



NEWS RELEASE

# Data from Second Independent Multi-Center Study of Patients with High-Risk Cutaneous Squamous Cell Carcinoma Confirms Independent Risk-Stratification Performance of DecisionDx®-SCC

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FRIENDSWOOD, Texas--(BUSINESS WIRE)-- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, today announced new data showing that DecisionDx-SCC can independently risk-stratify patients with cutaneous squamous cell carcinoma (SCC) and one or more risk factors according to their biologic risk of metastasis, consistent with findings in previous development and validation studies.<sup>1,2</sup> The poster was presented at the 2022 American College of Mohs Surgery (ACMS) Annual Meeting.

DecisionDx-SCC is Castle's prognostic 40-gene expression profile (GEP) test designed to use a patient's tumor biology to predict individual risk of metastasis for patients diagnosed with SCC who have one or more high-risk factors. The test stratifies patients into one of three classes based on their biologic risk of metastasis: Class 1 (low risk), Class 2A (moderate risk) or Class 2B (high risk).

"Identifying which patients are at an increased risk of disease progression and metastasis is a challenge for clinicians who may see hundreds of cutaneous squamous cell carcinoma cases in their practices each year," said study author Sarah T. Arron, M.D., Ph.D., Mohs surgeon and dermatologist at Peninsula Dermatology in Burlingame, California. "Using DecisionDx-SCC to add a patient's biologic risk to our existing clinical and pathologic risk-assessment methods can improve our decision-making and help us to personalize treatment for our patients."

The poster, titled "Performance of the prognostic 40-gene expression profile (40-GEP) test for high-risk cutaneous squamous cell carcinoma (cSCC) in a second independent cohort," highlights data from a second, independent,

multi-center study of high-risk SCC patients, consisting of 598 novel patient samples from 43 contributing centers. The poster can be viewed [here](#). With the cohort of patients in this study, combined with the cohort of patients from the first validation study (n=420), the ability of DecisionDx-SCC to independently stratify risk has been confirmed in a total of 1,018 patients.

Kaplan-Meier analysis showed a statistically significant difference in metastasis-free survival (MFS) rates between DecisionDx-SCC Class 1, Class 2A and Class 2B results ( $p < 0.0001$ , log-rank), demonstrating the ability of the test to risk-stratify patients according to their biologic metastatic risk. As demonstrated by univariate Cox regression analysis, DecisionDx-SCC Class 2A, Class 2B, traditional high-risk clinicopathologic risk factors, American Joint Committee on Cancer Eighth Edition (AJCC8) T3/T4 stages and Brigham and Women's Hospital (BWH) T2b/T3 stages were all statistically associated with metastatic risk. A DecisionDx-SCC Class 2B result had the highest hazard ratio, 10.71, which was the strongest predictor of metastasis among the analyses. Further, multivariate Cox regression analysis demonstrated that DecisionDx-SCC independently and significantly contributed to risk stratification of patients when combined with traditional high-risk clinicopathologic factors ( $p < 0.05$  for Class 2A and 2B), BWH ( $p < 0.001$  for Class 2A and  $p < 0.002$  for Class 2B) or AJCC8 ( $p < 0.001$  for Class 2A and 2B) staging. This reinforces that the test's results provide risk-stratification value on their own and can add clinical value when used as a complement to other risk-prediction systems.

Overall, the study data confirm what previous development and validation studies<sup>1,2</sup> have substantiated: DecisionDx-SCC can accurately classify risk for metastasis in SCC patients with one or more risk factors and provides significant prognostic information independent from current risk prediction methods. Additionally, the study data further support the use of DecisionDx-SCC test results in combination with other risk-assessment and staging systems to guide more refined and risk-aligned patient care.

## 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 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, Barrett's esophagus and mental health conditions. 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**.

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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 DecisionDx-SCC to accurately and independently risk-stratify patients with cutaneous SCC and one or more risk factors, improve clinical decision-making by helping clinicians personalize treatment for their patients, and add clinical value when used as a complement to other risk-prediction systems. The word "can" 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 or trial results and findings may contradict earlier study or trial results and findings or may not support the results obtained 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 Quarterly Report on Form 10-Q for the three months ended March 31, 2022, 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.

1Wysong, A, Newman J, Covington K et al. Validation of a 40-gene expression profile test to predict metastatic risk in localized high-risk cutaneous squamous cell carcinoma. JAAD 2021; 361-368. doi:

**<https://doi.org/10.1016/j.jaad.2020.04.088>**

2Ibrahim S, Kasprzak J, Hall M et al. Enhanced metastatic risk assessment in cutaneous squamous cell carcinoma with the 40-gene expression profile test. Future Oncology 2021. doi: **<https://doi.org/10.2217/fon-2021-1277>**

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