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# Interpace Diagnostics Presents Favorable New Data at the 88th Annual Meeting of the American Thyroid Association (ATA)

ThyGenX<sup>®</sup> and ThyraMIR<sup>®</sup> Data from Clinical Experience Study Shows Positive Results

PARSIPPANY, NJ, Oct. 15, 2018 (GLOBE NEWSWIRE) -- Interpace Diagnostics Group, Inc. (NASDAQ: IDXG) announced that the Company presented new data at the 88<sup>th</sup> Annual Meeting of the American Thyroid Association (ATA) on Friday, October 5<sup>th</sup> supporting its molecular tests for thyroid cancer. The new interim data spanning over 300 samples from a two-year, "real world," retrospective study highlighted the clinical utility of Interpace's ThyGenX<sup>®</sup> thyroid oncogene panel in combination with its micro-RNA classifier, ThyraMIR<sup>®</sup>. J. Woody Sistrunk, MD, founder of the Jackson Endocrine and Thyroid Clinic in Jackson, MS, presented the results during a live poster session and as part of the Product Expo Theater presentation. Currently, the data submission process for publication is underway and the complete results will be made available at that time.

Nine centers from across the U.S. participated in this study, including Dr. Sistrunk's clinic, and the data demonstrated that ThyGenX<sup>®</sup>/ThyraMIR<sup>®</sup> combination test results help avoid unnecessary surgical resections and identify nodules where surgery is appropriate in cytologically indeterminate thyroid nodules. Importantly, the study also demonstrated that surgical decisions made based on the combination test results were appropriately aligned with risk of malignancy over clinical follow-up consistent with a combination test that effectively rules-in and rules-out higher risk of malignancy. These results further confirm the value added by ThyGenX<sup>®</sup>/ThyraMIR<sup>®</sup> combination testing in the risk stratification of thyroid nodules when confronted with an indeterminate cytology diagnosis. These findings are aligned with data from the tests' original validation study conducted by Labourier et al., which was published in the Journal of Clinical Endocrinology and Metabolism (JCEM) in 2015.

The Company also found that the cancer rate among patients who underwent molecular testing was often much lower when compared to the rate of cancer typically reported for other molecular products. Accordingly, the data showed that a combination test which both rules-in and rules-out cancer is more clinically useful given the rule-in feature found in the ThyGenX<sup>®</sup>/ThyraMIR<sup>®</sup> combination test helps to single out those patients who exhibit a higher risk of cancer from the majority who do not.

Recently, Interpace launched an expanded mutation panel called ThyGeNEXT<sup>™</sup>, which includes additional markers such as TERT, PTEN, ALK, and RET among others. As the Company's Clinical Experience Study progresses, patients tested with ThyGeNEXT<sup>™</sup> will also be included to demonstrate the clinical utility of the latest version of the product.

Jack Stover, President and CEO of Interpace Diagnostics, stated, “We are pleased with the favorable response we have received since this data was presented.” He continued, “Having real-world data on how our products positively impact patient care should be well received by practitioners and further validates our novel combination thyroid test.”

### **About Thyroid Nodules and ThyGeNEXT Testing**

According to the American Thyroid Association, approximately 15% to 30% of the 525,000 thyroid fine needle aspirations (FNAs) performed on an annual basis in the U.S. are indeterminate based on standard cytological evaluation, and thus are candidates for ThyGeNEXT™ testing. ThyGeNEXT™ provides high predictive value in determining the presence of cancer in thyroid nodules. The test can improve risk stratification and surgical decision-making when standard cytopathology does not provide a clear diagnosis for the presence of cancer. ThyGeNEXT™ is covered by both Medicare and most Commercial insurers.

Like ThyGenX®, ThyGeNEXT™ utilizes state-of-the-art next-generation sequencing (NGS) to identify more than 150 genetic alterations associated with all forms of thyroid cancer, including papillary, medullary and follicular thyroid carcinomas. According to the American Cancer Society, thyroid cancer is the most rapidly increasing cancer in the U.S., with rates tripling in the last three decades. Most physicians have traditionally recommended thyroid surgery where thyroid nodule biopsy results are indeterminate, not clearly benign, or malignant following traditional cytopathology review; however, without the use of molecular testing, over 70% of these surgical procedures have been found to be ultimately unnecessary, with the nodules being benign.

Molecular testing using ThyGenX® has historically been shown to reduce the rate of unnecessary surgeries in indeterminate cases. To date, the Company has performed ThyGenX® and ThyraMIR® testing on over 25,000 patients and will continue to collect cases into the thyroid registry, which will provide the basis of a peer-reviewed publication confirming the impact of ThyGenX® and ThyraMIR® on physicians’ treatment decisions in real-world settings. The Company will continue to collect data adding to the thyroid registry in order to report utility of the expanded mutation panel, ThyGeNEXT™, over time.

### **About the American Thyroid Association**

The American Thyroid Association® (ATA) is the leading worldwide organization dedicated to the advancement, understanding, prevention, diagnosis, and treatment of thyroid disorders and thyroid cancer. ATA® is an international membership medical society with over 1,700 members from 70 countries around the world. Celebrating its 95<sup>th</sup> anniversary, the ATA® delivers its mission — of being devoted to thyroid biology and to the prevention and treatment of thyroid disease through excellence in research, clinical care, education, and public health.

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

Interpace is a fully integrated commercial and bioinformatics company 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. The Company currently has four commercialized molecular tests and one test in a clinical evaluation process (CEP); PancreGEN<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 45,000 patients who have been tested using the Company's current products, including over 25,000 molecular tests for thyroid nodules. Interpace has also been designated as one of the top 20 companies for providing bioinformatics solutions according to *CIO Applications* magazine, a publication that is known to offer professionals a comprehensive collection of industry trends. 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 Company's ability to adequately finance the business, its ability to restructure its liabilities and other obligations, 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 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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