

# Recently Published Data Confirm DecisionDx®-SCC as a Significant and Independent Risk-Stratification Tool in Patients with Squamous Cell Carcinoma and One or More Risk Factors

1/13/2022

Clinical performance study published in *Future Oncology* reinforces the independent value of DecisionDx-SCC to inform risk-appropriate patient management decisions

FRIENDSWOOD, Texas--(BUSINESS WIRE)-- Castle Biosciences, Inc. (Nasdaq: CSTL), a leader in transforming disease management and improving patient outcomes through innovative diagnostics, today announced the publication of clinical performance study data demonstrating that DecisionDx®-SCC provides significant and independent prognostic value for stratifying metastasis risk in patients with cutaneous squamous cell carcinoma (SCC) with one or more risk factors (high risk). The study, titled "Enhanced Metastatic Risk Assessment in Cutaneous Squamous Cell Carcinoma with the 40-Gene Expression Profile Test," is available online in [Future Oncology](#).

"As the criteria for high-risk SCC is broad, it can be challenging for clinicians to appropriately manage a patient's disease using only their clinicopathologic risk factors," said the study's first author, Sherrif Ibrahim, M.D., Ph.D., dermatologist and Mohs surgeon at Rochester Dermatologic Surgery, Victor, New York, and associate professor, Department of Dermatology at University of Rochester Medical Center, Rochester, New York. "DecisionDx-SCC is designed to provide powerful prognostic information regarding a patient's risk of metastasis, based on the biology of the individual patient's tumor. As a physician, I rely on this information to help me make informed and personalized decisions in the management and follow-up care of patients with SCC."

Study background:

- The annual incidence of SCC is high (approximately 2 million diagnosed cases/year in the U.S.) and continues to grow, resulting in a substantial number of patients with poor outcomes.
- An estimated 200,000 patients per year with SCC are broadly classified as having high-risk disease, based on clinicopathologic factors associated with increased likelihood of poor outcomes; while these and other factors are used to stratify patient risk, low accuracy, histopathologic discordance and lack of standardized reporting limit clinical utility of this clinicopathologic factor-based approach.
- DecisionDx-SCC is a 40-gene expression profile test that uses an individual patient's tumor biology to predict individual risk of metastasis in patients with SCC with one or more risk factors.
- The test result, in which patients are stratified into a Class 1 (low), 2A (moderate) or 2B (high) risk category, predicts individual metastatic risk to inform risk-appropriate management decisions.

#### Study methods and findings:

- A retrospective cohort of 420 cases of primary SCC tumors with known patient outcomes underwent testing with DecisionDx-SCC; test results were assessed using Kaplan-Meier and Cox regression analyses with traditional clinicopathologic factor-based assessment, including National Comprehensive Cancer Network (NCCN) classification, and current staging methods, including Brigham and Women's Hospital (BWH) and American Joint Committee on Cancer Eighth Edition (AJCC8) staging.
- DecisionDx-SCC stratified the clinical validation cohort for metastatic risk: 212 cases received a Class 1 result (low risk), 185 cases received a Class 2A result (moderate risk) and 23 cases received a Class 2B result (high risk), with metastasis rates of 6.6%, 20.0% and 52.2%, respectively. Kaplan-Meier analyses demonstrated statistically significant differences in three-year metastasis-free survival (MFS) rates for the overall cohort; 93.9%, 80.5% and 47.8% for Class 1, Class 2A and Class 2B, respectively (log-rank,  $p < 0.001$ ). MFS rates were also significantly different across Class 1, Class 2A and Class 2B for subsets of the cohort with one risk factor and  $\geq 2$  risk factors.
- DecisionDx-SCC further stratified risk within high-risk and very high-risk subgroups classified according to the current NCCN guidelines: for the high-risk subgroup, MFS rates were 95.9%, 84.3% and 62.5% for Class 1, Class 2A and Class 2B, respectively ( $p = 0.0001$ ); for the very high-risk subgroup, MFS rates were 89.6%, 75.9% and 40.0% for Class 1, Class 2A and Class 2B, respectively ( $p < 0.001$ ).
- When compared to the accuracy metrics for AJCC8 and BWH T staging, the positive predictive value of a DecisionDx-SCC Class 2B result (high risk) was 52.2% compared to 30.0% and 39.9% for high-stage AJCC8 (T3/T4) and BWH (T2b/T3), respectively, while maintaining similar negative predictive value (87.2% compared to 88.5% and 87.9%, respectively).
- The specificity of a DecisionDx-SCC Class 2B result (96.9%) and the sensitivity of a Class 2 result (77.8%) were significantly greater than the corresponding metrics for high-stage BWH and AJCC8. Together, these metrics demonstrated that DecisionDx-SCC identified tumors at high risk for metastasis with improved accuracy

