



NEWS RELEASE

# Castle Biosciences Presents New Data Demonstrating the Clinical Utility and Value of DecisionDx®-SCC in Moderately and Poorly Differentiated Cutaneous Squamous Cell Carcinoma Tumors

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Study finds that DecisionDx-SCC adds clarity and confidence to risk-aligned treatment decisions, independent of clinicopathologic factors and staging

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 how the Company's DecisionDx®-SCC test can provide objective, independent and significant risk-stratification for cutaneous squamous cell carcinoma (cSCC) tumors with uncertainty in differentiation status. The data were shared in an oral presentation given at the American Society of Dermatopathology (ASDP) 59<sup>th</sup> Annual Meeting by Sarah Estrada, M.D., dermatopathologist with Affiliated Dermatology in Scottsdale, Arizona.

Overall, these data demonstrate how DecisionDx-SCC can significantly stratify the risk of metastasis in high-risk cSCC patients with an ambiguous tumor differentiation status. Additionally, the study suggests that incorporating the test's results into clinical cSCC risk assessments could improve risk-stratification and enhance current patient management decisions to improve patient outcomes.

Subjective pathology variability in the histologic grading of cSCC tumors is an important clinical issue, particularly when comparing moderately differentiated tumors. Poor differentiation has been shown to be an independent risk factor associated with poor patient outcomes.<sup>1-3</sup> However, there is a lack of consistency in differentiation assessment<sup>4</sup> which can adversely impact the value of differentiation as a prognostic factor. In fact, the two most

widely used cSCC staging systems, American Joint Committee on Cancer Staging Manual Eighth Edition (AJCC8) and Brigham and Women's Hospital (BWH), vary on their inclusion of poor differentiation as a risk factor for staging; BWH includes it, while AJCC8 does not.

"A single clinicopathologic risk factor, including a cSCC tumor's differentiation status, can affect staging and thereby escalate or deescalate patient treatment plans," commented Estrada. "Objective risk-stratification that is independent of clinicopathologic factors and staging, as provided by DecisionDx-SCC test results, can identify high-risk cSCC lesions and provide clarity in challenging staging situations."

The presentation, titled "Incorporating the 40-GEP test for poorly differentiated cutaneous squamous cell carcinoma (cSCC) tumors mitigates risk assessment uncertainty from histologic grading," describes the results of a study involving a cohort of 420 high-risk cSCC patients divided into either moderately or poorly differentiated statuses, based on their pathology report and review by an independent dermatopathologist.

A sub-cohort of 171 tumors with differentiation uncertainty was then staged using BWH criteria. The differentiation status of the tumors in this "differentiation uncertainty cohort" was then manually changed so that poorly differentiated was changed to moderately differentiated and vice versa, and changes to BWH staging were analyzed.

The study data showed that:

- For 40% of patients in the sub-cohort, the BWH stage changed based upon the alteration of differentiation status, which could impact treatment decisions.
- DecisionDx-SCC independently and significantly stratified the sub-cohort according to metastatic risk; patients with a low-risk (Class 1) result had a statistically significant higher three-year metastasis free survival than both moderate-risk (Class 2A) and high-risk (Class 2B) patients (90.1% vs. 78.6% and 62.5%, respectively;  $p=0.02$ ).

## About DecisionDx<sup>®</sup>-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 Castle's tests 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](#).

DecisionDx-Melanoma, DecisionDx-CMSeq, DecisionDx-SCC, MyPath Melanoma, DiffDx-Melanoma, DecisionDx-UM, DecisionDx-PRAME, DecisionDx-UMSeq, TissueCypher and IDgenetix are trademarks of Castle Biosciences, Inc.

## 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 potential of DecisionDx-SCC test results to (i) provide objective, independent and significant risk-stratification for high-risk cSCC patients with an ambiguous tumor differentiation status; (ii) enhance current patient management decisions and potentially improve patient outcomes when incorporated into clinical cSCC risk assessments; and (iii) identify high-risk cSCC lesions and provide clarity in challenging staging situations. The words "can," "could," "potential" 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 macroeconomic events and conditions, including inflation, the COVID-19 pandemic and geopolitical events, among others, 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 September 30, 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.

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2. Cañueto J, Burguillo J, Moyano-Bueno D, et al: Comparing the eighth and the seventh editions of the American Joint Committee on Cancer staging system and the Brigham and Women’s Hospital alternative staging system for cutaneous squamous cell carcinoma: Implications for clinical practice. *J Am Acad Dermatol* 80:106-113.e2, 2019
3. Karia PS, Morgan FC, Califano JA, et al: Comparison of Tumor Classifications for Cutaneous Squamous Cell Carcinoma of the Head and Neck in the 7th vs 8th Edition of the AJCC Cancer Staging Manual. *JAMA Dermatol* 154:175, 2018
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