



## NEWS RELEASE

# Castle Biosciences to Present New DecisionDx®-SCC and DecisionDx®-Melanoma Data at the American Head & Neck Society's (AHNS) 11th International Conference on Head and Neck Cancer

7/7/2023

FRIENDSWOOD, Texas--(BUSINESS WIRE)-- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, will present new data on its gene expression profile (GEP) risk-stratification test for patients with cutaneous squamous cell carcinoma (SCC), DecisionDx®-SCC, and its GEP risk-stratification test for patients with cutaneous melanoma (CM), DecisionDx®-Melanoma, at the American Head & Neck Society's (AHNS) 11th International Conference on Head and Neck Cancer, being held July 8-12 in Montréal, QC, Canada.

Castle's podium presentation on DecisionDx-SCC will share data demonstrating significantly improved metastatic risk prediction in patients with SCC of the head and neck (SCC-HN) when the test's results are used both independently and in conjunction with American Joint Committee on Cancer 8th edition (AJCC8) and Brigham and Women's Hospital (BWH) staging systems. Details are as follows:

**Abstract ID:** 128656 | **Podium presentation:** Improved metastatic risk prediction with the 40-gene expression profile (40-GEP) test supports its use for risk-aligned decision making for patients with high-risk cutaneous squamous cell carcinoma of the head and neck

**Presenter and Study Author:** Jason G. Newman, M.D., F.A.C.S., Department of Otolaryngology Head and Neck Surgery at Medical University of South Carolina

**Session Date/Time:** Sunday, July 9, 1:45-3:15 p.m. Eastern time

## Session Name: Proffered Papers 9 - Skin 1 and Hot Topic Session

“Traditional staging methods rely on a limited set of clinicopathologic risk factors to categorize cancer patients into different stages,” said Newman. “While these factors provide important information, they may not fully capture the underlying biological heterogeneity and variability in tumor behavior. The study data demonstrated that using DecisionDx-SCC test results in combination with these traditional staging approaches can improve prognostic accuracy to help optimize and personalize treatment choices based on a patient's unique, biological risk profile.”

This multi-center study expands on a previously published study<sup>1</sup> and analyzed data from 622 patients with high-risk SCC-HN. In the study, DecisionDx-SCC significantly stratified patients according to their biologic risk of metastasis, independent of the clinicopathologic risk factors used in AJCC8 and BWH staging systems ( $p < 0.0001$ ). Additionally, the metastatic risk predictions provided by AJCC8 and BWH staging were significantly improved when DecisionDx-SCC test results were included. The data show that DecisionDx-SCC contributes independent prognostic value to the prediction of metastatic risk in SCC-HN patients, relative to staging alone, which can help clinicians make informed decisions regarding treatment and follow-up care. These may include closer monitoring, more frequent imaging scans and the timely initiation of adjuvant treatments to mitigate metastatic risk and improve patient outcomes.

Castle will also present a poster highlighting data from a large study of real-world, unselected patients with head and neck CM ( $n=985$ ) showing that combining DecisionDx-Melanoma test results with AJCC8 staging significantly improved risk prediction over either alone.

**Abstract ID:128718 | Poster presentation:** The 31-gene expression profile test stratifies melanoma-specific survival among patients with head and neck cutaneous melanoma tumors: A Surveillance, Epidemiology, and End Results (SEER) Program Collaboration

**Presenter and Study Author:** Matthew Goldberg, M.D., Senior Vice President, Medical, Castle Biosciences

**Poster Viewing Dates and Times:**

- Sunday, July 9, 5:15-6:45 p.m. (Welcome Reception)
- Monday, July 10, 10 a.m. – 4 p.m. and 5:30-7 p.m. (Wine and Cheese Poster Walk)
- Tuesday, July 11, 10 a.m. – 4 p.m.

In the study, DecisionDx-Melanoma testing and AJCC8 staging were independent predictors of mortality. The DecisionDx-Melanoma test classified 40% of the patients as having an increased risk of dying from their disease (Class 1B-2B test result) compared to 15% who were classified as having an increased risk by AJCC8 staging (IIB-III). Overall, the data demonstrated that combining the test's results with AJCC8 staging significantly improved risk prediction over use of either alone, providing actionable information that can enable 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), 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 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 March 31, 2023, DecisionDx-Melanoma has been ordered more than 128,000 times for patients diagnosed with cutaneous melanoma.

More information about the 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](#).

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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 potential of DecisionDx-SCC test results to (i) improve prognostic accuracy to help optimize and personalize treatment choices based on a patient's unique, biological risk profile and (ii) help clinicians make informed decisions regarding treatment and follow-up care (including closer monitoring, more frequent imaging scans and the timely initiation of adjuvant treatments to mitigate metastatic risk and improve patient outcomes); and the potential of DecisionDx-Melanoma to provide actionable information that can enable 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 or may not support the results shown in these studies, including with respect to the discussion of DecisionDx-SCC and DecisionDx-Melanoma 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 quarter ended March 31, 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.

1. Arron ST, Wysong A, Hall MA, et al. Gene expression profiling for metastatic risk in head and neck cutaneous squamous cell carcinoma. *Laryngoscope Investig Otolaryngol*. 2022;7(1):135-144. Published 2022 Jan 6. doi:10.1002/lio2.724

### Investor Contact:

Camilla Zuckero

**[czuckero@castlebiosciences.com](mailto:czuckero@castlebiosciences.com)**

### Media Contact:

Allison Marshall

**amarshall@castlebiosciences.com**

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