Media Contact:
Rebecca Ratcliffe
Tel: +44 7825 378 894
Rratclif@its.jnj.com

For Immediate Release

Biosense Webster Receives CE Mark Approval for QDOT MICRO®, The World's First Very High Power, Short Duration Ablation Catheter

QDOT MICRO reduces procedural time by almost 90 minutes and lowers procedure cost without compromising safety[1]

IRVINE, CA – August 13, 2020 – Johnson & Johnson Medical Devices Companies* today announced European CE mark approval of Biosense Webster, Inc.'s QDOT MICRO radiofrequency (RF) ablation catheter, a next-generation catheter that has demonstrated the ability to reduce total procedure time.† Reductions in procedure time are made possible by efficient and consistent lesion creation in conjunction with a simplified workflow. Using the very high power QMODE+™, it is the first catheter to enable ablation at up to 90 watts of RF power for up to four seconds in a temperature-controlled ablation mode, significantly improving ablation efficiency without compromising safety.[1] QDOT MICRO is approved for use in Europe and Japan and is investigational only in the United States.

Atrial fibrillation (AF), the most common type of cardiac arrythmia, affects over 11 million people in Europe and costs healthcare systems up to €3.3 billion annually.[2,3,4] Estimates state that by 2030 the number of people with AF is projected to increase by up to 70 percent.[5] As some patients with arrythmias are not successful or cannot tolerate drug therapy, catheter ablation may be a recommended treatment option. Catheter ablation is associated with a significant improvement in patient quality of life, with studies showing improvements of more than 50 percent, when compared to drug therapy.[6,7] Catheter ablation is also associated with significant reductions in AF burden and AF-related complications.[8]

The current practice of RF ablation with irrigated catheters involves the delivery of moderate power (20–40 watts) for a relatively long duration (up to 20 seconds).[9,10,11] QDOT MICRO with QMODE+™, enables ablation at up to 90 watts of RF power for four seconds or less, when using the nGEN™ generator. In prospective, non-randomized trials, QDOT MICRO saved an average of 87 minutes per procedure and ablation with QDOT MICRO had up to 78 percent shorter mean fluoroscopy times in QMODE+™.[9,10,11]† For patients, a shorter ablation time may require less anesthesia and radiation and may result in less nursing and facility time.[12,13] These time savings may also enable more procedures per day facilitating improved patient access, while reducing procedure costs by nearly €700 per procedure.[1,9,10,11,14,15]‡

"Reducing procedure time and increasing efficiency are two key goals in treating arrhythmias, but very high-power ablation has previously been out of reach because of limited temperature sensitivity," said Prof. Helmut Pürerfellner**, Department of Cardiology, Elisabethinen Hospital, Linz, Austria. "With increased sensitivity and the ability to more accurately delineate between healthy tissue and scar tissue, QDOT MICRO brings effective technological solutions to these challenges and will make a significant difference for my patients by shortening procedure times."

The first procedures with QDOT MICRO since receiving CE mark were successfully performed in St Jan Hospital, Bruges, Belgium, by Dr. Sebastien Knecht and Prof. Matthias Duytschaever; in OLV Hospital, Aalst, Belgium, by Dr. Tom De Potter, and in Elisabethinen Hospital, Linz, Austria, by Prof. Helmut Pürerfellner and Dr. Martin Martinek.

“Biosense Webster is committed to partnering with physicians and innovating new technology that helps diagnose and treat cardiac arrhythmias,” said Uri Yaron, Worldwide President of Biosense Webster, Inc. “With CE mark approval and the first procedures completed for QDOT MICRO, we are proud to help meet electrophysiologists’ needs for a higher power catheter with improved control that can safely, effectively, and efficiently restore patients’ heart rhythms.”

The catheter is fully integrated with the CARTO® 3 System, including CARTO SMARTTOUCH™ contact force technology and VISITAG SURPOINT™, enabling efficient and consistent lesion creation with a simplified workflow and lower total procedure time.[1]

About Johnson & Johnson Medical Devices Companies

As the world’s most comprehensive medical devices business, we are building on a century of experience, merging science and technology, to shape the future of health and benefit even more people around the world. With our unparalleled breadth, depth and reach across surgery, orthopedics, vision and interventional solutions, we’re working to profoundly change the way care is delivered. We are in this for life. For more information, visit www.jnjmedicaldevices.com.

About Biosense Webster, Inc.

Biosense Webster, Inc., is the global market leader in the science and technology behind the diagnosis and treatment of cardiac arrhythmias. Part of the Johnson & Johnson Family of Companies, the specialized medical-technology company is headquartered in Irvine, Ca., and works across the world to advance the tools and solutions that help electrophysiologists identify, treat, and deliver care. Learn more at www.biosensewebster.com and connect on LinkedIn and Twitter.

The QDOT MICRO Catheter is available for commercial sale in Europe. The device is currently not approved for use in the United States.

