen, Germany. Welcoming the enhanced functionality of the new devices, Professor Dr. Jung also added: "Clinically important changes in patient status are brought to our immediate attention with Home Monitoring®. Despite the growing number of cardiac device patients visiting our clinic, this new cardiac device with comprehensive telemonitoring capabilities allows me to focus more on those patients who need urgent care."

Lumax 540 devices offer the unique combination of advanced tachycardia therapy management, diagnostic capabilities and remote monitoring technologies which support physicians in creating efficient care pathways for their patients with cardiac devices and further improve patient care.

"We already remotely monitor all of our BIOTRONIK ICD patients; however, now with Lumax 540 ICD/CRT-D devices and BIOTRONIK Home Monitoring®, we can continuously monitor virtually all clinically significant device-related parameters for enhanced patient care," confirmed Professor Dr. Luc Jordaens, Erasmus Medical Centre, Rotterdam, The Netherlands, who also implanted one of the first Lumax 540 devices this morning. "Furthermore, Lumax 540 devices together with Home Monitoring® enable us to optimize our resources while providing improved patient management."

Acknowledgment

BIOTRONIK would like to extend its sincere thanks to all the physicians that participated in first worldwide implantations of the Lumax 540 series ICD and CRT-D cardiac devices:

Professor Dr. med. Angelo Auricchio, Cardiocentro Ticino, Lugano, Switzerland
Professor Jean-Claude Deharo, CHU La Timone Marseille, Marseille, France
Dr. med. Anja Dorszewski, Herz- und Diabeteszentrum NRW, Bad Oeynhausen, Germany
Professor Dr. Luc Jordaens, Erasmus Medical Centre, Rotterdam, The Netherlands
Professor Dr. med. Werner Jung, Schwarzwald-Baar Klinikum, Villingen-Schwenningen, Germany
Professor Antonis Manolis, Evangelismos General Hospital, Athens, Greece
Professor Dr. med. Tiziano Moccetti, Cardiocentro Ticino, Lugano, Switzerland
Dr. med. Dirk Müller, Charité Berlin Kampus UKBF, Berlin, Germany
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Dr. med. Alexander Schirdewan, Charité Berlin Kampus UKBF, Berlin, Germany
Dr. Raed Sweidan, King Fahad Armed Forces Hospital, Jeddah, Saudi Arabia
Dr. Professor Josep Brugada Terradellas, Hospital Clínic i Provincial de Barcelona, Barcelona, Spain
Dr. med. Jürgen Vogt, Herz- und Diabeteszentrum NRW, Bad Oeynhausen, Germany

Dr. med. Thomas Zerm, Asklepios St.Georg Hospital, Hamburg, Germany

About ICD Therapy and Cardiac Resynchronization Therapy (CRT)

Sudden cardiac death is caused by an electrical storm in the heart, which drastically reduces the blood flow, causing death within minutes. The ICD provides a very reliable and instant therapy during such events by delivering a high-energy electrical impulse to the heart which resets the electrical activity in the heart, so that it can start to beat regularly again.
Additionally, heart failure patients often suffer from asynchronous contractions of the heart chambers leading to insufficient pumping and reduced cardiac output, resulting in a significant negative impact on the patient's chances of survival and quality of life. A CRT device stimulates both ventricles of the heart to re-establish synchronous contraction and thus considerably improves the patient's prognosis.

About BIOTRONIK GmbH & Co. KG

As one of the worlds leading cardiovascular medical device companies, with several million implanted devices, BIOTRONIK is present in all world markets. Known for having its finger on the pulse of the medical community, BIOTRONIK helps to assess the challenges physicians face, and provides the best solutions, be they cardiac implants, minimal invasive devices or other products and services ranging from diagnosis to electrotherapy and vascular intervention or therapy management. Quality, innovation, and reliability define BIOTRONIK and its growing success, and deliver confidence and peace of mind to physicians and their patients worldwide.

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