



NEWS RELEASE

Castle Biosciences Announces Multiple Data Presentations at the 2023 American Society for Dermatologic Surgery Annual Meeting

11/14/2023

Video abstracts reinforce the clinical validity and utility of the Company's skin cancer test portfolio, including DecisionDx®-Melanoma, DecisionDx®-SCC and MyPath® Melanoma

FRIENDSWOOD, Texas--(BUSINESS WIRE)-- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, today announced that data spanning its dermatologic portfolio of gene expression profile (GEP) tests was recently presented at the 2023 American Society for Dermatologic Surgery (ASDS) Annual Meeting in Chicago.

"The robust data presented at ASDS underscores the value of GEP testing across multiple skin cancer indications" said Robert Cook, Ph.D., senior vice president of research and development at Castle Biosciences. "The studies presented reinforce our commitment to research and development and showcase the utility of our tests in guiding more informed and risk-aligned patient care."

Highlights from Castle's seven video abstracts presented at ASDS are included below.

DecisionDx®-Melanoma

- Clinically significant risk-stratification prediction in stage I cutaneous melanoma with the integrated 31-gene expression profile (i31-GEP)

Presenting Author: Michael Tassavor, M.D., Skin Cancer Center, Cincinnati

Summary: No specific risk threshold provides clinicians guidance regarding when to alter treatment plans or increase management intensity for patients with stage I cutaneous melanoma (CM). The study data demonstrated the ability of the DecisionDx-Melanoma test to identify patients with stage I CM at high risk of tumor recurrence (recurrence free survival of 89.8%, $p=0.002$).

- View video abstract [here](#).
- Validation of the i31-GEP for sentinel lymph node biopsy metastasis in patients with T1b-T2a cutaneous melanoma: Results of an independent performance study
First Author: Peter A. Prieto, M.D., MPH, University of Rochester Medical Center, Rochester, New York
Summary: National Comprehensive Cancer Network (NCCN) guidelines recommend that the sentinel lymph node biopsy (SLNB) procedure can be considered for patients with an expected risk of SLN positivity above 5%. In this independent cohort of patients with T1b-T2a tumors ($n=177$), the DecisionDx-Melanoma test identified patients with less than 5% risk of SLN positivity who may consider foregoing the procedure and could have reduced the number of SLNBs by 45% in T1b tumors, 14% in T2a tumors and 28% overall.
- View video abstract [here](#).

DecisionDx®-SCC

- Association of a 40-gene expression profile with risk of metastatic disease progression of cutaneous squamous cell carcinoma (cSCC) and benefit of adjuvant radiation therapy (ART)
Presenting Author: Sarah Arron, M.D., Ph.D., Peninsula Dermatology, Burlingame, California
Summary: ART is recommended based on high-risk clinicopathologic features of SCC, but these criteria are wide-ranging, encompassing a broad range of patients. Thus, many patients receive treatment with only a subset appearing to benefit. This study determined that the DecisionDx-SCC test can identify patients who would most likely benefit from ART to reduce metastatic disease progression. Specifically, patients with a Class 2B (highest metastatic risk) test result who were treated with ART had 50% higher metastasis-free survival rates than Class 2B patients who did not receive ART. Additionally, a DecisionDx-SCC Class 2B result was the only risk factor that successfully identified patients who would benefit from ART.
- View video abstract [here](#).
- Using the 40-gene expression profile (40-GEP) test in Medicare-eligible cutaneous squamous cell carcinoma (cSCC) patients reduces healthcare costs when guiding adjuvant radiation therapy (ART) decisions
Presenting Author: Aaron S. Farberg, M.D., Baylor Scott & White Health System, Dallas
Summary: The study aimed to determine if using the DecisionDx-SCC test to guide ART decisions could reduce healthcare costs in the management of cSCC. The study found that using the DecisionDx-SCC test to guide ART decisions for Medicare-eligible cSCC patients could result in cost savings to the healthcare system ranging from \$145 million to approximately \$1 billion annually.

- View video abstract [here](#).
- Incorporating the 40-gene expression profile (40-GEP) test in clinicopathologic staging improves metastatic risk assessment for cutaneous squamous cell carcinoma (cSCC) patients with one or more high-risk factors
Presenting Author: Sarah Arron, M.D., Ph.D.

Summary: Three clinicopathologic-based risk assessment systems (Brigham and Women’s Hospital (BWH) staging, American Joint Committee on Cancer 8th Edition (AJCC8) staging and NCCN) are used to guide treatment pathway decisions in patients with high-risk cSCC; however, each has accuracy limitations. The large, combined cohort (including 420 patients from the initial validation cohort and 534 patients from a novel, independent cohort) confirmed that the DecisionDx-SCC test provides significant risk stratification within high-risk cSCC patients. Multivariate and likelihood analyses demonstrate the improvement of metastatic risk prediction by the addition of DecisionDx-SCC in models that include NCCN, BWH or AJCC8 systems.

