## NEW STUDY: WHEN GERD RETURNS AFTER REFLUX SURGERY, PATIENTS EXPERIENCE 10 YEARS OF RELIEF FROM NON-SURGICAL STRETTA THERAPY

NORWALK, CT – Mederi Therapeutics Inc., manufacturers of Stretta Therapy for gastroesophageal reflux disease (GERD), have announced the publication of a new study in Surgical Endoscopy, the journal of the Society of American Gastrointestinal and Endoscopic Surgeons. The study offers 10-year data showing the safety and efficacy of Stretta in treating patients suffering from recurring GERD after the failure of anti-reflux surgery.

Stretta is a non-surgical treatment option for GERD that is an option for patients when symptoms persist despite medications. It is a versatile option that addresses the special needs of chronic GERD patients like: Patients whose GERD symptoms don't respond to PPIs, patients who are concerned about taking medications long-term, patients with GERD post-bariatric procedures, patients with respiratory symptoms of GERD (LPR), and patients who still have GERD post-fundoplication or other anti-reflux surgery. Importantly, Stretta does not preclude any other treatment option.

Patients with uncontrolled GERD often undergo a surgical procedure called laparoscopic Nissen fundoplication (LNF) to treat their reflux. This involves wrapping the upper portion of the stomach around the esophagus as a means to augment the sphincter and reduce reflux events. Although effective, LNF patients often suffer from long-term recurring GERD symptoms, requiring continuous use of medications or a reoperation. These options are not desirable for many patients and can come with significant complications. These failed or relapsed patients may be candidates for Stretta Therapy, a non-surgical procedure that uses a transoral catheter device to deliver non-ablative radiofrequency energy to the lower esophageal sphincter muscle, improving the barrier to reflux, and reducing GERD symptoms.

The new study, "Radiofrequency energy delivery to the lower esophageal sphincter improves gastroesophageal reflux patient-reported outcomes in failed laparoscopic Nissen fundoplication cohort," compared 10-year results of Stretta Therapy for refractory GERD patients in those who had failed previous LNF surgery, as well as those patients who had not had surgery.

The study's lead author is Dr. Mark Noar, director of The Heartburn and Reflux Study Center in Towson, MD. "In this prospective study, we compared the 10-year follow-up data from patients who had Stretta after failed LNF with data from patients who had Stretta but did not have previous surgery. We found that Stretta patients who had previous LNF surgery experienced a sustained improvement of GERD symptoms equivalent to the standard Stretta patients. Stretta Therapy helps these patients control GERD and reduce chronic medication use without the need for a second LNF surgery," stated Dr. Noar. He added, "Stretta effectively treats the underlying muscle without needing to wrap the stomach or perform other anatomical alteration, it should be considered first line treatment in patients who have failed Nissen."

Mederi CEO Bob Knarr noted that the new study reflects the company's commitment to improving the quality of life for patients who suffer from chronic GERD.

"Stretta's previously published 10-year data, showed that the long-term benefits are similar to the outcomes of surgery with a much lower complication rate. This study further notes the lasting benefits of Stretta for more GERD sufferers, even after other treatment options like surgery have failed," noted Knarr.

### ABOUT MEDERI® AND STRETTA®

Mederi manufactures innovative medical devices that use non-ablative radiofrequency (RF) energy to treat digestive diseases. Stretta has been proven safe and effective for treating GERD in more than 40 studies with long-term follow up showing 10 years of durable symptom relief. Stretta is available worldwide.

For more information please visit:
**stretta-therapy.com**
or call: **855-855-3639**

## CLINICAL GENOMICS ANNOUNCES THE LAUNCH OF COLVERA™ FOR COLORECTAL CANCER RECURRENCE MONITORING

***Centralized CLIA-registered Laboratory Commences Operations***

BRIDGEWATER, N.J., – Clinical Genomics, a private company developing evidence-based diagnostic tools for colorectal cancer, announced the launch of Colvera™, a blood-based test for colorectal cancer (CRC) recurrence monitoring. Colvera is the result of a decade of research, development and clinical

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validation in more than 4,000 patients. Colvera will be performed in Clinical Genomics' dedicated CLIA-registered laboratory in Bridgewater, NJ.

