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# Interpace Diagnostics Announces Publication of Important New Data on Thyroid Test Performance

*Data from Registry Study Confirms the Value of ThyGenX<sup>®</sup> and ThyraMIR<sup>®</sup> in a Clinical Setting*

PARSIPPANY, NJ, May 01, 2019 (GLOBE NEWSWIRE) -- Interpace Diagnostics Group, Inc. (NASDAQ: IDYG) ("Interpace" or "the Company") announced today that data from its thyroid registry has been published in the peer reviewed publication *Diagnostic Cytopathology* in a paper called "Clinical impact of testing for mutation and microRNA's in thyroid nodules." The new data from over 300 samples was compiled from a two-year, real-world, retrospective study and highlighted the clinical utility of Interpace's ThyGenX<sup>®</sup> thyroid oncogene panel in combination with ThyraMIR<sup>®</sup>, its micro-RNA classifier. Following the review and acceptance, the study is now available on the journal's website <https://onlinelibrary.wiley.com/doi/full/10.1002/dc.24190> and at <https://thygenext-thyramir.com/>.

In summary, the study shows results from ThyGenX<sup>®</sup> and ThyraMIR<sup>®</sup> combination testing demonstrated the ability to help avoid unnecessary surgical resections as well as help target nodules for which surgery is the accurate approach. Importantly, the study also showed that surgical decisions made with our combination thyroid tests were appropriately aligned with risk of malignancy over multiple years of clinical follow-up, which is consistent with a combination test that effectively rules-in and rules-out higher risk of malignancy. We believe these results further confirm the value that ThyGenX<sup>®</sup> and ThyraMIR<sup>®</sup> combination testing brings when confronted with an indeterminate cytology finding.

Importantly, Interpace conducted a bridge study using both ThyGenX<sup>®</sup> and its newest mutation panel, ThyGeNEXT<sup>®</sup>, that demonstrated 100% concordance between the tests. Further, the Company is now engaged in a separate multi-site clinical validation study of ThyGeNEXT<sup>®</sup> in combination with ThyraMIR<sup>®</sup>. Results from this additional study are expected to be released in the second half of 2019.

Dr. J. Woody Sistrunk, MD, the lead author on the paper said, "This new clinical data confirms the value of complementary use of ThyGenX<sup>®</sup> and ThyraMIR<sup>®</sup> testing in the management of my patients with indeterminate thyroid nodules by cytology. This combination testing approach has greatly reduced the number of unnecessary surgeries for patients in real-world clinical practice."

## About Thyroid Nodules, ThyGeNEXT<sup>®</sup> and ThyraMIR<sup>®</sup> Testing

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<sup>®</sup> and ThyraMIR<sup>®</sup>.

ThyGeNEXT<sup>®</sup> and ThyraMIR<sup>®</sup> 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 for the presence of cancer.

ThyGeNEXT<sup>®</sup> 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. ThyraMIR<sup>®</sup> 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<sup>®</sup> measures the expression of 10 microRNAs. Both ThyGeNEXT<sup>®</sup> and ThyraMIR<sup>®</sup> are covered by both Medicare and Commercial insurers, with more than 280 million patients covered.

### **About Interpace Diagnostics Group**

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. Interpace's mission is to provide personalized medicine through molecular diagnostics, innovation and data to advance patient care based on rigorous science. The Company currently has four commercialized molecular tests and one test in a clinical evaluation process (CEP); PancraGEN<sup>®</sup> for the diagnosis and prognosis of pancreatic cancer from pancreatic cysts; ThyGeNEXT<sup>®</sup> for the diagnosis of thyroid cancer from thyroid nodules utilizing a next generation sequencing assay; ThyraMIR<sup>®</sup> for the diagnosis of thyroid cancer from thyroid nodules utilizing a proprietary gene expression assay; and RespriDx<sup>®</sup> that differentiates lung cancer of primary vs. metastatic origin. BarreGEN<sup>®</sup> 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 50,000 patients who have been tested using the Company's current products, including over 25,000 molecular tests for thyroid nodules. Interpace has been designated by the 2018 edition of *CIO Applications* as one of the top 10 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](http://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. 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. Known and unknown risks, uncertainties and other factors include, but are not limited to, the fact that success in clinical studies may not be replicated in later studies or demonstrate the clinical utility of the test, the market's acceptance of its molecular diagnostic tests and the Company's ability to retain and secure reimbursement among other things. 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 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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