NEWS RELEASE

Castle Biosciences Presents Data Demonstrating the DecisionDx-Melanoma Test Improved AJCC-Based Risk Prediction for Melanoma Recurrence and Metastasis

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Test demonstrated high technical reliability in over 17,000 clinical orders

Friendswood, TX – July 30, 2018 – Castle Biosciences, Inc., the skin cancer diagnostics company providing molecular diagnostics to improve cancer treatment decisions, today announced the presentation of new data showing that the DecisionDx®-Melanoma test improved risk prediction beyond that using American Joint Committee on Cancer (AJCC) based staging. The study was presented at the DERM2018 NP/PA CME Conference held in Las Vegas, Nevada.

The study assessed the impact on risk assessment for patients with Stage I-III melanoma when including results from the DecisionDx-Melanoma test along with population-based AJCC staging in a 690-patient cohort. The DecisionDx-Melanoma test uses tumor biology to provide an individual risk assessment for patients with melanoma. Results from this analysis showed that the addition of the test result to clinicopathologic AJCC staging significantly improved risk stratification. Technical reliability in over 17,000 clinical test orders was also assessed, and showed 98.3% reporting success for samples with adequate tumor content.

Study Findings:

- Multivariate analysis demonstrated that the Class 2B result was an independent predictor of melanoma-specific survival (MSS) with a greater hazard ratio than using AJCC staging alone to determine risk.

- Results from this multicenter study in 690 patients with Stage I-III melanoma show that the addition of DecisionDx-Melanoma testing can significantly improve risk prediction based on AJCC 8th edition staging alone, and can better inform patient management decision-making.
- Using AJCC staging alone, patients with Stage I melanoma have an estimated 98% MSS 5 years following diagnosis. However, patients in the Stage I melanoma group who had a Class 2B (highest risk) DecisionDx-Melanoma test result had an 89.5% 5-year survival, similar to risk estimates for Stage IIB disease.
- For patients with Stage II melanoma, the DecisionDx-Melanoma test was able to further stratify patients from the AJCC-based 90% 5-year MSS into a low-risk (Class 1A) group with an MSS of greater than 99% (similar to Stage IA) and a Class 2B group with an MSS of 84.7% (similar to Stage IIB/C).
- Using AJCC estimates alone, patients with Stage III melanoma have an MSS of 77% at 5 years. Use of the DecisionDx-Melanoma test enabled further stratification into a lower-risk Class 1A group with an MSS of 94.8% (similar to low-risk Stage IIA) and higher-risk Class 2B group with an MSS of 61.2% (similar to Stage IIIC).

“Accurate risk assessment is important for clinical decision-making. These results show that use of the DecisionDx-Melanoma test can further inform clinicopathologic staging and help guide patient management choices,” said Federico A. Monzon, M.D., FCAP, Chief Medical Officer at Castle Biosciences. “Incorporating DecisionDx-Melanoma test results can drive improvements in follow-up and surveillance planning as well as sentinel lymph node biopsy discussions.”

Study Details:

- Data from archival cutaneous melanoma tumor samples from 18 U.S. centers (n=690, Stage I-III) from previously reported cohorts were employed. Stage I-II cases were restaged according to AJCC 8th edition criteria. Importantly, the 5-year MSS rates for Stages I, II and III in this cohort were similar (within ±1%) to those reported for the AJCC 8th edition cohort.
- Class 1A and 2B-predicted MSS outcomes for each stage were compared to 5-year MSS rates associated with AJCC 8th edition stage groups. Patients were assigned a binary risk group, with Stage I-IIA considered low risk and Stage IIB-III high risk, based on National Comprehensive Cancer Network (NCCN) guidelines for surveillance and follow up.
- Technical success was determined for 17,102 clinical DecisionDx-Melanoma orders received between July 2016 and April 2018, of which 96.3% had sufficient tumor content to perform the test. The DecisionDx-Melanoma test achieved a 98.3% technical success rate for samples with sufficient tumor content.

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 multi-center 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 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 their treatment and follow up care based on the individual molecular signature of their 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 development programs in other underserved cancers. 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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