Study Results Confirm Newly Developed Nomogram Using Castle Biosciences' DecisionDx-Melanoma Test Improves Assessment of Melanoma Patient Risk

October 31, 2019

Data presented at the American Society for Dermatologic Surgery (ASDS) 2019 Annual Meeting

FRIENDSWOOD, Texas--(BUSINESS WIRE)--Oct. 31, 2019-- Castle Biosciences, Inc. (Nasdaq: CSTL), a skin cancer diagnostics company providing personalized genomic information to improve cancer treatment decisions, today announced the presentation of results from a study validating a newly developed nomogram tool that combines information from the DecisionDx®-Melanoma test with clinicopathologic features to improve prediction of patients' risk of melanoma recurrence.

The study titled, "Development and validation of a clinically useful nomogram incorporating molecular clinicopathologic factors to predict risk of recurrence in patients with cutaneous melanoma," was presented during an Oral Abstract session at the American Society for Dermatologic Surgery (ASDS) Annual Meeting, October 24-27 in Chicago.

"The nomogram combines results from the DecisionDx-Melanoma prognostic test with clinical and pathological features to create an accurate tool that is designed to improve risk assessment beyond staging factors alone," said study co-author Ryan Thorpe, M.D., Ada West Dermatology, Meridan, Idaho. "Using the nomogram to estimate patient risk, we believe physicians can optimize treatment decisions such as sentinel lymph node biopsy, frequency of follow-up, the need for imaging, as well as evaluate entry into clinical trials."

Current melanoma guidelines recommend that treatment management be guided by an individual patient's risk of metastasis or recurrence, which is impacted by clinical and pathologic features. This study combined the DecisionDx-Melanoma test result with clinicopathologic features to develop a nomogram tool that provides a more accurate determination of the risk of recurrence in patients with melanoma compared to clinical and pathologic features alone.

The study included a prospective cohort of 1,124 patients with melanoma from nine dermatology centers participating in the Cutaneous Oncology Research Consortium (CORC). Those with at least one year of follow-up or a recurrence event who also had complete clinicopathologic information and a DecisionDx-Melanoma result available were included in the nomogram development (n=685). The median follow-up time of this cohort was 3.0 years and median age was 67 years. The majority of patients had thin melanoma (84% had a tumor 1 mm deep or less), and ulceration was present in 7% of patients. The DecisionDx-Melanoma prognostic test for cutaneous melanoma predicts 5-year risk of recurrence and metastasis as low risk (Class 1, 1A lowest risk) or high risk (Class 2, 2B highest risk).

Key Study Findings:

- Patients with Class 1A DecisionDx-Melanoma test results had significantly better recurrence-free survival (RFS) at 1.5 years compared to patients with Class 2B results (98.9% and 70.3%, respectively). Similar results were seen for distant metastasis-free survival (DMFS), with 99.6% survival for patients with a Class 1A result and 84.4% for those with a Class 2B result.
- In a multivariate Cox regression model including DecisionDx-Melanoma and clinical features, only Breslow thickness and DecisionDx-Melanoma results were significant predictors for RFS (hazard ratio [HR] 1.25, p=0.0002 and 9.02, p<0.0001, respectively).
- Researchers developed an optimized nomogram that includes American Joint Committee on Cancer (AJCC) T category (determined by tumor thickness and ulceration) and DecisionDx-Melanoma test results as the strongest variables contributing prognostic information. The nomogram was then independently validated for prediction of recurrence in a retrospective cohort of 901 patients who had a median follow-up of 5.8 years.
- Using clinical and molecular variables, the validated nomogram improved recurrence risk prediction beyond clinicopathologic factors alone.

About DecisionDx-Melanoma

DecisionDx-Melanoma is a gene expression profile test that uses an individual patient's tumor biology to predict individual risk of cutaneous melanoma metastasis or recurrence, as well as sentinel lymph node positivity, independent of traditional staging factors, and has been studied in more than 3,900 patient samples. Using tissue from the primary melanoma, the test measures the expression of 31 genes. The test has been validated in four archival risk of recurrence studies of 901 patients and five prospective risk of recurrence studies including more than 780 patients. Prediction of the likelihood of sentinel lymph node positivity has also been validated in two prospective multicenter studies that included more than 2,000 patients. Impact on patient management plans for one of every two patients tested has been demonstrated in four multicenter and single-center studies including more than 560 patients. The consistent performance and accuracy demonstrated in these studies provides confidence in disease management plans that incorporate DecisionDx-Melanoma test results.

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

About Castle Biosciences

Castle Biosciences (Nasdaq: CSTL) is a commercial-stage dermatologic cancer company focused on providing physicians and their patients with personalized, clinically actionable genomic information to make more accurate treatment decisions. The Company currently offers tests for patients with cutaneous melanoma (DecisionDx®-Melanoma, DecisionDx®-CM*Seq*; www.SkinMelanoma.com) and uveal melanoma (DecisionDx®-UM, DecisionDx®-PRAME and DecisionDx®-UM*Seq*; www.MyUvealMelanoma.com), with products in development for other underserved cancers, the two most advanced of which are focused on patients with cutaneous squamous cell carcinoma, and patients who have a difficult-to-diagnose pigmented lesion. Castle Biosciences is based in Friendswood, Texas (Houston), and has laboratory operations in Phoenix, Arizona. For more information, visit www.CastleBiosciences.com.

Forward-Looking Statements

The information in this press release contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning the ability of the nomogram results to improve risk assessment beyond staging factors; whether the nomogram can optimize physicians' treatment decisions; and the ability of the nomogram to more accurately determine risk of recurrence compared to clinicopathologic features alone. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks that future study results may be unable to support, or be inconsistent with, the study results discussed in this press release, physicians may not implement the nomogram tool for treatment management and the other risks set forth in our final prospectus filed with the SEC on July 26, 2019 relating to our Registration Statements on Form S-1 (File Nos. 333-232369 and 333-232796) and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the SEC on September 3, 2019, and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements, except as may be required by law.

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