



NEWS RELEASE

Castle Biosciences' Non-Invasive Gene Expression Profile Test Shown to Identify Sentinel Lymph Node Negative Melanoma Patients at High Risk of Metastasis

3/22/2014

PDF Version

Data presented at the Latest in Dermatology Research Symposium session of 72nd Annual Meeting of the American Academy of Dermatology

Denver, CO, March 22, 2014 – Castle Biosciences Inc. today announced study results showing its gene expression profile (GEP) test (DecisionDx-Melanoma) can identify primary cutaneous (skin) melanoma tumors that are likely to metastasize in patients who had a negative sentinel lymph node biopsy. The data are being presented at the Latest in Dermatology Research Symposium session of the 72nd Annual Meeting of the American Academy of Dermatology. The DecisionDx-Melanoma test completed validation in 2013 and is widely used to determine metastatic risk in Stage I and II melanoma patients.

“Although sentinel lymph node biopsy has traditionally been the best prognostic test available for melanoma patients, two out of three patients who eventually develop distant metastasis had a negative SLNB result,” said Pedram Gerami, M.D., study author and Associate Professor of Dermatology, Director of Melanoma Research at the Northwestern Skin Cancer Institute, Northwestern University. “The results from this study show the GEP test is an independent predictor of metastasis and death, and significantly improves upon sentinel lymph node biopsy for staging melanoma patients.”

[Study Details](#)

Researchers compared the results of the non-invasive 31-gene GEP test to sentinel lymph node biopsy (SLNB) results in 134 patients with Stage I, II, or III cutaneous melanoma. These 134 patients represented all patients in the initial clinical validation studies who had a documented sentinel lymph node procedure.

In patients with a negative sentinel lymph node biopsy (SLNB-), a result interpreted as a lower risk for metastasis, the GEP test identified the vast majority of melanomas that ultimately progressed over the subsequent 5-year period. According to study results, the rate of 5-year metastasis-free survival (MFS) was 55% for SLNB- patients compared to 37% for SLNB+ patients ($p=0.003$). The GEP test results showed improved prognostic accuracy in these same patients with an MFS of 87% for the low-risk (Class 1) patients and 31% for the high risk (Class 2) patients ($p<0.0001$).

Differences in overall survival (OS) paralleled the MFS rates, with SLNB- patients having a 5-year OS of 67% and SLNB+ having a 5-year OS of 55% ($p=0.024$). The GEP test again showed improved prognostic accuracy, with an OS for GEP Class 1 patients of 92% compared to 49% for Class 2 patients ($p<0.0001$).

Use of the GEP test was also analyzed in combination with SLNB status. As expected, the 20% of patients who had high risk results for both tests (GEP Class 2 and SLNB+) had lower survival rates (MFS=34%; OS=53%). Similarly, the 31% of patients who had low risk results for both tests (GEP Class 1 and SLNB-) had higher survival rates (MFS=86%; OS=92%).

Importantly, in the 49% of patients who had results that were discordant (high risk outcome for one test, low risk for the other) the GEP test result correctly predicted the patients' clinical outcomes. Net reclassification improvement of GEP class over SLNB status was greater than 50%.

Cox multivariate analysis comparing the GEP test to SLNB showed the GEP test to be the only independent and highly significant prognostic factor in this analysis ($p<0.000003$).

Continued Dr. Gerami, "Based upon this data, optimal use of the GEP test may be to identify high risk patients among those with a negative SLNB result, or for patients who are ineligible for or who decline a SLNB procedure."

"These results in patients who underwent sentinel node biopsies build on data we presented at ASCO last year showing the GEP test accurately identifies patients with Stage I and II tumors who are likely to metastasize," said Derek Maetzold, President and Chief Executive Officer of Castle Biosciences. "The non-invasive GEP test is now widely used clinically, and we continue to explore additional uses such as combination with sentinel lymph node biopsy where decision making can be improved through the use of more accurate test results."

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 melanomapatients. More information about the test and disease can be found at www.skinmelanoma.com.

About Castle Biosciences

Castle Biosciences 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.

PDF Version