C2 Therapeutics Announces Data from Four Studies Reinforcing the Safety and Efficacy of its C2 CryoBalloon™ Focal Ablation System

- Results presented at Digestive Disease Week® 2016 -

REDWOOD CITY, Calif. – May 24, 2016 – C2 Therapeutics, a privately-held medical device company founded to improve methods of eradicating unwanted tissue in endoscopic applications, today announced new data from four separate clinical studies designed to assess the safety and efficacy of its C2 CryoBalloon™ Focal Ablation System (CbFAS). The data, which support the safety and efficacy of the company's CbFAS, were presented at Digestive Disease Week (DDW) 2016, which is taking place May 21 – 24 in San Diego.

Abstract #638, "Multifocal Nitrous Oxide Cryoballoon Ablation With or Without Endoscopic Mucosal Resection (EMR) for Treatment of Neoplastic Barrett's Esophagus (BE): Preliminary Results of a Prospective Clinical Trial in Treatment-Naïve and Previously Ablated Patients", described results of a single-center, prospective, single-arm clinical trial of cryoballoon ablation in 35 BE patients. Of the 35 patients, 23 were treatment-naïve and 12 had persistent/recurrent disease despite prior therapy; 14 had low-grade dysplasia, 20 had high-grade dysplasia, and 1 had intramucosal adenocarcinoma. Prior to cryoballoon ablation, 37 percent of patients underwent EMR. Treatments were repeated every 10-12 weeks until eradication of intestinal metaplasia.

Of the 35 patients enrolled, 21 (10 treatment-naïve and 11 previously treated) were evaluable at a median follow-up of 6.7 months. The overall complete response rate for all dysplasia and cancer was 20 of 21 patients (95%), and the overall complete response rate for intestinal metaplasia was 15 of 21 patients (71%). No serious adverse events were noted, including perforations or bleeding and no patient had a persistent symptomatic stricture. Three patients developed mild inflammatory stenosis, all of which resolved. Study investigators concluded that nitrous cryoballoon ablation is a promising, safe, and potentially effective endoscopic intervention for BE-associated neoplasia.

"These preliminary results are extremely promising and suggest that cryoballoon ablation is a safe and highly effective modality for the treatment of neoplastic BE, even in this potentially challenging to treat patient population," said George Triadafilopoulos, M.D., a gastroenterologist in Mountain View, Calif. "A growing body of clinical evidence demonstrates that cryoballoon ablation is a simple, fast and reliable alternative to radiofrequency ablation, and supports an increasing role in clinical practice."

Abstract #Tu1186, "Nitrous Oxide Cryotherapy for Treatment of Esophageal Squamous Cell Neoplasia (ESCN): Initial Multicenter International Experience with a Novel Portable Cryoballoon Focal Ablation System (CbFAS)", reported the first application of successful cryoballoon ablation for curative treatment of primary or recurrent ESCN. Nine patients (4 treatment-naïve and 5 previously treated) referred from 4 centers in the United States and the Netherlands have been treated to date. patients underwent cryoballoon therapy every 6-8 weeks until ESCN was eradicated as evidenced by biopsy.

Squamous regeneration was seen in all treated areas, with complete pathologic response achieved in 5 evaluable patients who had completed therapy and had at least 1 post-treatment biopsy (mean follow-up time of 9.1 months).No major adverse events occurred and no strictures or bleeding developed. Median procedure time was 34 minutes and treatment was completed in all patients despite a single occurrence of minor device malfunction. The study investigators concluded that nitrous cryoballoon ablation is a promising, simple, well-tolerated and safe endoscopic therapy for treating ESCN.

"These data, demonstrating complete disease resolution in all evaluable patients, are highly encouraging and further underscore the utility of nitrous cryoaballoon ablation as a potentially curative treatment for primary and recurrent ESCN," said Blair Jobe, M.D., Director of the Allegheny Health Network Esophageal and Lung Institute.

Abstract #Mo2021, "Efficacy and Safety of the CryoBalloon Focal Ablation System (CBFAS) for the Eradication of Dysplastic Barrett's Esophagus Islands", describes preliminary results from an ongoing, prospective trial of CbFAS in patients with dysplastic Barrett's esophagus (BE) or residual BE after removal of early cancer. In this study, areas of dysplastic tissue, known as BE islands, or a group of BE islands were treated follow-up endoscopy performed 6-8 weeks following treatment. The primary outcome of the study was the percentage of BE areas that were completely eradicated at follow up.

As of December 2015, 26 patients had been enrolled and treated in the study. Of the 26 patients evaluated, 13 had low-grade dysplasia (LGD), 5 had high-grade dysplasia (HGD), and 8 had early carcinoma; 20 patients had undergone radiofrequency ablation prior to entering the study. In 25 of 26 patients who had undergone follow-up endoscopy, complete eradication was observed in 100 percent of BE islands that had been completely ablated during CbFAS treatment; No buried glands were found on biopsy. No adverse events occurred during the procedure. The median cryoablation time was 4 minutes and mean overall endoscopy duration was 13 minutes.

Abstract #Sa1276, "Use of the Cryoballoon Focal Ablation System for the Eradication of Esophageal Neoplasia: A Single-Center Experience", describes results from a single center case-series of patients with esophageal neoplasia. Cryoablation was used to treat residual BE in the esophagus in 7 patients, and 10 patients were treated for residual or recurrent disease at the GE junction. There were no intraprocedural complications. Twelve patients (10 BE) had at least one follow up endoscopy. Overall, 60 percent of patients had complete resolution, with no new strictures noted in any of the patients. Study investigators concluded that the use of cryoablation was feasible and safe for patients with mostly treatment resistant esophageal neoplasia and that further study is required to determine how to optimize treatment response and efficacy in both treatment resistant and naive patients.

"The C2 CryoBalloon Focal Ablation System offers physicians and patients an innovative approach to removing pre-cancerous and diseased tissue with potentially fewer side effects than conventional surgical or endoscopic procedures," said Peter Garcia-Meza, President and CEO of C2 Therapeutics. "The data presented this year at DDW provide additional support for the safety, efficacy, and clinical utility of the CryoBalloon System. Early interventions that effectively eradicate pre-cancerous or malignant cells are essential to preventing disease progression in these indications and C2 Therapeutics is committed to developing novel interventions that improve patient outcomes."

About C2 Therapeutics

C2 Therapeutics was founded in 2007 to address the limitations of current Barrett's esophagus treatment options. Headquartered in Redwood City, California, C2 is a privately held company whose Coldplay Systems set a new standard for simplicity in the endoscopic ablation of Barrett's Esophagus. The technology comprises a through-the-scope, highly compliant balloon catheter that is simultaneously inflated and cooled by an inert cryogen delivered through a small disposable handheld unit. Operation is intuitive, fast and cost-effective. The C2 Coldplay CryoBalloon™ Focal Ablation System eliminates the need for precise sizing, multiple deployment steps, and controller units.

For more information on C2 Therapeutics and its products, please visit www.c2therapeutics.com.

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