Prospective, Multicenter Study of DecisionDx-Melanoma Supports Accuracy and Performance in Prediction of Cutaneous Melanoma Outcomes

June 4, 2019

Results from cohort with median follow up of 3.2 years presented at 2019 ASCO Annual Meeting

Friendswood, TX – June 4, 2019 – Castle Biosciences, Inc., a skin cancer diagnostics company providing personalized genomic information to improve cancer treatment decisions, today announced the presentation of updated results from a prospective, multicenter study demonstrating the accuracy and performance of DecisionDx®-Melanoma at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting being held in Chicago, IL from May 31-June 4.

The study titled, “Three year survival outcomes in a prospective cohort evaluating a prognostic 31 gene expression profile (31-GEP) test for cutaneous melanoma” (Abstract #9519), was presented at ASCO during the Poster Discussion Session: Melanoma/Skin Cancers. Previously an initial report of this cohort was published with a median follow-up of 1.5 years.

This second report, with a median follow-up of 3.2 years, emphasized three points of analysis:

- Whether the study’s extended results demonstrate the accuracy of DecisionDx-Melanoma in predicting risk of recurrence, as previously reported.
- Whether the prospective outcomes in patients with cutaneous melanoma tumors ≤2 mm thick (pathologic stage T1-T2) who had a low-risk DecisionDx-Melanoma Class 1A test result support the use of the test for guiding sentinel lymph node biopsy (SLNB) surgery decisions.
- Overall, whether the study results show that DecisionDx-Melanoma can offer improvements in patient treatment beyond American Joint Committee on Cancer (AJCC) staging.

**Key Study Findings**

- Patients with the highest risk DecisionDx-Melanoma result (Class 2B) had significantly reduced recurrence-free survival, distant metastasis-free survival and overall survival (OS) compared to patients with the lowest risk (Class 1A) result (p≤0.0001), consistent with three previously published prospective studies.
- In the subgroup of patients with T1-T2 melanoma tumors, in which DecisionDx-Melanoma has been shown to predict sentinel lymph node status, Class 1A results were associated with favorable prognosis (OS=99.4%). This confirms the favorable prognosis in T1-T2 Class 1A melanomas reported in a long-term archival tissue study (5-year OS=98.2%) and provides support for the use of a Class 1A test result to identify patients at low risk for a positive SLNB surgery result and excellent prognosis who can avoid this surgical procedure.
- DecisionDx-Melanoma Class 2B result was a significant, independent predictor of recurrence, distant metastasis and mortality compared to AJCC staging (Stages IIB-III; p<0.05) in multivariate regression analysis. Furthermore, the hazard ratio for OS was 9.35 for a high risk Class 2B result compared to 2.33 for AJCC high risk.
- These prospective results demonstrate that DecisionDx-Melanoma is an accurate, independent predictor of outcomes, including in specific subgroups for whom the test has previously been shown to predict likelihood of recurrence and SLN positivity.

“A substantial proportion of melanoma-related deaths occur among patients who were traditionally staged as low risk, highlighting the importance of the improved risk prediction seen in this study,” commented investigator Eddy C. Hsueh, M.D., Professor and Director, Division of General Surgery, St. Louis University Hospital. “Use of DecisionDx-Melanoma to improve outcome prediction over traditional staging alone can result in more informed treatment management decisions including appropriate use of sentinel lymph node biopsy, surveillance and follow-up.”

**Study Details:**

Patients were prospectively enrolled in one of two clinical registries that were established to track patient outcomes and clinical utility. All patients underwent DecisionDx-Melanoma testing as part of their melanoma assessment.

The cohort included 342 patients with AJCC Stage I-III melanoma from 11 U.S. dermatologic and surgical centers with a median age of 58 years. The majority of patients (89%) had AJCC Stage I or II melanoma. Median Breslow thickness was 1.2 mm; 260 patients had tumors 2.0 mm thick or less (T1-T2). Median follow-up was 3.2 years for patients who did not experience an event.

The poster can be found in the Publications section of the Castle Biosciences website.

**Additional Castle Biosciences Data at 2019 ASCO**

Data demonstrating the economic impact of DecisionDx-Melanoma in Medicare-eligible patients were also presented as a poster at the 2019 ASCO meeting (Abstract #6630).
An economic model was developed to perform a cost-benefit analysis for use of the DecisionDx-Melanoma test to inform patient treatment decisions. Results from the economic model suggest that using the test to guide decisions regarding the SLNB surgery, completion lymph node dissection and surveillance for a Medicare-eligible population offers significant cost savings compared to traditional care. A net cost reduction is retained with addition of DecisionDx-Melanoma testing to guide surveillance decisions in Medicare-eligible patients with melanoma tumors greater than 2 mm thick (T3-T4). Combined with previously published data showing that patients ≥65 years with Class 1A, T1-T2 melanoma have low SLN positivity and favorable outcomes, the model can be used to determine the cost-benefit of using the DecisionDx-Melanoma test to guide SLNB decisions for Medicare-eligible patients.

**About DecisionDx-Melanoma**

DecisionDx-Melanoma is a gene expression profile test that uses an individual patient’s tumor biology to predict individual risk of cutaneous melanoma metastasis or recurrence, as well as sentinel lymph node positivity, independent of traditional staging factors, and has been studied in more than 3,100 patient samples. Using tissue from the primary melanoma, the test measures the expression of 31 genes. The test has been validated in four archival risk of recurrence studies of 901 patients and five prospective risk of recurrence studies including more than 780 patients. Prediction of the likelihood of sentinel lymph node positivity has also been validated in two prospective multicenter study cohorts that included more than 1,400 patients. Impact on patient management plans for one of every two patients tested has been demonstrated in four multicenter and single-center studies including more than 560 patients. The consistent performance and accuracy demonstrated in these studies provides confidence in disease management plans that incorporate DecisionDx-Melanoma test results.

More information about the test and disease can be found at [www.SkinMelanoma.com](http://www.SkinMelanoma.com).

**About Castle Biosciences**

Castle Biosciences is a skin cancer diagnostics company dedicated to helping patients and their physicians make more informed 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](http://www.SkinMelanoma.com)) and uveal melanoma (DecisionDx®-UM, DecisionDx®-PRAME and DecisionDx®-UMSeq; [www.MyUvealMelanoma.com](http://www.MyUvealMelanoma.com)), with products 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](http://www.CastleBiosciences.com).

DecisionDx-Melanoma, DecisionDx-CMSeq, DecisionDx-UM, DecisionDx-PRAME and DecisionDx-UMSeq are the trademarks of Castle Biosciences, Inc. Any other trademarks are the property of their respective owners.

**Contact**

Derek Maetzold, President and CEO

866-788-9007

IR@castlebiosciences.com