



NEWS RELEASE

New Data at ASTRO 2024 Shows Castle Biosciences' DecisionDx®-SCC Test Provides More Precise Risk Stratification Than BWH Staging Alone to Guide Intensified Treatment for Immune Suppressed Patients with High-Risk Cutaneous Squamous Cell Carcinoma

2024-09-27

In the study, patients with lower-stage Brigham and Women's Hospital (BWH) T1-T2a cutaneous squamous cell carcinoma (SCC) tumors were further stratified into distinct groups of those with more or less favorable survival by the DecisionDx-SCC test, including in the T2a immunosuppressed patient subset which showed a higher rate of metastasis

FRIENDSWOOD, Texas--(BUSINESS WIRE)-- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, today announced new data demonstrating the ability of its DecisionDx-SCC test to provide clinically impactful risk stratification in high-risk SCC patient sub-populations (i.e., patients with suppressed immune systems in this study) to guide potential treatment intensification, such as adjuvant radiation therapy (ART). The data will be shared in an oral presentation at the American Society for Radiation Oncology (ASTRO) 2024 Annual Meeting, being held Sept. 29-Oct. 2 in Washington, D.C.

"The DecisionDx-SCC test has been validated to independently predict likelihood of metastasis beyond staging and clinicopathologic risk factors to help inform important treatment decisions for patients with SCC," said Shlomo A. Koyfman, M.D., lead study author and radiation oncologist at Cleveland Clinic. ¹⁻³ "The data we are sharing at ASTRO highlights the utility of the test in immune suppressed patients with lower-stage SCC tumors, who may have an



elevated risk of metastasis due to their immune status and thus may benefit from intensified surveillance and adjuvant treatments, such as radiation, following tumor removal to reduce this risk.”^{4,5}

Details regarding Castle’s oral presentation at ASTRO are included below:

- Abstract title: Use of the 40-gene expression profile (40-GEP) test to identify immune suppressed patients with Brigham and Women’s Hospital (BWH) T1-T2a cutaneous squamous cell carcinoma (cSCC) at higher risk of metastasis: Implications for adjuvant radiation
- Abstract ID: 1065
- Lead Authors: Shlomo A. Koyfman, M.D., and Karina Brito, Cleveland Clinic
- Session Type: Quick Pitch
- Session: QP 12 - Sarcoma 2: Advancing Treatment Frontiers in Cutaneous Malignancies and Sarcoma
- Date & Time: Tuesday, Oct. 1, 2:30-2:40 p.m. Eastern Time
- Location: Room 151
- Summary: Data from an independent validation cohort of 954 SCC patients with at least one National Comprehensive Cancer Network (NCCN) high-risk factor and DecisionDx-SCC test results were analyzed for patients with BWH T1 and T2a tumors with no residual tumor after Mohs surgery; 441 patients with BWH T1 tumors and 336 with BWH T2a tumors were included in the study cohort. Patients with T1 tumors had similar metastasis-free survival (MFS) rates regardless of immune status yet were further stratified by their DecisionDx-SCC test result (3-year MFS: Class 1 test result: 96.9% vs. Class 2A/2B test result: 88.6%, $p < 0.001$). Immune suppressed patients with T2a tumors had significantly worse MFS than immune competent patients with T2a tumors (71.4% vs. 91.2%, $p < 0.001$). DecisionDx-SCC further stratified immune suppressed patients with T2a tumors into those with more favorable (Class 1 test result; 3-yr MFS of 83%) and less favorable survival (Class 2A/2B test result; 3-yr MFS of 57%). Given the study data, treatment intensification such as ART should be strongly considered in immune suppressed patients with BWH T2a SCC tumors guided by DecisionDx-SCC test results.

The full text abstract is available in the ASTRO Annual Meeting Portal and will be published in the International Journal of Radiation Oncology • Biology • Physics (Red Journal) .

About DecisionDx-SCC

DecisionDx-SCC is a 40-gene expression profile test that uses an individual patient’s tumor biology to stratify risk of metastasis in patients with cutaneous squamous cell carcinoma who have one or more NCCN high-risk factors. The test result, in which patients are stratified into a Class 1 (low), Class 2A (higher) or Class 2B (highest) risk category, predicts individual metastatic risk to inform risk-appropriate management and guide decision-making regarding the use of adjuvant radiation therapy. Peer-reviewed publications have demonstrated that DecisionDx-SCC is an

independent predictor of metastatic risk and that the test can significantly improve risk-stratification when used with traditional staging systems and clinicopathologic risk factors to guide risk-aligned management and treatment decisions. Learn more at 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 other diseases with high clinical need, including its test in development to help guide systemic therapy selection for patients with moderate-to-severe atopic dermatitis, psoriasis and related conditions. To learn more, please visit 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 continued ability of the DecisionDx-SCC test to provide more precise risk stratification than BWH staging alone to guide potential treatment intensification in patients with high-risk SCC; and Castle's ability to meaningfully improve the care of patients with high-risk SCC through its DecisionDx-SCC test. The words "can," "may" 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 DecisionDx-SCC 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 year

ended December 31, 2023, our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, 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. Wysong A, Newman JG, Covington KR, et al. Validation of a 40-gene expression profile test to predict metastatic risk in localized high-risk cutaneous squamous cell carcinoma. *J Am Acad Dermatol* . 2021;84(2):361–9. <https://doi.org/10.1016/j.jaad.2020.04.088> .
2. Ibrahim SF, Kasprzak JM, Hall MA, et al. Enhanced metastatic risk assessment in cutaneous squamous cell carcinoma with the 40-gene expression profile test. *Future Oncol* . 2022;18(7):833–47. <https://doi.org/10.2217/fon-2021-1277> .
3. Wysong A, Somani AK, Ibrahim SF, et al. Integrating the 40-gene expression profile (40-GEP) test improves metastatic risk-stratification within clinically relevant subgroups of high-risk cutaneous squamous cell carcinoma (cSCC) patients. *Dermatol Ther (Heidelb)* . 2024. <https://doi.org/10.1007/s13555-024-01111-5>
4. Arron ST, Cañueto J, Siegel J, et al. Association of a 40-gene expression profile with risk of metastatic disease progression of cutaneous squamous cell carcinoma (cSCC) and specification of benefit of adjuvant radiation therapy. *IJROBP* . 2024. doi: <https://doi.org/10.1016/j.ijrobp.2024.05.022>
5. Ruiz ES, Brito K, Karn EE, et al. Predicting adjuvant radiation therapy benefit in cutaneous squamous cell carcinoma with the 40-gene expression profile. *Future Oncol* . 2024. doi: <https://doi.org/10.1080/14796694.2024.2390820>

Investor Contact:

Camilla Zuckero

czuckero@castlebiosciences.com

Media Contact:

Allison Marshall

amarshall@castlebiosciences.com

Source: Castle Biosciences Inc.