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# Interpace Biosciences Announces Results of Seminal Clinical Validation Study for Thyroid Assays

***Study Demonstrates Superior Performance of ThyGeNEXT® and ThyraMIR® vs. Other Molecular Tests***

PARSIPPANY, NJ, Oct. 26, 2020 (GLOBE NEWSWIRE) -- Interpace Biosciences, Inc. (NASDAQ: IDXG) announced today that the study entitled "Multiplatform molecular test performance in indeterminate thyroid nodules" was published on-line in the peer-reviewed journal, *Diagnostic Cytopathology*. This paper represents the culmination of a multi-center, blinded clinical validation study in which gold standard unanimous histopathology consensus diagnosis was utilized. The study results demonstrate that ThyGeNEXT® + ThyraMIR® combination testing yield the highest positive predictive value (PPV) and similar negative predictive value (NPV) in comparison to other marketed tests for the same indication.

Approximately 25% of thyroid nodule fine needle aspirates (FNAs) have cytology that is indeterminate for malignant disease. Ancillary multiplatform testing with ThyGeNEXT® and ThyraMIR® assists in the accurate risk stratification of these FNAs, ultimately helping to distinguish patients who are more likely to benefit from conservative management from those who are more likely to benefit from surgical intervention.

The published manuscript is the first to report the performance characteristics of combination ThyGeNEXT® and ThyraMIR® testing in a blinded multicenter study. ThyGeNEXT® is the company's most recent next generation sequencing based test that was expanded from its original version (ThyGenX®) to include markers that have targeted therapies and those that can identify aggressive forms of thyroid cancer. The study demonstrates that combination testing with ThyGeNEXT® and ThyraMIR® has both high sensitivity (95%) and high specificity (90%) for identifying disease. It also highlights the important role that ThyraMIR®—the company's proprietary microRNA risk classifier—can play in helping to identify malignancy in nodules where single platform mutation panels commonly detect mutations that by themselves have suboptimal PPV for malignancy.

According to Jack Stover, President and CEO of Interpace, "The results of this independent study reported in a well-respected journal reflect the strong clinical performance and overall value of our combined thyroid assays in helping physicians manage their patients with potential thyroid cancer."

**About ThyGeNEXT® and ThyraMIR®**

ThyGeNEXT® is Interpace's most recent next generation sequencing test that was

expanded from its original version (ThyGenX®) to include markers that have targeted therapies and those that can identify aggressive forms of thyroid cancer.

ThyGeNEXT® utilizes state-of-the-art next-generation sequencing (NGS) to identify more than 100 genetic alterations associated with papillary and follicular thyroid carcinomas, the two most common forms of thyroid cancer, as well as Medullary Thyroid Carcinoma. ThyraMIR® is the first microRNA gene expression classifier. MicroRNAs are small, non-coding RNAs that bind to messenger RNA and regulate expression of genes involved in human cancers, including every subtype of thyroid cancer. ThyraMIR® measures the expression of 10 microRNAs. Both ThyGeNEXT® and ThyraMIR® are covered by Medicare and most Commercial insurers.

According to the American Thyroid Association, approximately 20% of the 525,000 thyroid fine needle aspirations (FNAs) performed on an annual basis in the U.S. are indeterminate for malignancy based on standard cytological evaluation, and thus are candidates for ThyGeNEXT® and ThyraMIR®.

ThyGeNEXT® and ThyraMIR® reflex testing yields high predictive value in determining the presence and absence of cancer in thyroid nodules. The combination of both tests can improve risk stratification and surgical decision-making when standard cytopathology does not provide a clear diagnosis.

**About Interpace Biosciences**

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

Clinical services, through Interpace Diagnostics, 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): PancraGEN® 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.

Pharma services, through Interpace Pharma Solutions, provides pharmacogenomics testing, genotyping, biorepository and other customized services to the pharmaceutical and biotech industries. Pharma services also advance 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](http://www.interpace.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. 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 filed on April 22, 2020, Current Reports on Form 8-K and Quarterly Reports on Form 10-Q. 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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