Newly Published Data from National Study Supports Interpace Diagnostics’ PancraGEN®

New Article in Peer-Reviewed Journal Highlights Important Role of PancraGEN® Testing

PARSIPPANY, NJ, Nov. 26, 2018 (GLOBE NEWSWIRE) -- Interpace Diagnostics Group, Inc. (NASDAQ: IDXG) announced today a new scientific paper was published and the primary conclusion showed that DNA analysis using PancraGEN® has a favorable impact on patient outcomes particularly in patients with cysts that have worrisome features supporting more accurate surgery and surveillance decisions. The paper entitled “The Incremental Value of DNA Analysis in Pancreatic Cysts Stratified by Clinical Risk Factors” was published in the November edition of Gastrointestinal Endoscopy, the official peer-reviewed publication of the American Society for Gastrointestinal Endoscopy. The three DNA abnormalities examined in the study, all of which are included in the PancraGEN® assay, included: elevated DNA quantity, KRAS mutation, and loss of heterozygosity (LOH) mutations among a panel of key tumor suppressor genes.

The authors of the article included Dr. James Farrell of Yale University, Dr. Mohammad Al-Haddad of Indiana University, and Dr. Tamas Gonda of Columbia University and the study assessed a total of 478 patients. Of this cohort, 209 had surgical pathology derived outcomes and 269 had clinical follow up of 2 to 8 years. Among patients with worrisome cysts, the presence of multiple DNA abnormalities significantly increased risk of malignancy and the absence of all DNA abnormalities significantly decreased risk to very low levels. Importantly, the absence of all DNA abnormalities deescalated risk in 50% of worrisome cysts, which is consistent with other reports concluding that ancillary DNA testing alters decisions for surgery in 54% of cases in which there are intermediate levels of concern; 79% of such decisions favored observation rather than surgery (Arner DM et al, Endosc Ultrasound 2018;7:29-33).

Jack Stover, President and CEO of Interpace, stated, “This newly published study representing nearly 500 patients authored by these luminaries from such highly respected institutions in a top tier peer reviewed journal provides the most important evidence to date that the use of PancraGEN® can significantly improve outcomes in targeted patient populations.”

About PancraGEN® and PanDNA®

PancraGEN® is a molecular, cancer risk classifier for cysts, solid lesions, and biliary strictures that have potential for pancreatic or bile duct cancer and that by using a small sample of fluid or duct brush, can aid in cancer risk assessment. PancraGEN® is 90% accurate according to clinical studies, enabling effective risk stratification of patients with pancreatic cysts and has been used in over 40,000 cysts since its commercial launch. PancraGEN® utilizes integrated molecular pathology (IMP) which incorporates clinical and imaging data, Carcinoembryonic Antigen (CEA) and Amylase values, and multiple molecular
markers evaluated using DNA sequencing. All elements are reviewed my molecular pathologists who assign each case a clinical risk stratification ranging from benign to malignant depending on the aggregate assessment encompassing all of these factors. The Company also now offers a ‘molecular only’ version of PancraGEN® called PanDNA® that only reports the molecular results, enabling clients to conduct their own comprehensive clinical risk assessment based on DNA abnormalities tested by PancraGEN®.

About Interpace Diagnostics Group, Inc.

Interpace is a fully integrated commercial and bioinformatics company that provides clinically useful molecular and related first line diagnostic tests and pathology services for evaluating risk of cancer by leveraging the latest technology in personalized medicine for improved patient diagnosis and management. The Company currently has four commercialized molecular tests and one test in a clinical evaluation process (CEP); PancraGEN® for the diagnosis and prognosis of pancreatic cancer from pancreatic cysts; ThyGenX® 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. BarreGEN®, for Barrett's Esophagus, is currently being “soft launched” with key opinion leaders as we continue to gather data on this assay that will assist us in seeking favorable reimbursement as well as important clinical information. Barrett's Esophagus is a rapidly growing diagnosis that affects over three million people in the US, and over time can progress to esophageal cancer. The Company’s data base includes data from over 45,000 patients who have been tested using the Company’s current products, including over 15,000 molecular tests for thyroid nodules. Interpace has been designated by CIO Applications magazine as one of the top 20 companies for providing bioinformatics solutions. Interpace’s mission is to provide personalized medicine through molecular diagnostics, innovation and data to advance patient care based on rigorous science. For more information, please visit Interpace’s website at www.interpacediagnostics.com

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, 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. Known and unknown risks, uncertainties and other factors include, but are not limited to, the Company’s history of losses, the Company’s ability to adequately finance the business, the market’s acceptance of its molecular diagnostic tests, its ability to retain or secure reimbursement, its ability to secure additional business and generate higher profit margins through sales of its molecular diagnostic tests, in-licensing or other means, projections of future revenues, growth, gross profit and anticipated internal rate of return on investments and its ability to maintain its NASDAQ listing. Additionally, all forward-looking statements are subject to the “Risk Factors” detailed from time to time in the Company's SEC filings, including its Annual...
Report on Form 10-K for the fiscal year ended December 31, 2017, filed on March 23, 2018, Quarterly Reports on Form 10-Q and other SEC filings. 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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