July 29, 2024

# Interpace Diagnostics® Announces Undefined Extension of Medicare Coverage for PancraGEN®, a Molecular Diagnostic Test That Assesses Cancer Risk of Pancreatic Cysts

**PARSIPPANY, NJ, July 29, 2024 (GLOBE NEWSWIRE) --** Interpace Diagnostics®, a subsidiary of Interpace Biosciences®, ("Interpace" or the "Company") (OTCQX: IDXG) today responded to the undefined extension granted by Centers for Medicare & Medicaid Services (CMS) to Novitas, its Medicare Administrative Contractor (MAC).

Novitas announced late last week that CMS granted an extension to the final decision for Local Coverage Determination (LCD) of Genetic Testing for Oncology (L39365) in order for all comments received in response to the proposed changes to be thoroughly considered.

LCD (L39365) includes PancraGEN®, a DNA-based diagnostic molecular 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.

Dr. Nicole Massoll, Chief Medical Officer for Interpace Diagnostics, stated, "We are extremely pleased that this extension allows us to provide PancraGEN to physicians and their patients for the foreseeable future, helping to ensure fully informed and optimized treatment decisions for a very serious and difficult to diagnose condition."

Because of the high mortality rate of pancreatic cancer, surgery is often performed as a cautious approach to treat suspicious pancreatic cysts. Yet studies have shown that 60% to 80% of surgeries reveal indolent cysts that did not necessarily require surgery. The surgery is also high-cost and subject to mortality and significant morbidity. First-line diagnostic tests and procedures—imaging, fluid chemistry (CEA, glucose, amylase), cytology, and patient risk factors—do not always provide a complete picture of malignancy risk.

Dr. Massoll continued, "Offered since 2013, PancraGEN has provided risk-stratification of pancreatic cysts for almost 70,000 patients and has helped to inform optimal patient management, including the reduction of unnecessary surgeries for suspicious cysts."

According to Tom Burnell, President and CEO of Interpace, "Our unique approach to integrating molecular and first-line test results to risk-stratify pancreatic cysts is highly valued by clinicians, as demonstrated by a marked increase in utilization of our testing services." Mr. Burnell continued, "This ever-increasing utilization is driven by the medical and scientific communities' growing understanding of molecular genetics, which is changing the standards of patient care. Because a non-coverage decision will result in unnecessary surgeries and

added healthcare costs, it is imperative that PancraGEN is able to be continually offered without interruption. As such, we will continue to vigorously challenge the proposed LCD (L39365) and request that it be immediately retired."

**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, provide 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](http://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 possibility that the Company's estimates of future revenue, cash flows and adjusted EBITDA may prove to be materially inaccurate, the Company's 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 BroadOak, 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 possible removal of the Company's common stock from trading on the OTCQX®.*

*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.*

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