Colospan Announces Extended IDE Approval for Its Intraluminal Bypass Device – an Alternative Approach to Diverting Stoma

CAMBRIDGE, MA, UNITED STATES, May 29, 2024 /EINPresswire.com/ -- Colospan, which develops novel solutions for colorectal surgery, announced today that the United States Food and Drug Administration (FDA) has approved a product line extension to its Intraluminal Bypass Device as part of the company's investigational device exemption (IDE) application. The line extension offers surgeons size selection for Colospan's flagship CG-100 product, a device designed to reduce diverting stoma rates in patients undergoing a gastrointestinal resection procedure. More than 1 million such procedures are performed annually in this $5B global market. The available sizes of CG-100 enable Colospan to address the diverse colon dimensions of patient populations. With the approval in hand, the company will now introduce the extended product line into its pivotal study for CG-100.

"We are pleased to receive FDA approval for our IDE supplement. We look forward to introducing the expanded product line into our on-going pivotal study. Colospan's pivotal study assesses the safety and clinical impact of our devices and their potential to improve patients' lives, significantly reduce healthcare costs and as a result empower physicians with an improved standard of care." said Boaz Assaf, Colospan's CEO, and founder.

About CG-100

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.

Boaz Assaf
Colospan Ltd
boaz@colospan.com
