Independent Study Verifies the Performance of Castle Biosciences' Cutaneous Melanoma Gene Expression Profile Test for Predicting Risk of Metastasis

Results presented at the 48th Annual Meeting of the American College of Mohs Surgery

Friendswood, TX – May 2, 2016 – Castle Biosciences, Inc., a provider of molecular diagnostics to improve cancer treatment, today announced results of an independent study with its noninvasive gene expression profile test, verifying the accuracy and utility of the assay to identify risk of metastasis in patients diagnosed with Stage I or II cutaneous melanoma. Results were presented in an oral presentation session at the 48th Annual Meeting of the American College of Mohs Surgery in Orlando, FL.

The study, titled "Estimation of Prognosis in Invasive Melanoma Using a Gene Expression Profile Test" is an independent, single-center performance study of 257 successfully tested, consecutively consented patients, some of whom were previously diagnosed. Residual formalin-fixed paraffin embedded tumor samples were obtained and analyzed using the previously validated 31-gene expression profile signature.

"Our independent study results demonstrate a strong Negative Predictive Value of 98.6% for any metastatic event and 99.5% for melanoma-specific mortality, and are consistent with Castle Biosciences' sponsored multi-center validation and performance studies for the test," said John A. Zitelli, M.D., Zitelli & Brodland Skin Cancer Center, Pittsburgh, PA. "Based on these study results and previously published data, our center employs an institutional protocol involving regular and intense clinical skin and nodal follow up exams on high risk Class 2 patients, and a lower intensity follow up regimen on low risk Class 1 patients."

Study Summary

This independent, single-center performance study included 256 successfully tested, consecutively consented patients, some of whom were previously diagnosed (mean follow-up time was 24 months). All patients underwent the DecisionDx®-Melanoma gene expression profile test, measuring the activity of 31 genes known to be associated with progression in this cancer. Based on the tumor's gene expression levels, each patient's tumor was classified as either low risk Class 1 or high risk Class 2. Metastatic-free survival was evaluated for frequency, accuracy statistics, and the predefined sub-classifications of normal versus reduced confidence. Melanoma-specific survival was evaluated for frequency.

Analysis of Metastatic Events for Predicted Outcomes

Metastatic-Free Survival Normal (N) vs Reduced Confidence (R) Cut-Point Analysis				
	N	# (%) events	(%) event free	p-value
Class 1N	193	2 (0.1%)	191 (98.9%)	p<0.0001
Class 1R	21	1 (4.8%)	20 (95.2%)	
Class 2R	16	2 (12.5%)	14 (87.5%)	
Class 2N	26	8 (30.8%)	18 (69.2%)	
Fisher's exact				

Metastatic-Free Survival (Accuracy Statistics)			
		95% Lower Confidence Limit	**95% Upper Confidence Limit**
Sensitivity	0.769	0.460	0.938
Specificity	0.868	0.818	0.907
Negative Predictive Value	0.986	0.956	0.996
Positive Predictive Value	0.238	0.126	0.398
Odds ratio	22.0	5.7	84.2

Analysis of Melanoma-Specific Mortality for Predicted Outcomes

Melanoma-Specific Mortality				
	N	# (%) deaths	# (%) survival	p-value
Class 1	214	1 (0.5%)	213 (99.5%)	p<0.0001
Class 2	42	7 (17%)	35 (83%)	
Fisher's exact				

"Consistent with the results from the first two published clinical validation studies, this independent performance study demonstrates that patients with a DecisionDx-Melanoma Class 2 signature were 22 times more likely to develop metastatic disease than those with a low risk Class 1 result. Implementing a follow-up management plan aligned with an individual patient's risk of recurrence is consistent with three other completed clinical utility studies and national guidelines," said Derek Maetzold, President and CEO of Castle Biosciences. "In this study, the DecisionDx-Melanoma test accurately identified both high risk patients who are missed by traditional staging systems, and patients who are at low risk of metastasis with a Class 1 designation. These data provide further confirmation that the DecisionDx-Melanoma test is a clinically important tool to

identify risk of metastasis and guide follow-up management for early stage patients."

To date, the DecisionDx-Melanoma test has been validated and evaluated in performance studies using archived tumor samples from more than 1,000 melanoma patients in prospectively designed archival tissue studies, in addition to independent performance studies such as this one, and has been used clinically in over 7,500 patients. 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 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 uveal melanoma and cutaneous melanoma, 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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