

Interpace Biosciences Announces New PLA Code and Medicare Reimbursement Increase for Proprietary Thyroid Assay, ThyGeNEXT®

Parsippany, NJ, April 05, 2021 (GLOBE NEWSWIRE) -- Interpace Biosciences, Inc. ("Interpace" or the "Company") (OTCQX: IDXG) announced today that Novitas, its Medicare Administrative Contractor, has agreed to recognize the new Proprietary Laboratory Analysis (PLA) code that specifically identifies ThyGeNEXT® as a distinct test from any other test or service. PLA codes are an addition to the current procedural terminology (CPT®) code set approved by the American Medical Association CPT® Editorial Panel. PLA codes are alphanumeric CPT codes with a corresponding descriptor for labs that want to more specifically identify their test. The new PLA code for ThyGeNEXT® is 0245U and the reimbursement for this code remains \$2,919, representing a significant price increase over the prior reimbursement level of \$560. In December, 2020, Novitas issued a new local coverage determination (LCD) for ThyGeNEXT® that reflects the test's enhanced mutation panel. In 2020, Interpace processed approximately 15,000 ThyGeNEXT® tests for over 700 physicians.

Further information regarding the billing and coding article related to this change is available on the Centers for Medicare & Medicaid Services (CMS) website under Biomarkers for Oncology (A52986). The change to the code will be officially published on-line when Novitas updates their website April 22nd, 2021.

According to Tom Burnell, President & CEO of Interpace, "This is an important milestone for our Company; it not only demonstrates the enhanced value that ThyGeNEXT[®] provides physicians and their patients, but recognizes the enhancements made to the assay since it was first developed and launched." He continued "This newly established code will also provide incremental financial value to the Company as we roll out the new code and its associated fee."

About ThyGeNEXT® and ThyraMIR®

ThyGeNEXT[®] 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[®] is the first microRNA gene expression classifier. MicroRNAs are small, noncoding 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 ThyGeNEXT[®] and ThyraMIR[®] 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® and ThyraMIR®.

ThyGeNEXT[®] and ThyraMIR[®] 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 five commercialized molecular tests and one test in a clinical evaluation process (CEP): PancraGEN® for the diagnosis and prognosis of pancreatic cancer from pancreatic cysts; PanDNA, a "molecular only" version of PancraGEN® that provides physicians a snapshot of a limited number of factors; 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 versus metastatic origin. In addition, BarreGEN®, a molecular based assay that helps resolve the risk of progression of Barrett's Esophagus to esophageal cancer, is currently in a clinical evaluation program (CEP) whereby we gather information from physicians using BarreGEN® to assist us in gathering clinical evidence relative to the safety and performance of the test and also providing data that will potentially support payer reimbursement.

Pharma services, through Interpace Pharma Solutions, provides pharmacogenomics testing, genotyping, biorepository and other customized services to the pharmaceutical and biotech industries. Pharma services also advances 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, while also improving patient care.

For more information, please visit Interpace Biosciences' website at <u>www.interpace.com</u>.

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 forwardlooking 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 statements including, but not limited to, the adverse impact of the COVID-19 pandemic on the Company's operations and revenues, the substantial doubt about the Company's ability to continue as a going concern, the possibility that the Company's estimates of future revenue may prove to be materially inaccurate, the Company's history of operating losses, the Company's ability to adequately finance its business, the Company's ability to repay its \$5M secured bridge loan, the Company's dependence on sales and reimbursements from its clinical services, the Company's ability to retain or secure reimbursement including its reliance on third parties to process and transmit claims to payers and the adverse impact of any delay, data loss, or other disruption in processing or transmitting such claims, the Company's revenue recognition being based in part on estimates for future collections which estimates may prove to be incorrect, and the Company's ability to remediate material weaknesses in internal controls. Additionally, all forward-looking statements are subject to the "Risk Factors" detailed from time to time in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 to be filed with the Securities and Exchange Commission, 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.