



NEWS RELEASE

Castle Biosciences Presents Prospective Data Supporting Use of DecisionDx-Melanoma Test to Inform Sentinel Lymph Node Biopsy Recommendations

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Initial data supporting feasibility of cutaneous squamous cell carcinoma prognostic test development program also presented

Friendswood TX – May 7, 2018 – Castle Biosciences, Inc., the skin cancer diagnostics company providing molecular diagnostics to improve cancer treatment decisions, today announced the presentation of data supporting clinical use of the DecisionDx[®]-Melanoma test to inform sentinel lymph node biopsy (SLNB) recommendations. The study was presented as a poster at the American College of Mohs Surgery (ACMS) 50th Annual Meeting in Chicago.

The study found that the DecisionDx-Melanoma test result can be used with clinicopathologic factors to inform patient discussions and recommendations for SLNB in line with national melanoma clinical practice guidelines.

Study Background:

- SLNB is recommended to assess prognosis of melanoma patients. Current guidelines recommend that clinicians discuss the SLNB procedure with patients who have a greater than 5% likelihood of SLN positivity; the guidelines do not generally recommend the procedure if a patient has a less than 5% likelihood of SLN positivity.
- Previously, a patient's risk for SLN positivity has been determined using traditional clinicopathologic features



such as Breslow's thickness and ulceration status. Importantly, it is recognized that older patients have a lower likelihood of SLN positivity but are at higher risk of recurrence and death from melanoma.

- The DecisionDx-Melanoma test is a 31-gene expression profile (GEP) test that uses tumor biology to provide an individual risk of recurrence in cutaneous melanoma patients. The validity and performance of the test has been confirmed in three multicenter archival tissue studies involving 690 patients and three prospective studies involving 702 patients. The test has been shown to be an independent predictor of recurrence compared to clinicopathologic factors of Breslow's thickness, ulceration status, mitotic rate and SLN status.
- This study was designed to determine whether the test could be used along with clinicopathologic factors to improve identification of patients with a low likelihood of SLN positivity (<5%) as well as those with a higher likelihood.

Key Study Findings:

- Using the DecisionDx-Melanoma GEP test in combination with clinicopathologic factors of age and T category, an algorithm predicting the likelihood of SLN positivity was validated in two independent, prospective, multicenter cohorts totaling 1,421 patients.
- For patients with T1-T2 tumors older than 65 years of age who had a Class 1A test result (lowest risk of recurrence), SLN positivity was less than the 5% threshold below which guidelines do not generally recommend the procedure.
- For patients with T1-T2 tumors who had a Class 2B test result (highest risk of recurrence), SLN positivity exceeded the 10% threshold for all age groups. Guidelines suggest that patients whose SLN positivity risk exceeds 10% be offered the SLNB procedure.
- The impact of not performing SLN biopsy in Class 1A patients was evaluated based on a retrospective dataset of 690 patients with long-term follow-up. At 5 years, Class 1A patients with T1-T2 tumors had a melanoma-specific survival of 99.6%, overall survival of 98.2%, and distant metastasis-free survival of 95.3%.

"The incorporation of the DecisionDx-Melanoma test result, along with tumor thickness and age, helps to identify a group of patients who have a likelihood of a positive sentinel lymph node of less than 5%, suggesting they may be able to safely avoid the SLNB procedure," said Federico Monzon, M.D., FCAP, Chief Medical Officer at Castle Biosciences. "Based on these study results, the DecisionDx-Melanoma test can inform the discussion of SLNB options with melanoma patients and provides an important advance in the management of early stage melanoma patients."

Oral Presentation Features Initial Data from Cutaneous Squamous Cell Carcinoma GEP Test Development Program

Also at the meeting, Dr. Sarah Arron, M.D., Ph.D., Associate Professor in the Department of Dermatology at the University of California San Francisco, presented initial data from Castle Biosciences' prognostic GEP test in

development for cutaneous squamous cell carcinoma (cSCC).

The goal of the development program is to validate a prognostic test that can predict which cSCC patients are at higher risk of metastasis or recurrence and thus inform clinical management decisions. Data from a development cohort of samples show that preliminary predictive models can improve upon current staging methods. These results support the feasibility of the program to develop a clinically valuable test to predict which cSCC patients are at higher risk for recurrence.

“For patients with cutaneous squamous cell carcinoma, accurate prediction of their individual risk of recurrence or metastasis remains a challenge,” commented Dr. Arron, who is an investigator for the study. “The development of a prognostic test that improves risk prediction could better inform important management decisions such as optimal surgical procedure, use of adjuvant radiation and selection of patients for SLNB or adjuvant immunotherapy, and has the potential to drive improvements in patient management.”

Continued collaborative site recruitment and development activities are ongoing.

About DecisionDx-Melanoma

The DecisionDx-Melanoma test uses tumor biology to predict individual risk of melanoma recurrence and sentinel lymph node positivity independent of 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 1,300 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 multicenter studies that included over 1,400 patients. Clinical impact has been demonstrated in multi-center and single-center studies showing that test results impact clinical management decisions for one of every two patients tested. 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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