



NEWS RELEASE

# Castle Biosciences Announces New York State Department of Health Approval of Its TissueCypher® Barrett's Esophagus Test

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With this approval, all of the tests in Castle's dermatology, gastroenterology and ophthalmology portfolios, as well as its clinical laboratories in Phoenix and Pittsburgh, are now approved by the state of New York

FRIENDSWOOD, Texas--(BUSINESS WIRE)-- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, today announced that it has received assay approval from the New York State Department of Health (NYSDOH) for its TissueCypher Barrett's Esophagus test. TissueCypher is the first AI-driven precision medicine test designed to predict a patient's individual risk of progression from Barrett's esophagus (BE) to esophageal cancer.

"We are proud of the expansion of our New York Clinical Laboratory Permit to include our TissueCypher test," said Kristen Oelschlager, chief operating officer of Castle Biosciences. "We believe this shift from conditional to full approval by the NYSDOH exemplifies Castle's commitment to providing high-quality, molecular tests that can guide informed care decisions and improve patients' lives."

"Successful completion of the rigorous New York state assay review process for TissueCypher, which involves a meticulous review of a test's analytical validity, clinical validity and clinical utility, is an important step toward ensuring all patients with BE in the United States have access to our test," added Derek Maetzold, president and chief executive officer of Castle Biosciences.

With access to TissueCypher, clinicians have a prognostic tool designed to risk stratify the estimated 5% of adults in



the United States with BE.<sup>1</sup> Chronic acid reflux from the stomach causes changes to the molecular and cellular features of the esophagus which can result in BE, the only known precursor condition to esophageal cancer. Esophageal cancer is one of the fastest-growing cancers (by incidence) in the United States and one of the deadliest, with a five-year survival rate of just 22%.<sup>2</sup> TissueCypher analyzes cancer-associated biomarkers and spatial biology features to identify a molecular signature of BE progression that can precede visible tissue changes in a patient's esophagus. By providing a patient's individual risk of progression from BE to esophageal cancer, TissueCypher helps to inform a risk-aligned surveillance approach or earlier interventions that can help prevent the development of cancer.

## 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). The TissueCypher Barrett's Esophagus test is indicated for use in patients with endoscopic biopsy confirmed BE that is graded non-dysplastic (NDBE), indefinite for dysplasia (IND) or low-grade dysplasia (LGD); its clinical performance has been supported by 14 peer-reviewed publications of BE progressor patients with leading clinical centers around the world. The test received Advanced Diagnostic Laboratory Test (ADLT) status from the Centers for Medicare & Medicaid Services (CMS) in March 2022. Learn more at [www.CastleBiosciences.com](http://www.CastleBiosciences.com).

## 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, Barrett's esophagus, mental health conditions and uveal melanoma. Additionally, the Company has active research and development programs for tests in these and other diseases with high clinical need, including its test in development for use in patients diagnosed with moderate-to-severe atopic dermatitis who are seeking systemic treatment. To learn more, please visit [www.CastleBiosciences.com](http://www.CastleBiosciences.com) and connect with us on [LinkedIn](#), [Facebook](#), [X](#) and [Instagram](#).

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## 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 ability of Castle’s tests to guide informed care decisions and improve patients’ lives; Castle’s ability to ensure that all patients with BE in the United States have access to TissueCypher; the ability of the TissueCypher test to inform a risk-aligned surveillance approach or earlier interventions to help prevent the development of cancer. The words “can,” “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: subsequent study or trial results and findings may contradict earlier study or trial results and findings or may not support the results shown in this study, including with respect to the discussion of TissueCypher in this press release; actual application of our TissueCypher test 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 year ended December 31, 2023 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.

1. National Institute of Diabetes and Digestive and Kidney Diseases. Last Reviewed August 2024. Accessed December 12, 2024. <https://www.niddk.nih.gov/health-information/digestive-diseases/barretts-esophagus/definition-facts>.
2. Siegel RL, Giaquinto AN, Jemal A. Cancer statistics, 2024. *CA Cancer J Clin.* 2024;74(1):12-49. doi:10.3322/caac.21820. <https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21820> ; accessed 11/5/24

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