compared to BWH and AJCC8 tumor staging, while distinctly stratifying these cases from those with Class 1 tumors which have risk levels similar to the general SCC patient population.

- The addition of DecisionDx-SCC results to binary T stage status identified subpopulations ranging from 5.7% to 71.4% (BWH) and 5.6% to 83.3% (AJCC8), compared to 12.1% to 33.9% (BWH) and 11.5% to 30.0% (AJCC8) for binary staging alone, which demonstrated that risk assessment was refined by combining DecisionDx-SCC results with tumor staging.
- Overall, the data demonstrated that:
  - DecisionDx-SCC enhanced clinicopathologic risk factor-based assessment and identified a group of SCC patients within a high-risk cohort with metastasis rates similar to the general SCC population (Class 1 result with one risk factor).
  - Patients identified by DecisionDx-SCC as having the highest risk for metastasis (Class 2B) consistently had metastasis rates  $\geq 50\%$ , regardless of having one or two or more risk factors.
  - Combining DecisionDx-SCC with clinicopathologic factor-based risk assessment, regardless of whether it is based on risk factor count or T stage, further stratified risk for metastasis in SCC patients and improved the accuracy of risk predictions to better inform risk-appropriate patient management decisions.

## About DecisionDx-SCC

DecisionDx-SCC is a 40-gene expression profile test that uses an individual patient's tumor biology to predict individual risk of cutaneous squamous cell carcinoma metastasis for patients with one or more risk factors. The test result, in which patients are stratified into a Class 1 (low), 2A (moderate) or 2B (high) risk category, predicts individual metastatic risk to inform risk-appropriate management.

Peer-reviewed publications have demonstrated that DecisionDx-SCC is an independent predictor of metastatic risk and that integrating DecisionDx-SCC with current prognostic methods can add positive predictive value to clinician decisions regarding staging and management.

More information about the test and disease can be found at [www.CastleTestInfo.com](http://www.CastleTestInfo.com).

## About Castle Biosciences

Castle Biosciences (Nasdaq: CSTL) is a leading diagnostics company that provides personalized, clinically actionable information to clinicians and patients to inform treatment decisions and improve health outcomes. The Company is focused on transforming the disease management paradigm in skin cancer and other diseases with high clinical need by leveraging advanced technologies for its portfolio of innovative diagnostic tests.

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](http://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

The information in this press release contains forward-looking statements and information 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 DecisionDx-SCC's ability to predict individual risk of metastasis for patients with SCC and one or more risk factors, help physicians make informed, risk-appropriate and personalized decisions in the management and follow-up care of patients with SCC, identify tumors at high risk for metastasis with improved accuracy compared to BWH and AJCC8 tumor staging, while distinctly stratifying these cases from those with Class 1 tumors which have risk levels similar to the general SCC patient population, and add positive predictive value to clinician decisions regarding staging and management. 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 that contradict earlier study results and findings, DecisionDx-SCC's ability to provide the aforementioned benefits to patients and the risks set forth in our Quarterly Report on Form 10-Q for the quarter ended Sept. 30, 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.

## Investor Contact:

Camilla Zuckero

**czuckero@castlebiosciences.com**

Media Contact:

Allison Marshall

**amarshall@castlebiosciences.com**

Source: Castle Biosciences, Inc.