[*] Comprising the surgery, orthopedics, vision and interventional solutions businesses within Johnson & Johnson’s Medical Devices segment

[**]Prof. Purerfellner has been one of the investigators of the QDOT FAST study

[***]Comparison includes the following irrigated, contact force catheters: TACTICATHTM Quartz Contact Force Ablation Catheter, THERMOCOOL SMARTTOUCH® Catheter, THERMOCOOL SMARTTOUCH SF catheter. Weighted average was determined using the procedure times reported in the following clinical and investigational device exemption (IDE) studies: TOCCATA (Reddy et al., 2012), SMART-AF (Natale et al, 2014), SMART-SF (Chinitz et al, 2017).

[†]Comparison based on a weighted average of the procedure time with QDOT MICRO™ Technology in QMODE (129.8 min; N = 42) and in QMODE+™ (105.2 min; N = 52),and the weighted average of the procedure time with irrigated, contact force RF catheters (202.8 min; 5 studies, N = 622).

[‡] Cost savings were calculated based on an average 87-minute reduction in procedure time and €7.41 cost/minute as per Klein et al. (2015)20. Costs were adjusted for inflation from 2010 Euros. Costs did not include the choice of medical device used when performing the procedure.

 148477-200803 EMEA

[1] Reddy VY, Grimaldi M, De Potter T, Vijgen JM, Bulava A, Duytschaever MF, Martinek M, Natale A, Knecht S, Neuzil P, Pürerfellner H, Pulmonary Vein Isolation with Very High Power–Short Duration Temperature-

Controlled Lesions: The First-in-Human QDOT-FAST Multicenter Trial, *JACC: Clinical Electrophysiology* (2019), doi: https://doi.org/10.1016/j.jacep.2019.04.009.
[2] Johan E.P. Waktare, MB, ChB, MRCP. Atrial Fibrillation. *Circulation.* 2002;106:14-16.
[3] Velleca M, Costa G, Goldstein L, et al. A Review of the Burden of Atrial Fibrillation: Understanding the Impact of the New Millennium Epidemic across Europe. EMJ Cardiol.. 2019; 7[1]:110-118.
[4] Ball J, Carrington MJ, McMirray JJ, Stewart S (2013) Atrial fibrillation: profile and burden of an evolving epidemic in the 21st century. *Int J Cardio.* 167 (5): 1807-1824.
[5] Zoni-Berisso M, Lercari F, Carazza T, Domenicucci S (2014) Epidemiology of atrial fibrillation: European perspective. *Clin Epidemiol.* 6: 213-220.
[6] Walfridsson, Håkan, et al. "Radiofrequency ablation as initial therapy in paroxysmal atrial fibrillation: results on health-related quality of life and symptom burden. The MANTRA-PAF trial." Ep Europace 17.2 (2015): 215-221.
[7] Blomström-Lundqvist, Carina, et al. "Effect of catheter ablation vs antiarrhythmic medication on quality of life in patients with atrial fibrillation: the CAPTAF randomized clinical trial." Jama 321.11 (2019): 1059-1068.
[8] Journal of Nursing: June 2019 - Volume 119 - Issue 6 - p 18 doi: 10.1097/01.NAJ.0000559795.09114.0b.
[9] Natale A, Reddy VY, Monir G, Wilber DJ, Lindsay BD et al. (2014) Paroxysmal AF catheter ablation with a contact force sensing catheter: results of the prospective, multicenter SMART-AF trial. *J Am Coll Cardiol.* 64 (7): 647-656.
[10] Reddy VY, Shah D, Kautzner J, Schmidt B, Saoudi N et al. (2012) The relationship between contact force and clinical outcome during radiofrequency catheter ablation of atrial fibrillation in the TOCCATA study. *Heart Rhythm.* 9 (11): 1789-1795.
[11] Chinitz LA, Melby DP, Marchlinski FE, Delaughter C, Fishel RS et al. (2017) Safety and efficiency of porous-tip contact-force catheter for drug-refractory symptomatic paroxysmal atrial fibrillation ablation: results from the SMART SF trial. *J Ep Europace.* 20 (FI_3): f392-f400.
[12] Klein G, Lickfett L, Schreieck J, Deneke T, Wieczorek M et al. (2015) Comparison of 'anatomically designed' and 'point-by-point' catheter ablations for human atrial fibrillation in terms of procedure timing and costs in German hospitals*. Europace.* 17 (7): 1030-1037.
[13] Yildiz M, Yilmaz Ak H, Oksen D, Oral S. Anesthetic Management In Electrophysiology Laboratory: A Multidisciplinary Review. J Atr Fibrillation. 2018;10(5):1775. Published 2018 Feb 28. doi:10.4022/jafib.1775.
[14] De Potter T, Grimaldi M, Jensen HK, Kautzner J, Neuzil P et al. (2019) Acute safety and performance of a novel catheter with optimized temperature control and microelectrodes in the treatment of patients with paroxysmal atrial fibrillation. European Hearth Rhythm Association. Lisbon, March 19, 2019. Pending formal publication.
[15] Taghji P, El Haddad M, Phlips T, Wolf M, Knecht S et al. (2018) Evaluation of a strategy aiming to enclose the pulmonary veins with contiguous and optimized radiofrequency lesions in paroxysmal atrial fibrillation: a pilot study. JACC: Clinical Electrophysiology 4 (1): 99-108.