



NEWS RELEASE

DecisionDx-Melanoma Test Independently Improved Identification of High-Risk Patients Compared to AJCC Staging in Stage I-II Cutaneous Melanoma

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Posters presented at the Real World Dermatology for Physician Assistants and Nurse Practitioners conference also include data demonstrating test's clinical utility

Friendswood TX – April 23, 2018 – Castle Biosciences, Inc., a provider of molecular diagnostics to improve cancer treatment decisions, today announced presentation of results demonstrating that the use of the DecisionDx[®]-Melanoma gene expression profile (GEP) test with American Joint Committee on Cancer (AJCC) staging can improve accuracy of recurrence and metastasis risk for patients with localized cutaneous melanoma.

The study titled, "Improved identification of high-risk, Stage I-II cutaneous melanomas with the combination of American Joint Committee on Cancer staging and a 31-gene expression profile test result," was presented as a poster at the 3rd Annual Real World Dermatology for Physician Assistants and Nurse Practitioners conference, held April 20-22, 2018 in Orlando, Florida.

"In this large Stage I-II melanoma study population, the DecisionDx-Melanoma test improved risk prediction when used in combination with AJCC risk assessment and showed independent prognostic value," commented study co-author Robert W. Cook, PhD, Vice President, Medical Affairs and R&D at Castle Biosciences. "Providing this information for risk assessment is important to help guide patient management decisions for improved patient outcomes."

Study Background

For patients with cutaneous melanoma, accurate assessment of recurrence risk is important to guide management plans including imaging based surveillance, follow-up frequency and sentinel lymph node biopsy recommendations that can lead to early detection of metastatic disease. National guidelines suggest surveillance plans based on AJCC stage, with Stage I-IIA considered low risk and Stage IIB-IV considered high risk. The DecisionDx-Melanoma GEP test accurately and independently predicts risk of recurrence and metastasis, classifying patients as Class 1A (lowest risk) Class 1B/2A (lower or intermediate risk) or Class 2B (highest risk).

This study of 485 Stage I and II patients from a multicenter cohort with long-term outcomes assessed the use of AJCC staging combined with results from the DecisionDx-Melanoma GEP test to improve recurrence risk prediction.

Key Study Findings:

- Patients who were classified as high risk by both AJCC staging (Stage IIB-C) and the GEP test (Class 2B) had significantly lower 5-year recurrence-free survival (RFS 33.4%), distant metastasis-free survival (DMFS 49.5%) and melanoma specific survival (MSS 86.7%) compared to those identified as low risk by both methods (RFS 96.1%, DMFS 97.3%, MSS 99.6%, $p < 0.0001$ for all comparisons).
- Importantly, patients who were assessed as low risk using AJCC staging (Stage I-IIA) but high risk using the GEP test also demonstrated significantly worse outcomes (RFS 60.9%, DMFS 75.8%, MSS 85.9%) compared to patients who were assessed as low risk using both methods ($p < 0.0001$ for all comparisons).
- Multivariate Cox regression analysis indicated that both GEP high risk and AJCC high risk were significant and independent predictors of RFS (GEP HR 6.8; AJCC HR 2.98, $p < 0.0001$, both groups) and DMFS (GEP HR 8.5; AJCC HR 2.5, $p < 0.001$, both groups). For MSS, GEP Class 2B was the only significant predictor (GEP HR 43.8, $p < 0.001$; AJCC HR 1.04, $p < 0.94$).

Clinical Impact of DecisionDx-Melanoma Test

A second poster titled, "Clinical impact of a 31-gene expression profile test for cutaneous melanoma patients: a review of clinical utility studies," was also presented at the conference.

The poster highlights key findings across 5 published clinical utility studies, including:

- In prospective and retrospective multicenter clinical utility studies, the inclusion of the DecisionDx-Melanoma test in risk assessment resulted in significant differences in follow-up and surveillance when comparing low- and high-risk patients.
- Findings across multiple clinical impact studies show that incorporation of the GEP test consistently impacts

clinical management decisions for approximately 1 in 2 patients tested.

- Use of the DecisionDx-Melanoma GEP test in combination with conventional staging methods can help develop a more efficient and individualized follow-up plan based on clinical factors and tumor biology.

About DecisionDx-Melanoma

The DecisionDx-Melanoma test uses tumor biology to predict individual risk of melanoma recurrence and sentinel lymph node positivity independent of traditional factors. Using tissue from the primary melanoma, the test measures the expression of 31 genes. The test has been validated in three multicenter studies that have included 690 patients and have demonstrated consistent results. Performance has also been confirmed in four prospective studies including 702 patients. The consistent high performance and accuracy demonstrated in these studies, which combined have included over 1,300 patients, provides confidence in disease management plans that incorporate DecisionDx-Melanoma test results. Prediction of the likelihood of sentinel lymph node positivity has also been validated in two prospective multicenter studies which included over 1,400 patients. Clinical impact has been demonstrated in multicenter and single-center studies showing that test results impact clinical management decisions for one of every two patients tested. More information about the test and disease can be found at www.SkinMelanoma.com.

About Castle Biosciences

Castle Biosciences is a molecular diagnostics company dedicated to helping patients and their physicians make the best possible treatment and follow-up care decisions based on the individual molecular signature of their tumor. The Company currently offers tests for patients with cutaneous melanoma (DecisionDx[®]-Melanoma; www.SkinMelanoma.com) and uveal melanoma (DecisionDx[®]-UM and DecisionDx[®]-PRAME; www.MyUvealMelanoma.com), with development programs in other underserved cancers. Castle Biosciences is based in Friendswood, TX (Houston), and has laboratory operations in Phoenix, AZ. More information can be found at www.CastleBiosciences.com.

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Contact

Derek Maetzold, President and CEO

866-788-9007

IR@castlebiosciences.com

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