



NEWS RELEASE

# Castle Biosciences' DecisionDx-Melanoma Test Performance Demonstrated in Newly Expanded Multicenter Cohort of 782 Patients

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Study presented at the International Pigment Cell Conference demonstrates continued robust test performance

Friendswood, TX–August 29, 2017 – Castle Biosciences, Inc., a provider of molecular diagnostics to improve cancer treatment decisions, today announced that results of the DecisionDx®-Melanoma prognostic test's performance in a cumulative cohort of 782 patients with cutaneous melanoma were presented during the 23rd International Pigment Cell Conference (IPCC 2017) held in Denver, CO from August 26-30. In the study cohort, DecisionDx-Melanoma demonstrated improved clinical risk assessment beyond current methods of prognostication, consistent with findings from previous retrospective and prospective studies.

The study titled, "Continued Evaluation of a 31-Gene Expression Profile to Predict Metastasis in an Expanded Cohort of 782 Cutaneous Melanoma Patients" (abstract 5175), combined results from 261 newly analyzed tumor samples with data from three previous DecisionDx-Melanoma validation studies, exclusive of the training set. In this cumulative population of 782 Stage I-IV patients, median age was 60 years and median time of follow-up was 6.9 years. The DecisionDx-Melanoma gene expression profile (GEP) test was performed to determine molecular class for each patient, with a Class 1 result indicating low 5-year risk of metastasis and a Class 2 result indicating high risk. Study endpoints included recurrence-free survival (RFS; time to regional or distant metastatic event), distant metastasis-free survival (DMFS; time to any metastatic event beyond the regional nodal basis) and melanoma-specific survival (MSS; time from diagnosis to death from melanoma).



## Key Study Findings:

- Results from this expanded multicenter cohort show the prognostic accuracy of the DecisionDx-Melanoma test with 5-year RFS rates of 89% for Class 1 (low risk) and 49% for Class 2 (high risk) patients ( $p < 0.0001$ ). DMFS 5-year rates were 93% for Class 1 and 59% for Class 2 ( $p < 0.0001$ ), while MSS 5-year rates were 98% for Class 1 and 81% for Class 2 ( $p < 0.0001$ ).
- Using Cox multivariate analysis, DecisionDx-Melanoma test class, Breslow thickness and node positive status were found to be significant predictors of RFS, DMFS and MSS ( $p$
- Class 2 patients who experienced a metastasis had a median time to event of 1.1 years.
- For patients who had undergone a sentinel lymph node (SLN) biopsy procedure ( $n=506$ ), the RFS rate was 87% for patients who were both SLN negative and Class 1 (compared to 74% for node negative status alone) and 32% for those who were SLN positive and Class 2 (compared to 41% for SLN positivity alone; see table below).

## Analysis of RFS and DMFS for combined DecisionDx-Melanoma and SLN predicted outcomes

“These results show the accuracy and performance of the DecisionDx-Melanoma prognostic test in a large combined cohort of patients from our validation studies, demonstrating that the test provides valuable information about a patient’s individual risk of metastasis that is independent of and complementary to traditional staging tools,” commented Federico A. Monzon, M.D., FCAP, Chief Medical Officer of Castle Biosciences. “We believe that use of the DecisionDx-Melanoma test can help improve identification of patients at high risk for distant metastasis, enabling implementation of management plans that are consistent with their individual risk.”

The poster can be found in the **Publications** section of the Castle Biosciences website.

**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 multicenter studies that have included 690 patients and have demonstrated consistent results. Performance has also been confirmed in three independent, prospective studies including 510 patients. The consistent high performance and accuracy demonstrated in these studies, which combined have included 1200 patients, provides confidence in disease management plans that incorporate DecisionDx-Melanoma test results. Clinical impact has been demonstrated in a multicenter and single-center study showing that test results add additional patient-specific prognostic information to complement traditional staging tools. More information about the test and disease can be found at [www.SkinMelanoma.com](http://www.SkinMelanoma.com).

**About Castle Biosciences** Castle Biosciences is a molecular diagnostics company dedicated to helping patients and their physicians make the best possible treatment and follow-up care decisions based on the individual molecular

signature of their tumor. The Company currently offers tests for patients with cutaneous melanoma (DecisionDx®-Melanoma; [www.SkinMelanoma.com](http://www.SkinMelanoma.com)) and uveal melanoma (DecisionDx®-UM and DecisionDx®-PRAME; [www.MyUvealMelanoma.com](http://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](http://www.CastleBiosciences.com).

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#### Media

BMC Communications

Brad Miles

646-513-3125

[bmiles@bmccommunications.com](mailto:bmiles@bmccommunications.com)

#### Investors

Derek Maetzold, President and CEO

866-788-9007

[IR@castlebiosciences.com](mailto:IR@castlebiosciences.com)

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