



NEWS RELEASE

Castle Biosciences Receives Advanced Diagnostic Laboratory Test (ADLT) Status for TissueCypher® Barrett's Esophagus Test from the Centers for Medicare & Medicaid Services (CMS)

3/29/2022

TissueCypher is Castle's fourth test to receive ADLT status

FRIENDSWOOD, Texas--(BUSINESS WIRE)-- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, today announced that the Centers for Medicare & Medicaid Services (CMS) granted Advanced Diagnostic Laboratory Test (ADLT) status for the TissueCypher® Barrett's Esophagus test, effective March 24, 2022. TissueCypher is Castle's prognostic test designed to predict future development of high-grade dysplasia (HGD) and/or esophageal cancer in patients with Barrett's esophagus (BE).

"Expanding access to Medicare beneficiaries for our innovative portfolio of diagnostic tests is key, as we strive to positively impact patient care," said Derek Maetzold, president and chief executive officer of Castle Biosciences. "ADLT status for TissueCypher is an exciting milestone for Castle and an important step toward ensuring patients with Barrett's esophagus have access to our test. This status supports the test's potential to help prevent esophageal cancer by helping physicians and patients make more informed disease management decisions based on the unique biology of an individual patient's esophageal biopsy."

ADLT status requires that a clinical diagnostic laboratory test provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests, among other criteria.¹ The announcement of ADLT status for TissueCypher confirms that the test meets these criteria established by CMS for laboratory tests under the Protecting Access to Medicare Act of 2014 (PAMA).

Chronic reflux in the esophagus causes changes to the molecular and cellular features of the esophagus, which often results in BE. BE is a serious complication of gastroesophageal reflux disease and a risk factor for the development of esophageal cancer, one of the fastest-growing cancers (by incidence) in the U.S., with a five-year survival rate of 18.8%.² The TissueCypher Barrett's Esophagus test is designed to provide clinicians with important information about a patient's unique risk of progression to esophageal cancer based on advanced analysis of the biopsy tissue to guide more personalized and risk-aligned management of BE patients.

TissueCypher is Castle's fourth test to receive ADLT status, joined by DecisionDx[®]-UM, DecisionDx[®]-Melanoma and myPath[®] Melanoma, and has been on the Medicare Clinical Laboratory Fee Schedule (CLFS) since January 2021.

Please visit **CMS.gov** for more information about PAMA, ADLTs and the approval of TissueCypher as a new ADLT.

About TissueCypher[®] Barrett's Esophagus Test

The TissueCypher[®] Barrett's Esophagus test is Castle's precision medicine test designed to predict future development of HGD and/or esophageal cancer in patients with BE. The TissueCypher Barrett's Esophagus test is indicated for use in patients with endoscopic biopsy confirmed BE that is graded non-dysplastic, indefinite for dysplasia or low-grade dysplasia; its clinical performance is supported by eight peer-reviewed publications of BE progressor patients with leading clinical centers around the world.

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 and Barrett's esophagus. 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, DecisionDx DiffDx-Melanoma, DecisionDx-UM, DecisionDx-PRAME, DecisionDx-UMSeq and TissueCypher 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 the potential of the TissueCypher® Barrett’s Esophagus test to help prevent esophageal cancer by helping physicians and patients make more informed disease management decisions based on the unique biology of an individual patient’s esophageal biopsy. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would” 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, the effects of the COVID-19 pandemic on our business and our efforts to address its impact on our business, subsequent study results and findings may contradict earlier study results and findings, including with respect to the discussion of the TissueCypher® Barrett’s Esophagus test 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 Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2021, 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.

¹Centers for Medicare & Medicaid Services: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/Guidance-for-Laboratories-on-ADLTs.pdf>

²Esophageal Cancer Action Network, <https://ecan.org/facts/>

Investor Contact:

Camilla Zuckero

czuckero@castlebiosciences.com

Media Contact:

Allison Marshall

amarshall@castlebiosciences.com

Source: Castle Biosciences, Inc.