Quest Diagnostics, the world's leading provider of diagnostic information services, will provide specimen collection and logistics services for Colvera test orders. Terms of the agreement were not disclosed.

"Colorectal cancer outcomes improve with early detection, but many recurrence monitoring tests fail to detect disease at a point when clinical intervention has the best chance to be effective," said Lawrence LaPointe, Ph.D., President and CEO of Clinical Genomics. "Colvera is a new test that can aid in the identification of molecular changes associated with cancer development. Colvera is intended to provide physicians with actionable information that can trigger further clinical assessment, which may lead to improved outcomes." Colvera is a qualitative test that indicates the presence or absence of two altered genes associated with CRC. Colvera measures methylation – a genetic change associated with cancer development – in circulating tumor DNA (ctDNA), the fragments of genetic material that leak from a tumor into the bloodstream. Unlike DNA mutations, which are frequent in cancer but may vary widely between patients and may undergo mutation shifts during the course of disease, methylation is a more stable feature in tumors that is readily measured. Colvera is not intended to stratify the risk of recurrence in colorectal cancer patients, but rather to identify the presence of disease at the time of testing.

In a study recently published in the peer-reviewed journal Cancer Medicine, clinical data showed that Colvera detected twice the number of recurrence cases as carcinoembryonic antigen (CEA) testing, the standard blood test used for CRC recurrence monitoring. As Colvera only requires a peripheral blood sample, the test can be administered along with other CRC surveillance tests, including CEA. Colvera does not require specialized equipment or modifications to clinical protocol.

"This is a welcome development in the field of colorectal cancer recurrence monitoring," noted Peter Mencel, M.D., a medical oncologist with Atlantic Hematology Oncology, in Manasquan, New Jersey. "Our goal is to help our patients by detecting a recurrence at the earliest possible time, when the opportunity to undertake curative surgery is greatest. I am hopeful that Colvera will provide clinicians with a new and more informative tool to guide management of our patients."

Clinical Genomics is actively pursuing several research-based collaborations with leading academic and private cancer centers to continue to expand the clinical applications of Colvera.

### *About Colorectal Cancer*

Colorectal cancer (CRC) is one of the leading causes of cancer-related deaths worldwide, accounting for more than 600,000 deaths each year. When diagnosed early, before cancer has spread, the relative five-year survival rate for CRC is 90 percent, but only approximately four out of 10 CRC cases are detected early. Among individuals undergoing surgical treatment for CRC, recurrence occurs in 30 to 50 percent of all cases, the majority of which present in the first two to three years following initial diagnosis and treatment.

### *About Clinical Genomics*

Clinical Genomics is a privately held biotechnology company committed to reducing the impact of colorectal cancer (CRC) through early detection of disease and clinically actionable, evidence-driven recurrence monitoring tools. With a broad intellectual property portfolio consisting of more than 20 patents, Clinical Genomics, via its wholly-owned subsidiary Enterix Inc., currently offers the user-friendly, patient-preferred CRC screening InSure® FIT™ assay, a fecal immunochemical test that detects blood in the stool. InSure is also marketed as a lab-based test in Australia and other countries (ColoVantage Home). Building on an established history in the field of CRC screening and diagnosis, Clinical Genomics developed Colvera, a blood-based circulating tumor DNA (ctDNA) test for colorectal cancer based on methylated DNA from two genes, *BCAT1* and/or *IKZF1*.

Clinical Genomics has offices and laboratories in Bridgewater and Edison, New Jersey and Sydney, Australia, and operates as an FDA-registered and TGA-licensed manufacturer and a NATA-accredited laboratory. For more information, please visit:

**colveratest.com**
**clinicalgenomics.com**