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Interpace Biosciences Announces Acceptance of first paper Demonstrating Clinical Performance of ThyGeNEXT with ThyraMIR

Parsippany, NJ, March 02, 2020 (GLOBE NEWSWIRE) -- Interpace Biosciences, Inc. (Nasdaq: IDYG) today announced acceptance of the first manuscript reporting the clinical performance of the company's ThyGeNEXT[®] and ThyraMIR[®] tests in the Journal of the American Society of Cytopathology. The article, entitled "Clinical performance of multiplatform mutation panel and microRNA risk classifier in indeterminate thyroid nodules", will be published online in the coming weeks.

The peer-reviewed manuscript will be the first to report the clinical performance of the combination of ThyGeNEXT[®] and ThyraMIR[®] in predicting cancer-free survival of patients with indeterminate thyroid nodules. ThyGeNEXT[®] is an expanded version of the previous NGS-based mutation panel test, ThyGenX[®], previously offered by the company. The expanded version now includes additional mutation markers, such as *NTRK* and *ALK* fusions that have targeted therapies and *TERT* and the *RET* proto-oncogene that can be predictive of aggressive disease.

In addition, the abstract has been accepted for a poster presentation at the upcoming Endocrine Society (ENDO) Annual Meeting being held in San Francisco, CA March 28-31st. The poster, entitled "Clinical Performance Of Multiplatform Mutation Panel MicroRNA Risk Classifier In Indeterminate Thyroid Nodules" will be presented in session P56, "Tumor Biology: Diagnostics, Therapies, Endocrine Neoplasias, and Hormone Dependent Tumors" on Sunday, March 29th from 1:00-3:00 p.m.

A study published in 2019 reported the clinical utility of combination ThyGenX[®] and ThyraMIR[®] testing, demonstrating that combination test negative results were associated with the same low rate (11%) of thyroid nodule surgical resection as other tests that effectively rule-out the need for surgery in indeterminate thyroid nodules. Furthermore, the study reported that combination test positive results were associated with high rates (84%) of surgical resection, supporting the effective use of the combination test in also ruling-in the need for surgery. Importantly, the authors also concluded that decisions to surgically treat indeterminate thyroid nodules were appropriately aligned with a patient's risk of malignancy, based on the outcomes of patients in the study who underwent ThyGenX[®] and ThyraMIR[®] testing.

The new publication will report the clinical performance of combination ThyGeNEXT[®] and ThyraMIR[®], in the same patients, with new mutation markers that are part of ThyGeNEXT[®]

highlighted and test results again compared to the clinical outcomes of patients. Both studies were led by Dr. Woody Sistrunk from Endocrinology Center, Jackson, MS.

According to Jack Stover, CEO of Interpace, “This new clinical utility paper expands the evidence that combined ThyGeNEXT[®] and ThyraMIR[®] testing appropriately identified patients with a surgical need from those who should be managed in an alternate manner. We are proud of this clinical report and anticipate future publications that will enhance the data available on the performance of our molecular tests.”

About ThyGeNEXT[®] and ThyraMIR[®]

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 Commercial insurers, with more than 280 million members covered.

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 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): 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.

Interpace's Biopharma provides pharmacogenomics testing, genotyping, biorepository and other customized services to the pharmaceutical and biotech industries. The Biopharma Business also advances 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.

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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