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# Interpace Diagnostics Announces Launch of New Thyroid Test

## Next Generation Mutation Panel, ThyGeNEXT®, to be Introduced at AACE

BOSTON, May 14, 2018 (GLOBE NEWSWIRE) -- Interpace Diagnostics Group, Inc. (NASDAQ:IDYG) ("Interpace" or "the Company"), a fully integrated commercial and bioinformatics company that provides clinically useful molecular diagnostic tests, bioinformatics, and pathology services for improved patient diagnosis and management, announced today that the Company will launch a proprietary new mutational panel for indeterminate thyroid nodules, ThyGeNEXT®, at the upcoming American Association of Clinical Endocrinologists (AACE) Annual Meeting in Boston, MA, being held May 16-19<sup>th</sup>.

ThyGeNEXT® includes numerous additional molecular markers, gene mutations, and RNA fusions compared to ThyGenX®. The new product represents a more comprehensive set of indicators to not only identify malignant or benign nodules, but also ascertain aggressiveness and other characteristics. "Molecular testing can play an important role in the overall assessment of patients with suspected thyroid cancer, and further advances in this area could provide new insights to better guide physician decision making," stated Tom Fahey, M.D., Chief of Endocrine Surgery at New York Presbyterian Weill Cornell Medical Center and Professor of Surgery at Weill Cornell Medical College.

Importantly, the Company further noted that Novitas, its Medicare Administrative Carrier (MAC), has confirmed that ThyGeNEXT® will immediately be a covered service for Medicare beneficiaries.

Jack E. Stover, President and CEO of Interpace, stated, "ThyGeNEXT®, which has been in development for over a year, represents a significant milestone and aggressive step forward to continue to make our Thyroid franchise one of the preeminent molecular diagnostic participants in this fast-growing sector." Mr. Stover continued, "The additional markers and indicators of aggressiveness should provide physicians more of the kind of incremental insights that they have been seeking to help decide the best approach to take in treating their patients."

ThyGeNEXT® represents the next generation in Interpace's thyroid cancer product line. The initial product, ThyGenX®, launched in August 2014, followed by the debut of ThyraMIR® in 2015. At the time of ThyraMIR®'s introduction, the combined ThyGenX®/ThyraMIR® test created the only combination-testing platform offered with the ability to both rule in and rule out cancer.

### 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 for malignancy based on standard cytological evaluation, and thus are candidates for ThyGeNEXT® testing. ThyGeNEXT® yields 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. Both Medicare and most Commercial insurers cover ThyGeNEXT®.

Like ThyGenX®, ThyGeNEXT® utilizes state-of-the-art next-generation sequencing (NGS) to identify more than 150 genetic alterations associated with papillary and follicular thyroid carcinomas, the two most common forms of thyroid cancer. 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, over 70% of these surgical procedures have been found to be ultimately unnecessary, with the nodules being benign.

Molecular testing using ThyGenX® has been shown to reduce the rate of unnecessary surgeries in indeterminate cases. To date, the Company has performed ThyGenX® and ThyraMIR® testing on over 15,000 patients; the Company is currently collating data from a Thyroid Registry that will provide the basis of a peer-reviewed publication confirming the impact ThyGenX® and ThyraMIR® have had on physicians' treatment decisions in real-world settings.

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

Interpace is a fully integrated commercial and bioinformatics company that provides clinically useful molecular diagnostic tests and pathology services 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® and now 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. 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 45,000 patients who have been tested using the Company's current products, including over 15,000 molecular tests for thyroid nodules. Interpace has been designated by *CIO Applications* magazine 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 [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 filed with the SEC on March 23, 2018 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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Source: Interpace Diagnostics Group, Inc.