

# **Interpace Diagnostics Announces Reimbursement Expansion of ThyGeNEXT™**

## **State of Pennsylvania and New York Approve Commercialization of New Thyroid Cancer Test**

PARSIPPANY, NJ, Sept. 24, 2018 (GLOBE NEWSWIRE) -- Interpace Diagnostics Group, Inc. (IDXG), announced today that it has received approval to launch its newest thyroid product, ThyGeNEXT™, in the States of Pennsylvania and New York. The Pennsylvania approval is final and the New York State approval is conditioned upon receipt of additional information requested. In the interim, Interpace is able to sell its unique ThyGeNEXT™/ThyraMIR® combination test to physicians in these States, which represent two of the largest state populations in the U.S. These approvals now enable physicians and patients in these markets where coverage has recently been granted by numerous payers to access ThyGeNEXT™.

ThyGeNEXT™ is the next generation panel in Interpace's thyroid cancer product line, representing an expansion of the former version, ThyGenX®, which was initially launched in August 2014. The Company's follow-on product, ThyraMIR®, was launched in 2015 thereby creating the only combination testing platform offered with the ability to both rule-in and rule-out thyroid cancer. To date, the Company has performed nearly 25,000 combination ThyGenX®/ThyraMIR® tests for over 400 physicians and hospitals nationwide.

ThyGeNEXT™ now includes numerous additional molecular markers, gene mutations, and RNA fusions than ThyGenX® and interrogates a more comprehensive set of indicators to not only identify malignant or benign nodules, but also ascertain aggressiveness of cancer and other characteristics. The list of additional clinically relevant markers in ThyGeNEXT™ includes PTEN, ALK, TERT, RET and NTRK, among others.

Jack Stover, President and CEO of Interpace Diagnostics, stated, "We are pleased that we are now able to sell our newest thyroid product in these key markets representing significant opportunity for us, but also for physicians and their patients in these States as well."

### **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. 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 papillary, medullary and follicular thyroid carcinomas, the 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 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; 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, 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); 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.

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 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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