NEWS RELEASE

Castle Biosciences' DecisionDx-Melanoma Test Accurately Predicts Metastatic Risk in Patients with Head and Neck Melanoma

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Data presented at the American College of Mohs Surgery 49th Annual Meeting

Friendswood, TX – May 1, 2017 – Castle Biosciences, Inc., a provider of molecular diagnostics to improve cancer treatment decisions, today announced results from a study evaluating the prognostic accuracy of the DecisionDx®-Melanoma gene expression profile (GEP) test in a cohort of patients with head and neck melanoma. Results demonstrated that the DecisionDx-Melanoma test accurately identifies metastatic risk for these clinically challenging patients, and can add valuable information beyond the use of traditional staging techniques such as sentinel lymph node biopsy (SLNB). The data were presented during the American College of Mohs Surgery 49th Annual Meeting (ACMS), held in San Francisco, CA from April 27-30.

In the study, "Prognostic Accuracy of a 31-Gene Expression Profile (GEP) in a Cohort of Patients with Cutaneous Melanoma of the Head and Neck" (Abstract #10), primary tumor tissue from 178 patients with cutaneous melanoma (CM) of the head and neck region—of whom 121 had documented SLNB results—was analyzed using the DecisionDx-Melanoma test under an IRB-approved multicenter protocol. Based on results from the GEP test, patients were assigned to either Class 1 (low risk) or Class 2 (high risk). To further refine risk prediction, patients were assigned a sub-classification of either "A" or "B" to reflect a better or worse prognosis, respectively, based on the proximity of their result to the crossover point between classes. Primary endpoints were recurrence-free survival (RFS) as defined by time to either regional or distant metastasis, distant metastasis-free survival (DMFS) as defined by time to any metastatic event beyond the primary tumor, and melanoma-specific survival (MSS) as

defined by time from diagnosis to death resulting from melanoma. Survival rates by sentinel lymph node (SLN) status were also included for patients who underwent SLN biopsy.

Summary of Study Results:

- Patients with a Class 2B (high risk) result demonstrated similar 5-year RFS, DMFS and MSS rates compared to patients with SLN-positive status (see Table 1 below).
- Low-risk Class 1A patients demonstrated better 5-year RFS, DMFS and MSS rates compared to patients with SLN-negative status (see Table 1 below).
- DecisionDx-Melanoma testing identified 74% of patients who experienced disease recurrence and 74% of patients who had a distant metastasis.
- In this cohort of 178 patients with melanoma of the head and neck, the DecisionDx-Melanoma test was shown to be a significant and independent predictor of risk in Cox multivariate models of RFS and DMFS (see Table 2 below).
- The DecisionDx-Melanoma test could be a clinically useful tool in patients with head and neck melanoma.

Table 1. 5-year survival rates for RFS, DMFS, and MSS by DecisionDx-Melanoma subclass result and SLN status

Table 2. Multivariate analysis of Cox proportional hazard model for RFS and DMFS (n=86 for cases with complete data for analysis)

“Melanoma incidence is on the rise and it is estimated that there will be over 87,000 new cases of the disease in 2017. Approximately 20% of melanoma patients have disease in the head and neck region, and these patients exhibit higher rates of recurrence, compared to melanoma in other locations,” commented Federico A. Monzon, M.D., FCAP, Chief Medical Officer of Castle Biosciences. “We believe that the DecisionDx-Melanoma test has the ability to address the growing challenge of providing accurate and reliable prognostic information that patients and physicians can use to make important management decisions—particularly in a disease setting such as head and neck melanoma, in which unique clinical challenges can hamper the prognostic value of traditional staging.”

Additional Study: Net Reclassification Index (NRI) Analysis of DecisionDx-Melanoma
Also presented at the ACMS annual meeting was a study evaluating the combined use of the DecisionDx-Melanoma test with lymph node status through the Net Reclassification Index, or NRI—a methodology that compares sensitivity, specificity, and the balance between the two, to evaluate two diagnostic approaches.

The study titled, “Comparative Analysis of Outcomes Prediction Between a Prognostic 31-Gene Expression Profile and Sentinel Lymph Node Biopsy in a Cohort of 690 Cutaneous Melanoma Subjects” found a significant net improvement of risk prediction when the DecisionDx-Melanoma test was used in combination with nodal status.

Study Highlights:

- NRI analysis was performed to compare the prognostic accuracy of nodal status alone to nodal status in combination with the DecisionDx-Melanoma test. The study included primary melanoma tumor samples from 690 patients with melanoma previously used to validate the GEP test.
- Nodal status combined with the GEP test results identified 87% of recurrences, 88% of distant metastases, and 95% of melanoma-specific deaths compared to 54%, 57%, and 67%, respectively, for nodal status alone.
- Considering both sensitivity and specificity, NRI analysis showed that the combination of the DecisionDx-Melanoma test with nodal status resulted in significantly improved determination of risk of recurrence and distant metastasis compared to nodal status alone.

About DecisionDx-Melanoma

The DecisionDx-Melanoma test uses tumor biology to provide a prediction of individual risk of melanoma recurrence beyond 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 three independent, prospective studies including 510 patients. The consistent high performance and accuracy demonstrated in these studies, which combined have included 1200 patients, provides confidence in disease management plans that incorporate DecisionDx-Melanoma test results. Clinical impact has been demonstrated in a multi-center and single-center study showing that test results add additional patient-specific prognostic information to complement traditional staging tools. 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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