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Interpace Biosciences Announces New Clinical Validation Data; Diagnostic Accuracy Significantly Improved

PARSIPPANY, NJ, Sept. 01, 2022 (GLOBE NEWSWIRE) -- Interpace Biosciences, Inc. ("Interpace" or the "Company") (OTCQX: IDXG), a fully integrated commercial company that provides clinically relevant molecular diagnostic tests and pathology services for improved patient diagnosis and management, today announced new clinical validation data for their thyroid cancer test platform which is comprised of a mutation panel (ThyGeNEXT®) and a microRNA (miRNA) risk classifier. The new data demonstrates that the addition of miRNA pairwise expression profiling (ThyraMIR®v2) provides clinically and statistically superior risk stratification of indeterminate thyroid nodules (ITN) beyond that of the algorithmic classification analysis provided by the original ThyraMIR® assay.

ThyraMIRv2 was developed and validated in a fully blinded cohort (n=197) from a previous retrospective validation study. The new data analysis revealed improvement in the number of true negative results and reduction of false positive results with a subsequent improvement in the specificity and PPV at positive threshold, while preserving a high sensitivity and NPV. The ROC AUC increased from 0.85 to 0.97 (p<0.001), and the diagnostic accuracy at the positive threshold increased significantly (p<0.05) from 83% (CI, 76-88) to 93% (CI, 89-96). ThyraMIRv2 optimized risk stratification of nodules with *RAS*-like (weak driver) mutations, minimally invasive follicular carcinomas, low-grade PTC, and Hürthle cell predominant nodules—providing significant improvement in test accuracy and the highest NPV and PPV of commercially available tests. The study has recently been published in THYROID®, the leading peer-reviewed journal for original research on thyroid cancer, and can also be accessed by visiting www.thyroiddx.com/pairwise.

Dr. Syd Finkelstein, Chief Scientific Officer of Interpace Diagnostics, commented that "miRNA analysis may also reduce the risk of RNA sampling error because miRNAs can migrate throughout the thyroid nodule. As a result, they may be less affected by spatial variability than the distribution of cells with DNA mutations."

Further commenting was Dr. Carl Malchoff, Professor Emeritus, Medicine/Endocrinology, Founder of the Endocrine Neoplasia Program at UConn Health, and a co-author of the manuscript, "The addition of pairwise microRNA expression profiling represents a clinically important development in precision molecular diagnosis of indeterminate thyroid nodules. For 87% of samples, the positive and negative predictive values are ≥90% across a broad range of cancer prevalence (16% to 84%). Furthermore, as with earlier versions, this assay is performed using fresh FNA samples or diagnostic cytology slides, eliminating the need for an additional biopsy, refrigerated storage, or special shipping."

Tom Burnell, PhD, President and CEO of Interpace Biosciences, added: "Mutational analysis

alone is often insufficient to accurately “rule-in” or “rule-out” malignancy in indeterminate thyroid nodules. We have previously demonstrated the utility of pairwise miRNA analysis in the diagnosis of medullary thyroid cancer and are excited to be able to bring this more precise risk estimation to clinicians, who must integrate various risks and benefits when deciding for or against surgery.” He further stated, “The diagnosis and prognosis of thyroid and other cancers aligns fully to the Interpace corporate goal of improving healthcare by enabling personalized medicine.”

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 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 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 adverse impact of the COVID19 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, 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 with Comerica Bank and 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, and the Company's revenue recognition being based in part on estimates for future collections which estimates may prove to be incorrect. 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, 2021, 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

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