

# Interpace Diagnostics Expands Application of Pancreatic Cancer Test

# PancraGEN® Gaining Further Guideline Support and Expanded Use for Multiple New Indications

PARSIPPANY, N.J., July 19, 2018 (GLOBE NEWSWIRE) -- Interpace Diagnostics Group, Inc. (NASDAQ:IDXG) (the "Company" or "Interpace Diagnostics"), a fully integrated commercial and bioinformatics company that provides clinically useful molecular diagnostic tests and pathology services for improved patient diagnosis and management, announced today that the Company has expanded the application of PancraGEN® beyond pancreatic cysts to include both biliary strictures and solid pancreatic lesions while gaining further Guideline support in the marketplace. PancraGEN® is the first and only commercially available integrated molecular pathology test for pancreaticobiliary cancers.

Since 2015, when the Company first published data from the National Pancreatic Cyst Registry (NPCR) demonstrating PancraGEN®'s effectiveness compared to standard international guidelines, the Company has been the leader in evaluating pancreatic cysts to determine their likelihood of developing in to cancer. Now the use of PancraGEN® is expanded beyond just pancreatic cysts to include solid pancreaticobiliary lesions based on guideline supported use of molecular testing and newly published clinical studies related to use of PancraGEN® to diagnose both pancreatic and bile duct cancer (cholangiocarcinoma).

Specifically, the most recent National Comprehensive Cancer Network (NCCN) Guidelines (2018) for Hepatobiliary Cancers recommend molecular testing in symptomatic patients with biliary obstruction or abnormality on imaging in order to diagnose the presence of cholangiocarcinoma and to help select a treatment pathway. Furthermore, the most recent American College of Gastroenterology Guidelines for the management of primary sclerosing cholangitis (PSC) recommend molecular testing in order to exclude the diagnosis of cholangiocarcinoma.

In addition, the National Comprehensive Cancer Network (NCCN) Guidelines for Pancreatic Cancer (2018) include three separate references to molecular testing including a reference to the important role of endoscopic ultrasound (EUS) as well as molecular testing for better characterization of the lesion. The NCCN Guidelines also now clearly spell out the most common somatic mutations that occur in pancreatic cancer and, importantly, these genes are all interrogated in PancraGEN®'s molecular analysis. Additionally, the NCCN Guidelines now emphasize the fundamental role that molecular analysis plays in determining the best strategies for patient management.

Three new peer reviewed publications support the use of PancraGEN® in biliary strictures and solid pancreatic lesions for diagnosing malignancy. The papers are: "Mutation Profile

and Fluorescence in Situ Hybridization Analyses Increase Detection of Malignancies in Biliary Strictures", Clinical Gastroenterology and Hepatology, Tamas Gonda, M.D., et. al.; "The Diagnostic Yield of Malignancy Comparing Cytology, FISH, and Molecular Analysis of Cell Free Cytology Brush Supernatant in Patients with Biliary Strictures Undergoing Endoscopic Retrograde Cholangiography (ERC): A Prospective Study", Journal of Clinical Gastroenterology, Vladimir Kushnir, M.D., et. al.; and "Mutation Profiling Impacts Clinical Decision Making and Outcomes of Patients with Solid Pancreatic Lesions Indeterminate by Cytology", Journal of the Pancreas, Ananya Das, M.D., et. al. All three of these papers are based on independent research conducted at Columbia University, Washington University, and the Arizona Center for Digestive Health respectively.

According to Syd Finkelstein MD, Chief Medical & Scientific Officer of Interpace, "The recent NCCN Guidelines are an encouraging sign that molecular testing is now becoming the standard of care for diagnosis of both pancreatic and bile duct cancers and molecular results will be used more broadly to establish optimal treatment plans." He added, "These peer reviewed papers also provide clear support for the expanded use of PancraGEN® in solid lesion types, not just pancreatic cysts."

In addition, Jack Stover, President & CEO of Interpace, stated "We are pleased to see the updated NCCN Guidelines and the multiple peer reviewed papers that further support the use of molecular diagnostics in assessing the potential for pancreatic and bile duct cancers across a more expansive patient population." Mr. Stover continued, "We are already seeing the enhanced utilization of PancraGEN® which can potentially now serve as a one-stop shop for physicians and patients who need to know, as early as possible, whether or not they have or will develop cancer."

#### About PancraGEN®

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. Pancreatic cancer is often difficult to diagnose in early stages and typically spreads rapidly with signs and symptoms appearing when the cancer is significantly advanced. Because of this, and that complete surgical removal of the pancreas is not possible, pancreatic cancer is one of the leading causes of cancer deaths.

## **About Interpace Diagnostics Group, Inc.**

Interpace is a fully integrated commercial and bioinformatics company that provides clinically useful molecular 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 60,000 patients who have been tested using the Company's current products, including over 25,000 molecular tests for thyroid nodules. Interpace has been designated 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 <a href="https://www.interpacediagnostics.com">www.interpacediagnostics.com</a>

### **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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