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Interpace Biosciences Announces Collaborative Study with University of North Carolina to Assess the Use BarreGEN® after Ablation of Dysplastic Barrett's Esophagus

Parsippany, NJ, Jan. 06, 2020 (GLOBE NEWSWIRE) -- Interpace Biosciences, Inc. (Nasdaq: IDXG), a leader in enabling personalized medicine, today announced that the Company's wholly-owned subsidiary, Interpace Diagnostics has entered into a collaborative study aimed at exploring the potential use of BarreGEN® in patients undergoing radiofrequency ablation (RFA). RFA is typically known as a cancer preventative therapy that either delays or arrests the progression of Barrett's Esophagus to esophageal cancer. Evidence to date suggests that BarreGEN® may identify non-dysplastic Barrett's Esophagus patients in need of ablation, making targeted ablation a potentially cost-effective treatment option. This new collaborative study performed in partnership with the University of North Carolina Division of Gastroenterology under the direction of Nick Shaheen, MD MPH, using the BarreGEN® assay developed by Interpace aims to target the potential for molecular changes to predict resistance or relapse following RFA.

The study is a prospective, single site study which will be performed using BarreGEN® and targeted to evaluate approximately 60 patients with dysplastic Barrett's undergoing RFA. Use of BarreGEN® may allow clinicians to adjust ablative protocols providing optimal treatment response and improved patient outcome. The assay may also aid in recognition of patients at risk for recurrence of Barrett's after initially successful ablation. The study is expected to begin enrolling patients early in the first quarter of 2020 with the hope of readout later in the year.

Historically, BarreGEN® has been evaluated under a Clinical Experience Program (or CEP) and has been used only by patients with non-dysplastic Barrett's Esophagus to help physicians assess the risk of progression to esophageal cancer to enable optimal management decisions. This new study will evaluate the ability of BarreGEN® results to predict RFA treatment resistance in patients with dysplastic Barrett's and the need for additional or alternative intervention.

"We look forward to reporting the results of this novel study that will combine Interpace's molecular expertise in Barrett's with UNC's clinical and research expertise" said Jack Stover, CEO of Interpace Biosciences. He continued "We believe this is another important step in bringing our BarreGEN® test more broadly to the market to potentially modify treatment plans that can improve patient outcomes. Defining the value of BarreGEN® in this new

patient population may give clinicians a new use for this powerful assay.”

About Interpace Biosciences

Interpace Biosciences is a leader in enabling personalized medicine, offering specialized services along the therapeutic value chain from early diagnosis and prognostic planning to targeted therapeutic applications.

Interpace Diagnostics is a fully integrated commercial and bioinformatics business unit that provides clinically useful molecular diagnostic tests, bioinformatics and pathology services for evaluating risk of cancer by leveraging the latest technology in personalized medicine for improved patient diagnosis and management. Interpace has four commercialized molecular tests and one test in a clinical evaluation process (CEP): PancreGEN[®] for the diagnosis and prognosis of pancreatic cancer from pancreatic cysts; ThyGeNEXT[®] for the diagnosis of thyroid cancer from thyroid nodules utilizing a next generation sequencing assay; ThyraMIR[®] for the diagnosis of thyroid cancer from thyroid nodules utilizing a proprietary gene expression assay; and RespriDX[®] that differentiates lung cancer of primary vs. metastatic origin. In addition, BarreGEN[®] for Barrett’s Esophagus, is currently in a clinical evaluation program whereby we gather information from physicians using BarreGEN[®] to assist us in positioning the product for full launch, partnering and potentially supporting reimbursement with payers.

Interpace Pharma Solutions provides pharmacogenomics testing, genotyping, biorepository and other customized services to the pharmaceutical and biotech industries while also advancing personalized medicine by partnering with pharmaceutical, academic, and technology leaders to effectively integrate pharmacogenomics into their drug development and clinical trial programs with the goals of delivering safer, more effective drugs to market more quickly, and improving patient care.

For more information, please visit Interpace Biosciences’ website at www.interpace.com.

About BarreGEN[®]

BarreGEN[®] is a molecular based assay performed on esophageal specimens from patients with Barrett’s esophagus to help assess risk of progression to esophageal cancer. Barrett’s esophagus, often diagnosed in patients with long standing gastroesophageal reflux disease, is a known risk factor for esophageal cancer. BarreGEN[®] analysis quantifies mutational load providing an indication of cumulative genomic instability. Understanding future risk of progression to esophageal cancer based on genomic changes can help limit unnecessary repeat endoscopies in patients with low risk and justify more aggressive management, such as ablative therapy or surgery, in patients with higher risk.

About Dr. Nicholas Shaheen

Nicholas Shaheen, MD MPH is Chief of the Division of Gastroenterology & Hepatology University of North Carolina School of Medicine, Chapel Hill. As a prominent gastroenterologist and epidemiologist, Dr. Shaheen has been awarded the Bozymski-Heizer Distinguished Professorship at the University of North Carolina School of Medicine. He has authored more than 400 papers and book chapters with focus on pre-cancerous and

cancerous conditions of the esophagus, as well as esophageal motility disorders and reflux disease.

Dr. Shaheen is well known for his groundbreaking research on Barrett's esophagus. A major theme of his research has been developing and testing new endoscopic methods for treatment of patients with Barrett's. He was the principal investigator of a 19 center U.S. trial of radiofrequency ablation for dysplastic Barrett's esophagus, demonstrating the efficacy and safety of this procedure. The paper was published in the New England Journal of Medicine. He was also the lead investigator of a 10-center study defining the efficacy of cryotherapy in subjects with Barrett's and high-grade dysplasia. These endoscopic technologies have fundamentally changed the care of patients with early esophageal neoplasia. He is also a member of several consortia that are conducting translational studies of Barrett's patients.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, relating to the Company's future financial and operating performance. The Company has attempted to identify forward looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are based on current expectations, assumptions and uncertainties involving judgments about, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the Company's control. These statements also involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results to be materially different from those expressed or implied by any forward-looking statement. Additionally, all forward-looking statements are subject to the "Risk Factors" detailed from time to time in the Company's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10Q. Because of these and other risks, uncertainties and assumptions, undue reliance should not be placed on these forward-looking statements. In addition, these statements speak only as of the date of this press release and, except as may be required by law, the Company undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

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