

# Interpace Diagnostics Announces Launch of Enhancement to Thyroid Testing Services

# New Molecular Marker of Aggressiveness Being Added to ThyGenX Test Offering

PARSIPPANY, N.J., May 24, 2017 /PRNewswire/ -- Interpace Diagnostics Group, Inc. (NASDAQ: IDXG) (the "Company" or "Interpace Diagnostics"), a fully integrated commercial company that provides clinically useful molecular diagnostic tests and pathology services for improved patient diagnosis, announced today that the Company is launching a new biomarker to be ordered along with its current molecular thyroid testing options. The TERT marker is a strong molecular predictor of the aggressiveness of thyroid cancer and adds additional insights in to a patients' molecular profile. Currently, the ThyGenX™ mutation panel includes the following markers that are predictive of thyroid cancer from cytologically indeterminate thyroid nodules, including BRAF, HRAS, KRAS, NRAS, RET/PTC, PAX8/PPARy, and PIK3CA. By adding TERT, the panel will not only continue to be a strong positive predictor of thyroid cancer, but will also provide evidence that a positive result indicates the cancer is likely to be more aggressive in nature.

Telomerase reverse transcriptase or TERT encodes the reverse transcriptase component of telomerase, which adds telomere repeats to chromosome ends, enabling cell replication. Published data suggests that TERT mutations can extend the life span of the tumor cell and allow time for other mutations to develop. Mutations in the TERT promoter region are found in thyroid cancers and seem to act synergistically when they occur with the BRAF V600 mutation. The coexistence of mutations in TERT and BRAF genes have been shown to dramatically increase the risk of thyroid cancer aggressiveness, tumor recurrence and thyroid cancer-specific deaths.

Physicians will be able to order TERT as part of the ThyGenX mutation panel or on an individual basis. To date, the Company has performed the ThyGenX/ThyraMIR test combination assay on over 10,000 patients on behalf of over 250 physicians and hospitals nationwide.

ThyGenX - ThyraMIR represents the only test in the market that combines the rule-in properties of next-generation sequencing of a patient's DNA and RNA, with rule-out capabilities of a micro-RNA classifier to provide physicians with clinically actionable test results. Based on current performance, over 80% of the Company's total cases are reflexed to ThyraMIR for additional assessment. The Company first launched ThyGenX in October, 2014, ThyraMIR in April, 2015, and both products in the State of NY in September, 2016, making the combination test available to Endocrinologists and Pathologists nationwide.

According to the American Cancer Society, thyroid cancer is the most rapidly increasing cancer in the U.S., tripling in the past 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, 70%-80% of these surgical outcomes are ultimately benign. Molecular testing using ThyGenX – ThyraMIR has been shown to reduce the rate of unnecessary surgeries in indeterminate cases.

Jack E. Stover, President and CEO of Interpace Diagnostics stated, "We are pleased to be launching this enhancement to our Thyroid services at the request of our customers. This marker will provide physicians and their patients with incremental insights into their risk for particularly aggressive thyroid cancer."

# About Thyroid Nodules, ThyGenX and ThyraMIR 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 ThyGenX and ThyraMIR.

ThyGenX and ThyraMIR reflex testing yield 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.

ThyGenX 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 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 measures the expression of 10 microRNAs. Both ThyGenX and ThyraMIR are covered by both Medicare and Commercial insurers.

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

Interpace Diagnostics is a 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. 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. We have 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 our control. These statements also involve known and unknown risks, uncertainties and other factors that may cause our 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 our business, our ability to restructure our liabilities and other obligations, the market's acceptance of our molecular diagnostic tests, our ability to retain or secure reimbursement, 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, and our ability to maintain our NASDAQ listing. Additionally, all forward-looking statements are subject to the risk factors detailed from time to time in our periodic filings with the Securities and Exchange Commission (SEC), including without limitation, the Annual Report on Form 10-K related to our year ended December 31, 2016 filed with the SEC on March 31, 2017, as amended on April 28, 2017, and the Quarterly Report on Form 10-Q related to our guarter ended March 31, 2017 filed with the SEC on May 12, 2017. 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, we undertake no obligation to revise or update publicly any forward-looking statements for any reason.

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