NEWS RELEASE

# Two New Studies at the 2018 AAD Annual Meeting Highlight the Clinical Impact and Utilization of the DecisionDx-Melanoma Test for Cutaneous Melanoma

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First prospective clinical impact study confirms that the test impacts 1 in 2 patient management decisions

San Diego, CA – February 16, 2018 – Castle Biosciences, Inc., a provider of molecular diagnostics to improve cancer treatment decisions, today announced the presentation of two studies highlighting the clinical use of the DecisionDx®-Melanoma gene expression profile test, which uses tumor biology to provide an individual risk of recurrence in cutaneous melanoma patients. The data will be presented during the 74th Annual Meeting of the American Academy of Dermatology (AAD), held in San Diego, CA from February 16-18.

The clinical impact study titled, "A Prospective Multicenter Study to Evaluate the Clinical Impact of a 31-Gene Expression Profile Test on Physician Recommendations for Management of Melanoma Patients," (Abstract 6798) will be presented during the Late-Breaking Research: Basic Science/Cutaneous Oncology/Pathology session at the meeting. Researchers found that physicians used test results to inform risk-appropriate changes in patient management while remaining within the context of established practice guidelines.

The second study titled, "Factors Impacting Dermatologists' Decision to Utilize a 31-Gene Expression Profiling Test to Assess Metastatic Risk for Melanoma Patients," (Abstract 7061) examined clinicopathologic factors that impact dermatologists' decisions to recommend the DecisionDx-Melanoma test for patients. The study found that a majority of clinicians would order the DecisionDx-Melanoma test for tumor thickness of 0.5 mm or greater with or without ulceration, and for thinner tumors if a factor such as ulceration were present.

Clinical Impact Study

This multicenter, prospective clinical impact study included 247 patients from 15 dermatology, medical oncology or surgical oncology centers. Patients were clinical Stage I or II at time of enrollment. The patient cohort has a median age of 63 years and median Breslow thickness of 1.1 mm.

Pre and post-test management recommendations were collected, including laboratory tests, imaging, frequency of clinical visits, adjuvant treatment discussion, and plans for referral to surgical or medical oncology. To assess clinical impact of the test, changes between pre- and post-test plans were categorized as an increase, decrease or no change in care.

Key Study Findings:

- 181 patients (73%) had a Class 1 (low-risk) result and 66 (27%) had a Class 2 (high-risk) result.
- Overall 49% of patients tested experienced a change in clinical management recommendations following the receipt of the DecisionDx-Melanoma test.
- Class 1 patients showed a 36% post-test change in management plans, while 85% of Class 2 patients had a change following the DecisionDx-Melanoma test.
- 79% of management changes were assessed to be in a risk-appropriate direction based on test result, with 91% of decreases in care documented for low-risk (Class 1) patients, and 72% of increases in care provided for high-risk (Class 2) patients.
- The most significantly changed management modalities were follow-up frequency and imaging.

“Across the different practice settings in this study, the DecisionDx-Melanoma test informed risk-appropriate patient management decisions, consistent with previous publications demonstrating that the test impacts one in two clinical management decisions,” said Federico Monzon, MD, Chief Medical Officer, Castle Biosciences. “These findings align with national guidelines, which recommend that a patient’s individual risk of recurrence should drive management decisions.”

Utilization of Clinicopathologic Factors for Decision-Making

Results from a clinical utility study designed to determine which factors impact clinicians’ decisions to use the DecisionDx-Melanoma prognostic test were also presented during the AAD meeting. The impact on use of the test by Breslow thickness, ulceration, and sentinel lymph node biopsy (SLNB) status were evaluated using clinical vignettes and an interactive response methodology. The vignettes included tumors with Breslow thicknesses of 0.26, 0.50, 0.76 and 2.10 mm, with or without ulceration or knowledge of SLNB status. A total of 181 dermatologists completed the study.

Key Study Findings:

- 87% of dermatologists in this study would recommend the DecisionDx-Melanoma test for all tumors with a Breslow thickness of 0.5 mm or greater in the absence of ulceration and 78% in the presence of ulceration.
- Presence of ulceration was associated with an increase in the number of dermatologists who would recommend the test for all but the thickest tumor assessed (2.10 mm).
- For the thinnest tumor assessed (0.26 mm) the presence of ulceration significantly increased the number of dermatologists who would recommend the test from 22% to 67% ($p<0.001$).
- SLNB negative status was associated with an increase in the number of physicians recommending the test for the thinnest tumors from 22% to 34% ($p=0.033$).

“Overall, tumor thickness and presence of ulceration were found to be the most impactful factors influencing clinicians’ decisions to order the DecisionDx-Melanoma test,” said study co-author Darrell S. Rigel, M.D., M.S., Clinical Professor at New York University School of Medicine. “The study shows that dermatologists are making appropriate decisions to use the test as an important part of metastatic risk assessment in early stage patients.”

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 four prospective studies including 702 patients. The consistent high performance and accuracy demonstrated in these studies, which combined have included over 1300 patients, provides confidence in disease management plans that incorporate DecisionDx-Melanoma test results. Prediction of the likelihood of sentinel lymph node positivity has also been validated in two prospective multi-center studies which included over 1400 patients. Clinical impact has been demonstrated in multi-center and single-center studies showing that test results change approximately 50% of management decisions. 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 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 cutaneous melanoma (DecisionDx®-Melanoma; www.SkinMelanoma.com) and uveal melanoma (DecisionDx®-UM, DecisionDx®-PRAME and DecisionDx®-UMSeq; 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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