

July 21, 2020



# Interpace Announces Acceptance of Seminal Clinical Validation Study for Thyroid Assays

***Podium Presentation Accepted for the American Society of Cytopathology (ASC) Annual Meeting***

PARSIPPANY, NJ, July 21, 2020 (GLOBE NEWSWIRE) -- Interpace Biosciences, Inc. (NASDAQ: IDYG) announced today that a peer-reviewed manuscript describing results from a seminal clinical validation study of the combination of ThyGeNEXT<sup>®</sup> and ThyraMIR<sup>®</sup> has been accepted for publication in the highly respected journal, *Diagnostic Cytopathology*. The study, led by Dr. Mark Lupo from the Thyroid and Endocrine Center of Florida, reported on the ability of the combination of ThyGeNEXT<sup>®</sup>/ThyraMIR<sup>®</sup> tests to successfully stratify nearly 200 indeterminate thyroid nodules for risk of malignancy. Sites participating in this multicentered study included Cedars-Sinai Medical Center, Jackson Thyroid & Endocrine Clinic, University of Michigan, Massachusetts General Hospital/Harvard Medical School, and the University of Arkansas for Medical Sciences.

According to Jack Stover, President and CEO of Interpace, "We're excited that this important study will soon be published in such a prominent peer reviewed journal and will be further highlighted at the ASC Annual Meeting in November." He continued "We look forward to sharing these results with the physician and payer communities shortly."

## **About ThyGeNEXT<sup>®</sup> and ThyraMIR<sup>®</sup>**

ThyGeNEXT<sup>®</sup> is Interpace's most recent next generation sequencing test that was expanded from its original version (ThyGenX<sup>®</sup>) to include markers that have targeted therapies and those that can identify aggressive forms of thyroid cancer.

ThyGeNEXT<sup>®</sup> 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, as well as Medullary Thyroid Carcinoma. ThyraMIR<sup>®</sup> 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<sup>®</sup> measures the expression of 10 microRNAs. Both ThyGeNEXT<sup>®</sup> and ThyraMIR<sup>®</sup> are covered by Medicare and Commercial insurers, with more than 280 million members covered.

According to the American Thyroid Association, approximately 20% 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<sup>®</sup> and ThyraMIR<sup>®</sup>.

ThyGeNEXT<sup>®</sup> and ThyraMIR<sup>®</sup> reflex testing yields 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.

### **About Interpace Biosciences**

Interpace Biosciences is an emerging leader in enabling personalized medicine, offering specialized services along the therapeutic value chain from early diagnosis and prognostic planning to targeted therapeutic applications.

Clinical services, through Interpace Diagnostics, 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. Interpace has four commercialized molecular tests and one test in a clinical evaluation process (CEP): PancraGEN<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. In addition, BarreGEN<sup>®</sup> for Barrett's Esophagus, is currently in a clinical evaluation program whereby we gather information from physicians using BarreGEN<sup>®</sup> to assist us in positioning the product for full launch, partnering and potentially supporting reimbursement with payers.

Pharma services, through Interpace Pharma Solutions, provides pharmacogenomics testing, genotyping, biorepository and other customized services to the pharmaceutical and biotech industries. Pharma services also advance personalized medicine by partnering with pharmaceutical, academic, and technology leaders to effectively integrate pharmacogenomics into their drug development and clinical trial programs with the goals of delivering safer, more effective drugs to market more quickly, and improving patient care.

For more information, please visit Interpace Biosciences' website at [www.interpace.com](http://www.interpace.com).

### **About ASC**

The American Society of Cytopathology (ASC), founded in 1951, is a 3,000 member distinguished national professional society of physicians, cytotechnologists and scientist who are dedicated to the cytologic method of diagnostic pathology. The ASC's diverse membership includes representatives from other countries who share a vision of education, research and continuous improvement in the standards and quality of patient care. The ASC is a unique society that provides a forum where physicians and cytotechnologists can interact and network with each other on both a personal and professional level.

### **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, including the adverse impact of the Coronavirus (COVID-19) pandemic, our history of operating losses and the limited revenue generated by our clinical and pharma services customers, our dependence on sales and reimbursements from our clinical services, our reliance on third parties to process and transmit claims to payers for our clinical services, and any delay, data loss, or other disruption in processing or transmitting such claims could have an adverse effect on our revenue and financial condition, our revenue recognition being based in part on our estimates for future collections which estimates may prove to be incorrect, that we will be able to meet our revenue projections and that there is no guarantee that we will be successful in completing development or realize any revenue or benefit from our efforts to launch a new product line of antibody testing of the COVID-19 virus. 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 on April 22, 2020, Current Reports on Form 8-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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Source: Interpace Biosciences, Inc.