



C2 THERAPEUTICS ANNOUNCES INITIATION OF COLDPLAY III TRIAL VALIDATING THE C2 CRYOBALLOON™ FOCAL ABLATION SYSTEM FOR PRIMARY TREATMENT OF BARRETT'S ESOPHAGUS

REDWOOD CITY, Calif. – June 7, 2016 – C2 Therapeutics today announced the initiation of its Coldplay III trial with treatment of the first patient at University Hospitals in northeast Ohio. The patient was treated with the C2 CryoBalloon™ Focal Ablation System by John Dumot, D.O., Director, Digestive Health Institute, University Hospitals, commencing the clinical trial to validate the efficacy and safety of the system in patients with Barrett's esophagus.

The prospective, multi-center, non-randomized, single arm study ([NCT02514525](https://clinicaltrials.gov/ct2/show/study/NCT02514525)) will enroll 60 patients with multifocal Barrett's esophagus less than 6 cm in full circumferential size and no previous treatment. The primary outcomes measure is eradication of any grade Barrett's esophagus at 12 months post-treatment. This will be evaluated by using the Seattle protocol surveillance strategy that involves targeted biopsies of mucosal abnormalities, plus four-quadrant biopsies obtained at every 1 cm. The presence of Barrett's esophagus and degree of disease will be confirmed by histopathologic analysis.

Participating trial centers include: Columbia University Medical Center in New York, New York; Geisinger Medical Center in Danville, Pennsylvania; John Hopkins Medicine in Baltimore, Maryland; Temple University Hospital in Philadelphia, Pennsylvania; University Hospitals Ahuja Medical Center in Beachwood, Ohio; University of North Carolina in Chapel Hill, North Carolina; and University of Rochester Medical Center in Rochester, New York.

"Although radiofrequency ablation is effective in treating Barrett's esophagus, Cryoablation has inherent potential benefits to the patient including reduced scarring, less post-procedural pain and decreased likelihood of stricture," said Dr. Dumot. "A growing body of scientific literature supports use of the C2 CryoBalloon Focal Ablation System as an effective and simple therapeutic intervention and we are excited to be participating in this critical study to further validate cryoablation as a primary treatment option and move beyond that of a salvage therapy to failed radiofrequency ablation."

The C2 CryoBalloon Focal Ablation System is used to destroy unwanted tissue in the esophagus by applying extreme cold to the affected area – a procedure known as "cryoablation." Nitrous oxide (N₂O) cryogen is delivered through a handheld controller, in combination with a self-sizing balloon catheter that is inserted into the working channel of a 3.7mm therapeutic endoscope (a diagnostic endoscope can also be used with the C2 CryoBalloon Sidecar Working Channel).

"This study represents C2 Therapeutics' ongoing commitment to improving treatment solutions for patients affected by Barrett's esophagus," said Peter Garcia-Meza, President and CEO of C2 Therapeutics. "This condition is highly treatable if detected and managed early, and our ultimate goal is to eradicate Barrett's esophagus before it develops into deadly esophageal cancer that takes more than 15,000 lives annually. We sincerely appreciate the dedication and support of our collaborating study investigators and participating trial centers."

Coldplay III enrollment is ongoing with a target completion date of October 2016. For more information please visit <http://www.c2therapeutics.com/clinical-trials>.



About C2 Therapeutics

C2 Therapeutics was founded in 2007 to address limitations of current Barrett's esophagus treatment options. Headquartered in Redwood City, California, C2 Therapeutics is a privately-held company whose Coldplay CryoBalloon® Focal Ablation System set a new standard for simplicity in the endoscopic ablation of Barrett's esophagus.

For more information about C2 Therapeutics, please visit www.c2therapeutics.com.

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