Colospan Receives FDA Breakthrough Device Designation for Its Intraluminal Bypass Device

CAMBRIDGE, MA, UNITED STATES, August 13, 2024 /EINPresswire.com/ -- Colospan, which develops novel solutions for colorectal surgery, announced today that the United States Food and Drug Administration (FDA) has granted Breakthrough Device Designation to its CG-100 Intraluminal Bypass Device.

FDA's Breakthrough Devices Program is intended to provide patients and health care providers with timely access to novel medical devices by expediting the assessment and approval process. The Breakthrough Devices Program reflects the FDA´s commitment to device innovation leading to more effective treatment or diagnosis of life threatening or irreversibly debilitating human diseases.

CG-100 Intraluminal Bypass Device is a single use, temporary intraluminal bypass device, intended for patients with colorectal cancer requiring an anastomosis and are to receive a protective stoma under routine clinical practice.

"We are excited to receive this important recognition from the FDA," said Boaz Assaf, Colospan's CEO, and founder. "Breakthrough Device Designation is only awarded to innovations that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversible debilitating diseases or conditions, and it may help to accelerate Colospan's future review process with the FDA, enabling us to introduce our product to market sooner for the benefit of patients."

CG-100's available sizing options enable Colospan to address the diverse colon dimensions of patient populations. More than 1 million such procedures are performed annually in this $5B global market.

About CG-100 Intraluminal Bypass Device

In the U.S., Colospan's CG-100 is an investigational device for patients with colorectal cancer requiring an anastomosis and are to receive a protective stoma under routine clinical practice. The CG-100 Intraluminal Bypass Device is a silicone tubular sheath that is introduced into the colon using a designated delivery system. The protective sheath is held in place by a mechanism that consists of inflatable balloons and an extra-luminal ring that encircles the colon, preventing the sheath from moving downstream while protecting the anastomotic site. After approximately ten days, when the risk for anastomotic leakage is reduced and the anastomosis integrity is confirmed, the sheath and ring are removed without any surgical intervention. The CG-100 Intraluminal Bypass Devices are CE marked (under Medical Device Regulation)in the European Union (EU) and in Israel and under investigational use (IDE) in the USA.

About Colospan Ltd.

Colospan is a clinical stage medical device company that has developed a novel and proprietary solution for colorectal surgery. The company is dedicated to addressing the clinical and economic consequences of anastomotic leaks, the first and foremost challenge in colorectal surgery.

Colospan's team consists of seasoned professionals in marketing, sales, and development of surgical devices for colorectal surgery, supported by key opinion leaders from Israel, Europe and the United States. The CG-100 is not approved for sale in the United States and is limited to investigational use. For more information, please visit www.colospan.com.

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