

# Interpace Diagnostics Receives Medicare Coverage For Its ThyraMIR™ Micro RNA Gene Expression Classifer

PARSIPPANY, N.J., Feb. 17, 2016 /PRNewswire/ -- Interpace Diagnostics Group Inc. (NASDAQ: IDXG), a fully integrated molecular diagnostics company focused on developing and commercializing innovative diagnostic tests, announced today that its Medicare Administrative Carrier (MAC), Novitas Solutions, has determined that the Company's ThyraMIR™ micro RNA (miRNA) Classifier is medically necessary for patients with fine needle aspiration (FNA) biopsies of the thyroid that are deemed indeterminate by cytology. As a result, the ThyraMIR test is now accessible to more than 50 million covered Medicare patients nationwide effective immediately. ThyGenX® is already covered by Medicare, therefore, the addition of coverage for ThyraMIR provides Medicare covered patients the benefits of the ThyGenX/ThyraMIR combination test.

The ThyraMIR™ miRNA Classifier is used in conjunction with the ThyGenX® Oncogene Panel. Each test consists of markers strongly associated with thyroid cancer and whose detection in preoperative thyroid nodule aspirations has been shown to be highly predictive for thyroid cancer. "The combined testing is a novel diagnostic strategy that can improve the preoperative diagnosis and surgical management of patients with indeterminate thyroid nodules," said Jack Stover, Interim CEO of Interpace Diagnostics. "This expanded coverage, along with our recently announced collaboration with LabCorp, should contribute to increased volume for our ThyGenX/ThyraMIR tests during 2016."

Thyroid nodules are becoming increasingly prevalent. According to the American Thyroid Association, approximately 15% to 30% of the 525,000 thyroid FNAs performed on an annual basis in the U.S. are indeterminate based on standard cytological evaluation, and thus are candidates for ThyGenX and ThyraMIR. Guidelines from the National Comprehensive Cancer Network (NCCN) indicate that molecular diagnostic approaches may be useful in the evaluation of thyroid FNA samples that are indeterminate to assist in patient management, including identifying patients who are appropriate candidates for surgery and those for whom active surveillance is the appropriate course of action.

#### ThyGenX® Oncogene Panel

ThyGenX is used to improve risk stratification and surgical decision-making when standard cytopathology does not provide a clear diagnosis of thyroid cancer. Accordingly, ThyGenX assists physicians in distinguishing between benign and malignant genotypes in indeterminate thyroid nodules by utilizing 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 malignancies. The ThyGenX panel design is based on the miR*Inform*® test, whose high predictive value has been validated in a recent prospective clinical study involving over 600 patients. Interpace Diagnostics acquired the miR*Inform* test from Asuragen in 2014, and the test has subsequently been upgraded to

an NGS platform, providing greater genomic insights and increased panel content.

## ThyraMIR™ Micro RNA Classifier

ThyraMIR miRNA Classifier is the first and only 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 and, when used in combination with ThyGenX, yields high negative predictive value and high positive predictive value. This results in improved molecular classification of both benign and malignant thyroid nodules independent of thyroid cancer prevalence in the clinical setting.

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

Interpace Diagnostics is focused on developing and commercializing molecular diagnostic tests, leveraging the latest technology and personalized medicine for better patient diagnosis and management. The company currently has three commercialized molecular tests; PancraGen® for the diagnosis and prognosis of pancreatic cancer from pancreatic cysts; ThyGenX, for the diagnosis of thyroid cancer from thyroid nodules utilizing a next generation sequencing assay and ThyraMIR, for the diagnosis of thyroid cancer from thyroid nodules utilizing a proprietary gene expression assay. Interpace Diagnostics mission is to provide personalized medicine through molecular diagnostics and innovation to advance patient care based on rigorous science.

### **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 our 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 company's control. These statements also involve known and unknown risks, uncertainties and other factors that may cause 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, our ability to adequately finance the business, the market's acceptance of our molecular diagnostic tests; our ability to secure additional business and generate higher profit margins through sales of our molecular diagnostic tests, in-licensing or other means, projections of future revenues, growth, gross profit and anticipated internal rate of return on investments. Additionally, all forward-looking statements are subject to the risk factors detailed from time to time in the company's periodic filings with the Securities and Exchange Commission (SEC), including without limitation, the Annual Report on Form 10-K filed with the SEC on March 5, 2015 and in the company's Form 10-Q filed with the SEC on November 12, 2015. 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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