BD Initiates Study to Further Advance the Treatment of Portal Hypertension

First patient enrollment in ARCH study begins investigation of the safety and effectiveness of the BD Liverty™ Transjugular Intrahepatic Portosystemic Shunt (TIPS) Stent Graft to reduce complications associated with portal hypertension.

FRANKLIN LAKES, N.J. (August 10, 2023) – BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced the enrollment of the first patient in the investigational device exemption (IDE) study, "ARCH." The study is a global, prospective, multi-center, single-arm clinical study for the treatment of complications from portal hypertension, assessing the safety and effectiveness of the investigational BD Liverty[™] TIPS Stent Graft.



BD announced the enrollment of the first patient in the investigational device exemption study, "ARCH," which is a global, prospective, multi-center, single-arm clinical study for the treatment of complications from portal hypertension.

More than 100 million people are living with some form of liver disease in the US, including cirrhosis.¹ Cirrhosis can

lead to portal hypertension, which is increased pressure within the veins that drain the liver. Common symptoms of portal hypertension are bleeding from veins in the esophagus and fluid build-up in the abdomen or chest. The creation of a TIPS is an interventional therapy aimed at decreasing the portosystemic pressure gradient and helping to relieve those symptoms.

The investigational BD Liverty[™] TIPS Stent Graft is a novel, self-expanding, ePTFE encapsulated implant with the capability for a tailored expansion diameter in incremental steps to achieve the desired pressure gradient. It is deployed from a delivery system that provides control over each step of stent graft release.

"The BD Liverty[™] TIPS Stent Graft is part of our larger effort to work closely with our physician partners to develop and deliver innovations that simplify this complex and time-consuming procedure," said Tim Hug, vice president and general manager of global peripheral vascular disease at BD. "Similar to our BD Liverty[™] TIPS Access Kit, the BD Liverty[™] TIPS stent graft is also designed to provide the implanting physician a greater level of control in order to optimize procedural efficiency."

The ARCH Study will include 175 patients at up to 40 clinical study sites across the United States and Europe. Follow-up for all treated patients will be performed at various points after treatment -- starting at one month and ending at 24 months.

The first patient was enrolled in Charlottesville, Virginia by the Global Principal Investigator, Ziv J. Haskal, MD.

"The BD Liverty[™] TIPS Stent Graft gives us the desired flexibility and diameter options needed to tailor TIPS to specific patient needs, to maximize control of their ascites and/or bleeding while limiting encephalopathy and overshunting risks," said Dr. Haskal. "With this investigational device, our hope is we will be able to improve the care and quality of life of patients with portal hypertension."

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 77,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect 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. For more information on BD, please visit bd.com or connect with us on LinkedIn at <u>www.linkedin.com/company/bd1/</u> and Twitter @BDandCo.

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¹ https://liverfoundation.org/about-your-liver/facts-about-liver-disease/how-many-people-have-liver-disease/.

https://news.bd.com/2023-08-10-BD-Initiates-Study-to-Further-Advance-the-Treatment-of-Portal-Hypertension