



NEWS RELEASE

Results from a Randomized Controlled Trial Show That TissueCypher® Barrett's Esophagus Test Results Can Significantly Improve the Accuracy of Risk Assessments and Adherence to Guideline-Recommended Patient Management

10/13/2022

Data presented during the 30th United European Gastroenterology (UEG) Week in Vienna, Austria

FRIENDSWOOD, Texas--(BUSINESS WIRE)-- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, today announced new data from a randomized controlled trial (RCT) showing that use of TissueCypher® Barrett's Esophagus Test results can significantly improve a physician's accuracy in assessing the risk of progression to high-grade dysplasia (HGD) or esophageal adenocarcinoma (EAC) in patients diagnosed with Barrett's esophagus (BE), as well as adherence to guideline-recommended patient management strategies.

EAC is an aggressive form of esophageal cancer associated with poor outcomes, and the only known precursor condition to its development is BE. TissueCypher is Castle's precision medicine test designed to predict progression to HGD and/or EAC within five years for patients diagnosed with BE.

"The study data showed that participants who ordered or received TissueCypher test results were up to 65.6% more likely to predict progression to HGD or EAC, ($p < 0.001$), when compared to physicians who did not receive TissueCypher test results in our randomized trial," noted John W. Peabody, M.D., Ph.D., first study author and President of QURE Healthcare. "Importantly, subsequent to receiving test results and making their assessment, the

intervention group was also more likely to adhere to guideline-recommended management strategies.”

These and other results of the RCT were presented through a moderated poster presentation, titled “Results from a randomized controlled trial: introducing a precision medicine diagnostic tool increases adherence to guidelines in patients with Barrett’s esophagus,” shared during the 30th United European Gastroenterology (UEG) Week. The poster may be viewed [here](#).

In the RCT, 259 physicians were randomized to three groups and asked to evaluate clinical performance and value (CPV) vignettes with high- and low-risk patient scenarios based on clinical risk factors. A quality-of-care percentage (0-100%) score was generated from the CPVs based on the American College of Gastroenterology (ACG) and the American Society of Gastrointestinal Endoscopy (ASGE) guidelines. Quality-of-care scores improved significantly across all patient cases after physicians were given the TissueCypher test results.

“Barrett’s esophagus remains a persistent and real-world clinical challenge for endoscopists and patients. Individuals with non-dysplastic Barrett’s esophagus constitute the vast majority of cases, and for years, we have seen few updates in the management strategy of this patient population in particular,” said Craig Munroe, M.D., gastroenterology medical director at Castle Biosciences. “We were very excited to present the results of the QURE study, which help further demonstrate TissueCypher’s potential to meaningfully advance the care of this important patient population. We believe the clinical utility and objective information provided by our test can equip physicians with the information they need to make more informed treatment plan decisions and move beyond the limitations in the current standard of care for risk stratification of patients with BE.”

About TissueCypher® Barrett’s Esophagus Test

The TissueCypher Barrett’s Esophagus test is Castle’s precision medicine test designed to predict future development of high-grade dysplasia (HGD) and/or esophageal cancer in patients with Barrett’s esophagus (BE). TissueCypher is indicated for use in patients with endoscopic biopsy confirmed BE that is graded non-dysplastic (ND), indefinite for dysplasia (IND) or low-grade dysplasia (LGD); its clinical performance has been supported by nine peer-reviewed publications of BE progressor patients with leading clinical centers around the world. The TissueCypher Barrett’s Esophagus Assay is a proprietary Laboratory Developed Test with its own unique CPT PLA code (0108U) and has been on the Medicare Clinical Laboratory Fee Schedule since January 2021. Additionally, the test received Advanced Diagnostic Laboratory Test (ADLT) status from the Centers for Medicare & Medicaid Services (CMS) in March 2022.

About Castle Biosciences

Castle Biosciences (Nasdaq: CSTL) is a leading diagnostics company improving health through innovative tests that

guide patient care. The Company aims to transform disease management by keeping people first: patients, clinicians, employees and investors.

Castle's current portfolio consists of tests for skin cancers, uveal melanoma, Barrett's esophagus and mental health conditions. Additionally, the Company has active research and development programs for tests in other diseases with high clinical need, including its test in development to predict systemic therapy response in patients with moderate-to-severe psoriasis, atopic dermatitis and related conditions. To learn more, please visit **www.CastleBiosciences.com** and connect with us on **LinkedIn, Facebook, Twitter** and **Instagram**.

DecisionDx-Melanoma, DecisionDx-CMSeq, DecisionDx-SCC, MyPath Melanoma, DiffDx-Melanoma, DecisionDx-UM, DecisionDx-PRAME, DecisionDx-UMSeq, TissueCypher and IDgenetix are trademarks of Castle Biosciences, Inc.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning: TissueCypher's potential to meaningfully advance the care of patients diagnosed with BE and significantly improve a physician's accuracy in assessing the risk of progression in patients diagnosed with BE, as well as adherence to guideline-recommended patient management strategies; and our belief that the clinical utility and objective information provided by TissueCypher can guide patient care in an area of significant unmet clinical need and equip physicians with the information they need to make more informed treatment plan decisions and move beyond the limitations in the current standard of care. The words "believe," "can," "potential" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation: subsequent study or trial results and findings may contradict earlier study or trial results and findings or may not support the results obtained in this study, including with respect to the discussion of TissueCypher in this press release; actual application of our tests may not provide the aforementioned benefits to patients; and the risks set forth under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the three months ended June 30, 2022, and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements, except as may be required by law.

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