NEWS RELEASE

# Castle Biosciences' DecisionDx-Melanoma Test Identifies High-Risk Melanoma Patients Among Those Traditionally Staged as Low Risk in Newly Published Study

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Results from this cumulative validation study are consistent with prior multicenter and single-center, independent prospective studies

Friendswood, TX – January 7, 2019 – Castle Biosciences, Inc., a skin cancer diagnostics company providing molecular diagnostics to improve cancer management decisions, today announced a new publication demonstrating that the DecisionDx®-Melanoma gene expression profile (GEP) test can identify high-risk patients who are likely to recur or die from melanoma within groups of patients often considered low risk based on traditional staging metrics. Results from this multicenter study of 690 patients demonstrated that the DecisionDx-Melanoma test is an independent predictor of risk for recurrence, metastasis and melanoma-specific death. The study was published in the January 2019 issue of the Journal of the American Academy of Dermatology (JAAD).

"In this study of a large, contemporary melanoma population, the GEP test identified patients at high risk for recurrence and death from melanoma among groups that are deemed low risk by traditional staging metrics," commented study co-author John Vetto, M.D., Professor of Surgery, Division of Surgical Oncology and Director of the Cutaneous Oncology Program at the Department of Surgery, Oregon Health & Science University. "The 31-gene GEP test provides independent information that improves risk prediction and enables physicians to develop tailored care for their patients with melanoma."

Study Details:

Patients from three previously published DecisionDx-Melanoma validation studies were combined to enable analysis of test performance in the following three clinically important subgroups that are traditionally considered low risk based on current national melanoma guidelines: (1) patients who had a negative sentinel lymph node (SLN) biopsy; (2) those with American Joint Committee on Cancer (AJCC) Stage I-IIA melanoma; and (3) those with thin (≤1 mm) tumors.

The DecisionDx-Melanoma test was performed to determine molecular class for each patient, with a Class 1A result indicating the lowest 5-year risk of metastasis and a Class 2B result indicating the highest risk. Study endpoints included recurrence-free survival (RFS; time to local, regional or distant recurrence), distant metastasis-free survival (DMFS; time to any distant metastasis) and melanoma-specific survival (MSS; time to documented death from melanoma).

In this population of 690 unique Stage I-III patients with at least 5 years of follow-up or a metastatic event, median age was 59 years and median Breslow thickness was 1.3 mm. Seventy percent of patients had Stage I or II melanoma.

Key Study Findings:

- In the pooled cohort, patients with Class 1A results had significantly higher RFS, DMFS and MSS rates compared to Class 2B ($p<0.0001$ for all comparisons).
- Seventy percent of the patients who were SLN negative and experienced metastasis were identified as Class 2 by the DecisionDx-Melanoma test. Similarly, 79% of melanoma-specific deaths among those who were SLN negative were identified as having a Class 2 result.
- Patients with Stage I-IIA melanoma who received a Class 2B DecisionDx-Melanoma test result had significantly worse RFS, DMFS and MSS rates compared to patients with a Class 1A DecisionDx-Melanoma result ($p<0.0001$ for all comparisons).
- Based on Cox multivariate analysis in the Stage I-IIA subgroup that included tumor thickness, ulceration and mitotic rate, DecisionDx-Melanoma test class was found to be the only significant predictor of all three endpoints (RFS, DMFS and MSS; $p<0.05$ for all).
- For patients with thin tumors (≤1 mm), although most patients were low risk Class 1, 15 patients had the highest risk Class 2B result. Those patients with a Class 2B test result had a significantly reduced RFS of 64.6% compared to those with a Class 1A result (96.8%; $p<0.0001$).

Results of the study extend previous findings of high prognostic accuracy of the DecisionDx-Melanoma GEP test to subgroups of patients at high risk, yet for whom current national melanoma guidelines recommend low intensity

follow-up and surveillance. Additionally, the study's authors suggest that the results could have an important impact on clinical trials evaluating adjuvant treatment of Stage II disease with immunomodulatory or targeted therapies, as the identification of high-risk Stage II patients may guide appropriate patient enrollment in such trials.

The manuscript can be accessed at **https://www.jaad.org/article/S0190-9622(18)32328-4/fulltext**

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 and has been studied in over 2,900 patients. Using tissue from the primary melanoma, the test measures the expression of 31 genes. The test has been validated in three multi-center studies that have included 690 patients and have demonstrated consistent results. Performance has also been confirmed in four prospective studies including over 700 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 that included over 1,400 patients. Impact on patient management plans for one of every two patients tested has been demonstrated in multi-center and single-center studies. 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 decisions about treatment and follow up care based on the individual molecular signature of the patient's tumor. The Company currently offers tests for patients with cutaneous melanoma (DecisionDx®-Melanoma, DecisionDx®-CMSeq; www.SkinMelanoma.com) and uveal melanoma (DecisionDx®-UM, DecisionDx®-PRAME and DecisionDx®-UMSeq; www.MyUvealMelanoma.com), with programs in development for other underserved cancers, the most advanced of which is focused on patients with cutaneous squamous cell carcinoma. Castle Biosciences is based in Friendswood, Texas (Houston), and has laboratory operations in Phoenix, Arizona. More information can be found at www.CastleBiosciences.com.



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