



NEWS RELEASE

# Study Confirms the Ability of Castle Biosciences' DecisionDx®-SCC Test to Predict Likelihood of Benefit from Adjuvant Radiation Therapy in Patients with High-Risk Cutaneous Squamous Cell Carcinoma

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This is the second study to demonstrate the ability of the DecisionDx-SCC test to identify patients who are more or less likely to benefit from adjuvant radiation therapy (ART), confirmed in an independent cohort of high-risk cutaneous squamous cell carcinoma (SCC) patients

FRIENDSWOOD, Texas--(BUSINESS WIRE)-- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, today announced the publication of a **new study in Future Oncology** further substantiating use of its DecisionDx-SCC test in guiding patient selection and decision-making related to the use of ART in patients with high-risk SCC based on the ability of the test to identify patients likely to benefit from treatment.

"Some patients with high-risk SCC are eligible for adjuvant radiation therapy once their primary tumor has been removed; however, determining which patients should seek treatment is complicated and involves weighing numerous pros and cons against the risk of the patient's cancer returning," said Emily S. Ruiz, M.D., MPH, FAAD, lead author, board-certified dermatologist and Mohs micrographic surgeon at Brigham and Women's Hospital in Boston, and Associate Professor of Dermatology at Harvard Medical School. "In this study, we were successful in validating, in an independent SCC patient cohort, that DecisionDx-SCC can objectively inform these challenging decisions by identifying patients for whom ART would be beneficial, as well as those who may be best served by avoiding it."

In the study, a novel, independent cohort of patients with high-risk SCC tumors (399 patients; 423 tumors) from two academic centers were tested using DecisionDx-SCC and analyzed for five-year metastasis-free survival and projected time to metastasis. Similar to the recent 2024 study by **Arron et al.**, samples were controlled for bias by clinicopathologically matching ART-treated and untreated patients. <sup>1</sup>

A comparison of both studies (Arron et al. and Ruiz et al.) demonstrates very similar results:

- Both studies showed that patients with DecisionDx-SCC Class 2B (highest metastatic risk) test results who were treated with ART had a 50% decrease in metastatic disease progression, on average, and a significant deceleration of disease progression compared to patients who did not receive ART.
- Both studies reported no difference in disease progression rates when comparing ART-treated and untreated patients with DecisionDx-SCC Class 1 (lowest metastatic risk) test results, suggesting these patients may consider deferring treatment due to low metastatic risk and a low likelihood of benefitting from treatment. The majority of patients had Class 1 results, confirming the significance of clinical utility in ruling out ART in these patients.
- Additionally, both studies observed a lack of ART-related benefit for patients with Class 2A (higher metastatic risk) test results, despite having an intermediate-level risk of metastasis compared to patients with Class 1 and Class 2B test results. This suggests that a specific pattern of gene expression captured uniquely by a DecisionDx-SCC Class 2B result may be driving the identification of the benefit from ART.

“This marks the sixth study since the start of 2024 demonstrating the value of DecisionDx-SCC test results in improving risk-aligned patient care through precise, tumor-biology-based risk stratification,” said Derek Maetzold, president and chief executive officer of Castle Biosciences. “The more than 20 peer-reviewed papers published since the launch of our test four years ago speaks to the breadth of evidence supporting the test’s validity, as well as its ability to improve upon clinicopathologic-based staging systems to drive optimized decision-making regarding appropriate treatment pathways for patients with high-risk SCC.”

## 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](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 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](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 continued ability of the DecisionDx-SCC test to guide patient selection and decision-making related to the use of ART in patients with high-risk SCC. 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. 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>

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