NEWS RELEASE

Study Shows Castle Biosciences' Gene Expression Profile Test Successfully Identified High Risk Disease in a Cohort of 217 Melanoma Patients Who Underwent Sentinel Lymph Node Biopsy

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Study selected as a "Poster Highlights" presentation at ASCO 2014

Chicago, IL, June 2, 2014 – Castle Biosciences, Inc. today announced results of a 217-patient study demonstrating that its gene expression profile (GEP) test, DecisionDx-Melanoma, identified primary cutaneous (skin) melanoma tumors that were sentinel lymph node biopsy negative but were at high risk of metastasis. The GEP test also identified tumors that were unlikely to become metastatic, independent of nodal status. The data are being reviewed today at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO) in the Melanoma/Skin Cancers Poster Highlights Session by David H. Lawson, M.D., Professor of Hematology and Medical Oncology, Winship Cancer Institute, Emory University.

"These data show that GEP testing may provide clinically significant information for assessing risk in melanoma patients beyond what we are seeing with sentinel lymph node status alone," commented Emory's Dr. Lawson. "Although the sentinel lymph node biopsy is our best tool for staging melanoma patients, many node-negative patients become metastatic. The results of this study indicate that this test may help further classify risk regardless of node status."

Study Details

In a multicenter protocol, researchers performed the GEP test on 217 Stage I, II, or III cutaneous melanoma tumor samples from patients who also had documented sentinel lymph node biopsies (SLNB). The predictive accuracy of each method was compared at year 5 for DMFS (distant metastasis-free survival) and OS (overall survival).

Data highlights from the study:

- A Class 2 GEP test result (high risk) and positive SLNB status provided comparable prediction of distant metastasis (positive predictive value for GEP=50%; SLNB=55%).
- The GEP test provided better prediction of low risk of distant metastasis compared to SLNB outcome (negative predictive value for GEP=82% vs. SLNB=67%).
- Patients with both a low risk GEP test (Class 1) and a negative SLNB status had a lower risk of their disease spreading, compared to negative SLNB status alone (5-year DMFS 86% vs. 64%, respectively).
- In this study the GEP test was more accurate than SLNB when the two methods showed discordant outcome predictions (Class1/SLNB+ or Class 2/SLNB-).
- In this study GEP testing of SLNB eligible patients provided clinically significant prognostic information independent of SLNB status and warrants consideration as an additional prognostic tool to enhance patient management.

A summary of the results:

“Although SLNB has been shown to be the most valuable tool for staging high risk melanoma patients, twice as many node-negative as positive patients will develop advanced disease,” said Derek Maetzold, President and CEO of Castle Biosciences. “It is known that many melanomas spread through non-lymphatic mechanisms or are biologically cleared from the lymphatic system prior to SLNB, underscoring the need for prognostic methods that are independent of the lymphatic system to more accurately assess metastatic risk and determine the most appropriate follow-up care.”

The DecisionDx-Melanoma test is designed to predict metastasis by measuring the level of expression of 31 genes in the 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 in prospectively designed archival tissue studies. More information about the test and disease can be found at www.skinmelanoma.com.

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. It 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. So, while it represents just 4% of skin cancers, melanoma accounts for about 80% of skin cancer-related deaths.

About Castle Biosciences

Castle Biosciences, Inc. is a molecular diagnostics and prognostics company dedicated to helping patients and physicians make optimal decisions regarding treatment and follow-up care based on the tumor's unique molecular signature. The Company currently offers prognostic tests for patients with rare cancers including uveal and cutaneous melanoma, esophageal, thymoma and brain cancers as well as malignant pleural mesothelioma. More information can be found at www.castlebiosciences.com.

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