NEWS RELEASE

Study of Castle Biosciences' Skin Melanoma Gene Test Published in Clinical Cancer Research

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Results show DecisionDx-Melanoma test is powerful indicator of metastatic risk

Friendswood, TX – January 6, 2015 – Castle Biosciences, Inc. today announced the publication of a clinical validation study of its gene expression profile (GEP) test for cutaneous melanoma. DecisionDx-Melanoma accurately predicts metastatic risk independent of current diagnostic modalities including AJCC staging. The paper, "Development of a Prognostic Genetic Signature to Predict the Metastatic Risk Associated with Cutaneous Melanoma," was published today in Clinical Cancer Research, a publication of the American Association for Cancer Research (AACR).

The results show that DecisionDx-Melanoma accurately predicts metastatic risk in Stage I or Stage II melanoma patients who have no sign of disease beyond the original tumor.

"The behavior of melanoma tumors is highly variable, and often cannot be accurately predicted using traditional staging methods," commented Pedram Gerami, M.D., a study author and Associate Professor of Dermatology, Director of Melanoma Research at the Northwestern Skin Cancer Institute, Northwestern University. "These results demonstrate that a gene signature can accurately predict metastasis, particularly in tumors that were assumed to be lower risk due to stage, size and other characteristics. This test can have a significant impact on the management and potentially long term outcomes of these melanoma patients."

Study Highlights

In the multicenter development and clinical validation studies published today, formalin-fixed, paraffin-embedded

specimens from biopsy or wide excision procedures of primary cutaneous melanoma tumors were analyzed to observe changes in the expression of 28 discriminating genes. There are 3 control genes, resulting in a 31 gene panel. Based on the GEP test results, melanoma tumors were classified as either Class 1 (low risk of metastasis) or Class 2 (high risk). Patients' clinical outcomes at 5 years after diagnosis were compared with the GEP test prediction.

Overall, Kaplan-Meier analysis indicated that the 5-year disease free survival (DFS) rates in the independent validation study (n=104) were 97% and 31% for predicted Class 1 and 2, respectively ($p<0.0001$). These results are comparable to results from a separate analysis of the development cohort (n=100), which found DFS rates of 100% and 38% for predicted Class 1 and Class 2 cases, respectively ($p<0.0001$).
The DecisionDx-Melanoma test demonstrated an ability to identify high and low risk tumors in Stage I and Stage II melanoma subgroups across the development and validation study cohorts (n=220):

- The GEP test accurately identified as Class 1 (low risk) 120 of 134 (90%) Stage I and IIA patient cases without documented evidence of metastasis.
- It correctly identified 24 of 30 (80%) Stage I and IIA cases with documented metastasis as Class 2 (high risk).
- Importantly, of 9 Stage I patient cases with documented metastasis, 5 (56%) were accurately classified as Class 2 (high risk) by the GEP test.
- Conversely, 104 of 110 (95%) Stage I cases without documented metastasis were accurately classified as low risk (Class I) by the GEP test.

"The ability to more accurately stratify patients based on actual risk can have a significant impact on patients diagnosed with Stage I or II cutaneous melanoma," commented David H. Lawson, M.D., Professor of Hematology & Medical Oncology, Winship Cancer Institute, Emory University and study author. "Patients identified as high risk may choose to be monitored as if they were Stage III. Additionally, the psychological and emotional burden of a melanoma diagnosis may be lessened for patients receiving a Class 1, low risk diagnosis. This test, in combination with AJCC staging, provides caregivers with the most accurate prognostic tools currently available for managing patients diagnosed with melanoma. Ongoing studies will further define how this test can best be used in conjunction with the current AJCC staging system and to determine whether adjuvant therapy for the higher risk patients can alter the natural history of this disease."

The paper can be accessed at **http://clincancerres.aacrjournals.org/content/21/1/175.full**.

About Melanoma
Cutaneous melanoma is diagnosed in approximately 76,000 people in the U.S. each year, according to the American Cancer Society. Seventy-five percent are diagnosed as Stage I or II, meaning there is no evidence of the melanoma spreading beyond the primary tumor. Unfortunately, while these patients as a group are at lower risk of disease progression, two of three patients that will metastasize and die from melanoma were Stage I or II at diagnosis.

Cutaneous melanoma is not the most prevalent form of skin cancer, but it is the most aggressive. Unlike other more common skin malignancies such as basal cell and squamous cell carcinomas, melanoma often spreads to other parts of the body, either via the lymphatic or blood system, resulting in cancers of distant organs including the brain or lungs.

About DecisionDx-Melanoma

The DecisionDx-Melanoma is validated for clinical use in Stage I, II, and III melanoma patients. The test is designed to predict metastasis by measuring the level of expression of 31 genes from a sample of the primary melanoma tumor. The test stratifies patients as Class 1 (low risk of metastasis), or Class 2 (high risk of metastasis). To date, the test has analyzed archived tumor samples from more than 600 melanoma patients. More information about the test and disease can be found at www.skinmelanoma.com.

About Castle Biosciences

Castle Biosciences, Inc. is a molecular diagnostics and prognostics 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 rare cancers including uveal and cutaneous melanoma, thymoma, esophageal and brain cancers. More information can be found at www.castlebiosciences.com.

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