BD Acquires TVA Medical to Advance Leadership in Solutions for Chronic Kidney Disease

everlinQ(TM) endoAVF System Receives FDA De Novo Marketing Authorization

PR Newswire

FRANKLIN LAKES, N.J., July 9, 2018 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced it has completed the acquisition of TVA Medical, Inc., a company that develops minimally invasive vascular access solutions for patients with chronic kidney disease requiring hemodialysis.

In the U.S. alone, there are more than 440,000 patients with End-Stage Renal Disease (ESRD) who are surviving on hemodialysis(i). The addition of TVA Medical enables BD to offer the everlinQ(TM) endoAVF System, a new endovascular arteriovenous (AV) fistula creation technology that adds to the company's ESRD portfolio of dialysis catheters, drug coated balloons, standard angioplasty balloons and endovascular stent graft products. This technology will further improve BD's ability to serve physicians and their patients by providing a minimally invasive option for creating critical AV fistulas (joining arteries to veins to create a circuit) for hemodialysis procedures.

"The addition of TVA Medical allows BD to provide another innovative device to physicians who treat patients suffering from chronic kidney disease requiring hemodialysis," said Steve Williamson, worldwide president of Peripheral Intervention at BD. "This technology is highly complementary to our Peripheral Intervention offerings, and we will continue to bring new technologies to market that improve our category-leading ESRD portfolio. This is a great example of our continued strategy to use tuck-in acquisitions to advance category leadership."

Hemodialysis, a form of treatment for kidney failure patients, is a procedure that removes wastes, salts, and fluid from a patient's blood when the kidneys can no longer perform these functions. Vascular access is considered a "lifeline" for hemodialysis patients. Options for vascular access include central venous catheters, AV grafts and surgical AV fistulas. Surgical fistulas are currently the preferred vascular access option for hemodialysis patients, resulting in lower mortality rates, fewer infections and lower cost of dialysis delivery compared to central venous catheters(ii,iii,iv).

On June 22, the U.S. Food and Drug Administration (FDA) announced De Novo marketing authorization for the everlinQ endoAVF System. The system uses two, thin, flexible, magnetic catheters that are inserted into the ulnar artery and the ulnar vein in the arm through a small puncture. When placed close to each other, the magnets in each catheter attract, pulling the vessels together. After confirming alignment, an electrode from the venous catheter delivers radiofrequency energy to create the connection between the artery and vein. Embolization of the brachial vein is then recommended. The fistula is confirmed with an angiogram (X-ray image of the vascular system) to show that arterial blood is flowing to the low-pressure venous system. The procedure minimizes the amount of vessel and skin trauma compared to traditional fistula creation using open surgery. The everlinQ endoAVF System enables an additional AV fistula location for patients than what is typically done surgically. The device is already commercially available in Europe and Canada. For more information on the everlinQ endoAVF System, visit http://tvamedical.com/product/. The product name will be transitioned to WavelinQ(TM) EndoAVF System during integration.

"The FDA's authorization and joining BD are the culmination of many years of hard work by a dedicated team of innovators at TVA Medical, and I'd like to thank them for their tireless efforts to get us to these important milestones," said Adam L. Berman, co-founder of TVA Medical. "BD will enable us to deliver to physicians and patients what we believe is a highly-desirable and transformative endovascular technology as an integral part of a broader ESRD-focused portfolio of solutions. I look forward to the next chapter of our history as part of the BD family."

This transaction is not expected to have a material impact on BD results for fiscal 2018 or 2019. Future results for TVA Medical will be reported under the Peripheral Intervention business within the Interventional Segment at BD. The company used cash on hand to finance the transaction. This transaction does not impact the company's previously-communicated commitment to deleverage as part of the Bard acquisition. Terms of the transaction were not disclosed.

About BD
BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help improve patient

outcomes, improve the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to better diagnose disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. In 2017, BD welcomed C. R. Bard and its products into the BD family. For more information on BD, please visit bd.com.

Forward Looking Statement
This press release contains certain estimates and other forward-looking statements (as defined under Federal securities laws), including regarding BD's future performance and product development. All such statements are based upon current expectations of BD and involve a number of business risks and uncertainties. Actual results could vary materially from anticipated results described, implied or projected in any forward-looking statement. With respect to forward-looking statements contained herein, a number of factors could cause actual results to vary materially. These factors include, but are not limited to: risks relating to the integration of the C.R. Bard operations, products and employees into BD and the possibility that the anticipated synergies and other benefits of the proposed acquisition will not be realized or will not be realized within the expected timeframe; our ability to successfully integrate TVA Medical or any other businesses we acquire; the impact of the recent U.S. tax reform; legislative or regulatory changes to the U.S. health care system, potential cuts in governmental health care spending or measures to contain health care costs, each of which could result in reduced demand for our products or downward pricing pressure; adverse changes in regional, national or foreign economic conditions, particularly in emerging markets, including any impact on our ability to access credit markets and finance our operations, the demand for our products and services, utilization rates or otherwise, or our suppliers' ability to provide products needed for our operations; changes in interest or foreign currency exchange rates; new or changing laws and regulations impacting our business (including changes in laws impacting international trade) or changes in enforcement practices with respect to such laws; the adverse impact of cyber-attacks on our information systems or products; competitive factors including technological advances and new products introduced by competitors; interruptions in our supply chain or manufacturing processes; pricing and market pressures; difficulties inherent in product development, delays in product introductions and uncertainty of market acceptance of new products; adverse changes in geopolitical conditions; increases in energy costs and their effect on, among other things, the cost of producing BD's products; product efficacy or safety concerns resulting in product recalls or actions being taken by the FDA or other regulators; fluctuations in costs and availability of raw materials and in BD's ability to maintain favorable supplier arrangements and relationships; risks relating to our ability to continue to successfully integrate CareFusion's operations in order to fully obtain the benefits of the transaction; uncertainties of litigation (as described in BD's filings with the Securities and Exchange Commission); future health care reform outside the U.S., including changes in government pricing and reimbursement policies or other cost containment reforms; and issuance of new or revised accounting standards, as well as other factors discussed in BD's filings with the Securities and Exchange Commission. We do not intend to update any forward-looking statements to reflect events or circumstances after the date hereof except as required by applicable laws or regulations.

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(i) United States Renal Data System (USRDS). 2017 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2017.
(ii) Woo K., et al. Influence of Vascular Access Type on Sex and Ethnicity-Related Mortality in Hemodialysis-Dependent Patients. Perm J 2012 Spring;16(2):4-9.
(iii) USRDS 2012 Annual Report.
(iv) USRDS 2010 Annual Report.

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