January 27, 2025

PancraGEN® Will Continue to be Offered While Interpace Re-evaluates its Previously Announced Re-structuring Plan

PARSIPPANY, NJ, Jan. 27, 2025 (GLOBE NEWSWIRE) -- Interpace Diagnostics®, a subsidiary of Interpace Biosciences®, ("Interpace" or the "Company") (OTCQX: IDXG) today announced notification that the Centers for Medicare & Medicaid Services (CMS) directed its Medicare Administrative Contractors, Novitas and First Coast Service Options, Inc., to delay implementation of the Genetic Testing for Oncology Local Coverage Determination (LCD) (L39365), from February 23, 2025, to April 24, 2025.

This change of effective date will allow the incoming Trump administration time to fully review the proposed policy changes, re-evaluate for themselves the supporting clinical evidence for the PancraGEN® assay, and fully assess the negative impact on patient care if the currently proposed LCD comes into effect.

PancraGEN, a report option of PathFinderTG®, is a DNA-based molecular diagnostic test. It uniquely assesses the risk of pancreatic cyst progression to cancer by integrating the results of first-line tests and procedures with molecular test results. The assay provides physicians with insights to aid their diagnosis of pancreatic cancer by differentiating high from low malignancy potential in pancreatic cysts. PancraGEN can help physicians and patients determine a course of treatment that is best suited to each individual, including the reduction of unnecessary surgeries.

PancraGEN has been continuously covered by Medicare for more than 10 years under a test-specific LCD, has helped over 80,000 patients, and has been proven by up to ~8 years of follow-up. According to Tom Burnell, President and CEO of Interpace, "On behalf of the patients and physicians that rely on PancraGEN for optimal care, we are grateful for this delay. We plan to use this additional time to work with the incoming administration to further demonstrate that there has not been any new evidence to justify non-coverage, which would effectively remove this test from the market."

Burnell added, "While the Company is sustainable without PancraGEN with our testing franchise for indeterminant thyroid nodules, ThyGeNEXT® + ThyraMIR®v2, this extension allows Interpace to continue offering PancraGEN and the related Point2® fluid chemistry tests for amylase, CEA, and glucose. We are thrilled that this extension decision also supports the dozens of employees who meticulously process specimens and otherwise would have lost their jobs."

Dr. Burnell went on to say, "Interpace is extremely pleased that we will be able to continue to support our employees by continuing to offer PancraGEN to physicians and their patients during this extension. Further review and evaluation of the clinical validation and utility of

PancraGEN demonstrates the incoming Trump administration's commitment to proven, cost-effective patient care."

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.

Interpace provides clinically useful molecular diagnostic tests and 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 program (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®v2, used in combination with ThyGeNEXT®, for the diagnosis of thyroid cancer utilizing a proprietary microRNA pairwise expression profiler along with algorithmic classification; 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 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.

For more information, please visit Interpace Biosciences' website at www.interpace.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 statements, including, but not limited to, the reimbursement of the Company's tests being subject to review by CMS, the Company's ability to continue to perform, bill and receive reimbursement for our PancraGEN® molecular test under the existing local coverage determination ("LCD"), given that such LCD is currently under review by Novitas Solutions, Inc., the Company's Medicare administrative contractor, the possibility

that the Company's estimates of future revenue, cash flows and adjusted EBITDA may prove to be materially inaccurate, the Company's prior history of operating losses, the Company's ability to adequately finance its business and seek alternative sources of financing, the Company's ability to repay borrowings with BroadOak, the Company's dependence on sales and reimbursements , 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 uplist its common stock onto Nasdaq.

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, 2023, as amended, Current Reports on Form 8-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission. 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.

Contacts:

Investor Relations
Interpace Biosciences, Inc.
(855)-776-6419
Info@Interpace.com

Source: Interpace Biosciences, Inc.