- View video abstract [here](#).
- The 40-gene expression profile (40-GEP) test demonstrates impactful clinical utility in the management of cutaneous squamous cell carcinoma (cSCC) patients

Presenting Author: Brent R. Moody, M.D., Skin Cancer Surgery Center, Nashville, Tennessee

Summary: This multicenter, retrospective study was designed to explore physician management patterns for patient follow-up, surveillance and treatments when including DecisionDx-SCC test results as part of clinical care of patients with high-risk cSCC. The study found that in a real-world patient cohort, the risk stratification provided by the DecisionDx-SCC test was the most influential factor in risk-aligned management changes. Additionally, the test’s results were more significant in the physicians’ decision to escalate or de-escalate care than any other traditional risk factor considered in the study.

- View video abstract [here](#).

MyPath® Melanoma

- Gene expression profiling in the diagnostic work-up of melanocytic lesions
Presenting Author: Hadas Skupsky, M.D., F.A.A.D., Laser Skin Care Center, Long Beach, California; University of California Irvine, Irvine, California
Summary: MyPath Melanoma testing is available for ambiguous melanocytic neoplasms to add clarity to diagnoses. Case studies were presented utilizing a variety of immunohistochemical stains and testing with MyPath Melanoma to aid in the determination of a final diagnosis and inform surgical planning for otherwise diagnostically ambiguous cases.
- View video abstract [here](#).

About DecisionDx®-Melanoma



DecisionDx-Melanoma is a gene expression profile risk stratification test. It is designed to inform two clinical questions in the management of cutaneous melanoma: a patient's individual risk of sentinel lymph node (SLN) positivity and a patient's personal risk of melanoma recurrence and/or metastasis. By integrating tumor biology with clinical and pathologic factors using a validated proprietary algorithm, DecisionDx-Melanoma is designed to provide a comprehensive and clinically actionable result to guide risk-aligned patient care. DecisionDx-Melanoma has been shown to be associated with improved patient survival and has been studied in more than 10,000 patient samples. DecisionDx-Melanoma's clinical value is supported by more than 40 peer-reviewed and published studies, providing confidence in disease management plans that incorporate the test's results. Through Sept. 30, 2023, DecisionDx-Melanoma has been ordered more than 146,000 times for patients diagnosed with cutaneous melanoma.

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), Class 2A (moderate) or Class 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.

About MyPath® Melanoma

MyPath Melanoma is Castle's gene expression profile test designed to provide an accurate, objective result to aid dermatopathologists and dermatologists in characterizing difficult-to-diagnose melanocytic lesions. Of the approximately two million suspicious pigmented lesions biopsied annually in the U.S., Castle estimates that approximately 300,000 of those cannot be confidently classified as either benign or malignant through traditional histopathology methods. For these cases, the treatment plan can also be uncertain. Obtaining accurate, objective ancillary testing can mean the difference between a path of overtreatment or the risk of undertreatment. Interpreted in the context of other clinical, laboratory and histopathologic information, MyPath Melanoma is designed to reduce uncertainty and provide confidence for dermatopathologists and help dermatologists deliver more informed patient management plans.

More information about Castle's tests can be found at 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 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](#).

DecisionDx-Melanoma, DecisionDx-CMSeq, DecisionDx-SCC, MyPath 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 continued value of GEP testing across multiple skin cancer indications; our ability to improve the care of patients with skin cancers and inflammatory skin conditions through innovative tests that can guide more informed disease management decisions; the potential of the DecisionDx-Melanoma test to identify patients with stage I CM at high risk of tumor recurrence; the continued ability of the DecisionDx-Melanoma test was validated to identify patients with less than 5% risk of SLN positivity; the ability of the DecisionDx-SCC test to (i) identify patients who would most likely benefit from ART to reduce metastatic disease progression, (ii) result in cost savings to the healthcare system ranging from \$145 million to approximately \$1 billion annually, (iii) provide significant risk stratification within high-risk cSCC patients, (iv) influence physicians' decisions to escalate or de-escalate care; the ability of MyPath Melanoma to (i) aid in the determination of a final diagnosis and inform surgical planning for otherwise diagnostically ambiguous cases and (ii) reduce uncertainty and provide confidence for dermatopathologists and help dermatologists deliver more informed patient management plans; and the ability of DecisionDx-Melanoma to provide a comprehensive and clinically actionable result to guide risk-aligned patient care. 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, including with respect to the discussion of DecisionDx-Melanoma, DecisionDx-SCC, MyPath Melanoma and Castle's inflammatory skin disease pipeline test 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, 2022, our Quarterly Report on Form 10-Q for the three months ended September 30, 2023, 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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