FDA Advisory Committee Votes in Favor of Cardinal Health's INCRAFT® AAA Stent Graft System for the Endovascular Treatment of Infrarenal Abdominal Aortic Aneurysms

DUBLIN, Ohio, June 12, 2018 /PRNewswire/ -- Cardinal Health (NYSE: CAH) today announced that the U.S. Food and Drug Administration (FDA) Circulatory System Devices Panel of the Medical Devices Advisory Committee has provided a favorable recommendation on the premarket approval application for INCRAFT® AAA Stent Graft System (INCRAFT). The panel voted 11 to 4 in favor of the benefits of the INCRAFT system.

The INCRAFT system is an advanced endovascular aneurysm repair (EVAR) technology for the treatment of infrarenal abdominal aortic aneurysms (AAAs), a severe and complex condition.

"We are pleased with the panel's recommendation today, which brings us one step closer to making the INCRAFT system available for thousands of high-risk patients in the U.S.," said Dr. Shaden Marzouk, chief medical officer at Cardinal Health. "We appreciated the opportunity to present our data supporting the INCRAFT system and look forward to continuing discussions with the FDA to bring this technology to doctors and patients."

An abdominal aortic aneurysm is a bulging, weakened area in the wall of the lower part of the aorta, the main artery of the body, which, unless treated, can rupture and lead to a life-threatening hemorrhage. An estimated 1.5 million people in the United States have AAA, and more than 200,000 new diagnoses are made each year[1]. These aneurysms account for approximately 10,000 deaths annually in the U.S[2]. Once identified, treatment options for AAAs include medical monitoring, open surgical repair, or EVAR, a minimally invasive endovascular treatment option with the potential to reduce perioperative mortality and morbidity.

While several EVAR devices are currently available in the U.S., treatment options are limited for many AAA patients with small femoral or iliac arteries or with heavily calcified or tortuous vessels that could lead to complications during the introduction of EVAR devices.

The INCRAFT system is an ultra-low profile and flexible stent-graft system designed to prevent rupture of infrarenal AAAs in a wide range of patient population.

The favorable vote of the advisory committee followed a review of clinical data from the pivotal INSPIRATION trial, a prospective, multi-center, single-arm study to evaluate the safety and effectiveness of the INCRAFT system in patients with AAA. The trial showed that the INCRAFT system met the primary safety and effectiveness endpoints, with a low rate of major adverse events at 30 days and a high rate of successful aneurysm treatment at 1 year[3]. As presented at the Circulatory System Devices Panel meeting earlier today, the trial demonstrated high survival of nearly 80% and no aneurysm ruptures through 4 years of follow up.

The INCRAFT system, which received a CE mark in 2014, is commercially available in 39 countries. The INCRAFT system is an investigational device not available for sale in the United States.

About Cardinal Health
Cardinal Health, Inc. is a global, integrated healthcare services and products company, providing customized solutions for hospitals, healthcare systems, pharmacies, ambulatory surgery centers, clinical laboratories and physician offices worldwide. The company provides clinically proven medical products, pharmaceuticals and cost-effective solutions that enhance supply chain efficiency from hospital to home. Cardinal Health connects patients, providers, payers, pharmacists and manufacturers for integrated care coordination and better patient management. To help combat prescription drug abuse, the company and its education partners created Generation Rx, a national drug education and awareness program. Backed by nearly 100 years of experience, with approximately 50,000 employees in nearly 60 countries, Cardinal Health ranks #14 on the *Fortune* 500. For more information, visit cardinalhealth.com, follow @CardinalHealth on Twitter, @cardinalhealthwings on Facebook and connect on LinkedIn at linkedin.com/ company/cardinal-health.

About Abdominal Aortic Aneurysms

Abdominal aortic aneurysms occur when a weakened area in the wall of the aorta results in enlargement of the vessels of at least 50 percent of their normal diameter. While aortic aneurysms can develop anywhere along the length of the aorta, the majority are located in the abdominal aorta. More than 90 percent of abdominal aneurysms are located below the renal arteries and can extend into the iliac arteries. They generally start small and remain asymptomatic for years, however, once an aneurysm forms, it will gradually increase in size. Unless treated, there will be a progressive weakening of the aneurysm wall that may rupture and lead to a life- threatening hemorrhage, and since most go undetected for quite some time, many of them are complex by the time they are treated.

[1]Lifetime Risk and Risk Factors for Abdominal Aortic Aneurysm in a 24 Year Prospective Study: the ARIC Study. Atherosclerosis, Thrombosis, and Vascular Biology. 2016;36:2468-2477

[2]Centers for Disease Control and Prevention (CDC), 2017

[3]Ohki, One-Year Outcomes of the INSPIRATION Study of the INCRAFT® Stent-Graft System for Treatment of Abdominal Aortic Aneurysms (AAAs), Society for Vascular Surgery 2015

SOURCE Cardinal Health

For further information: Media: Ellen Barry, (614) 553-3858, ellen.barry@cardinalhealth.com ; Investors: Lisa Capodici, (614) 757-5035, lisa.capodici@cardinalhealth.com

---

https://newsroom.cardinalhealth.com/2018-06-12-FDA-Advisory-Committee-Votes-in-Favor-of-Cardinal-Healths-INCRAFT-R-AAA-Stent-Graft-System-for-the-Endovascular-Treatment-of-Infrarenal-Abdominal-Aortic-Aneurysms