Castle Biosciences Presents Second Study Confirming Ability of DecisionDx-Melanoma to Inform Sentinel Lymph Node Biopsy Decisions at the 8th International Congress on Cancer Metastasis

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FRIENDSWOOD, Texas--(BUSINESS WIRE)--Oct. 28, 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 data supporting clinical use of the DecisionDx®-Melanoma test to inform decisions of whether to discuss or recommend the sentinel lymph node biopsy (SLNB), a surgical procedure used to provide additional prognostic information. The study found that DecisionDx-Melanoma test results can be used with clinicopathologic factors to identify patients at low risk of sentinel lymph node (SLN) positivity. This information can inform patient discussions and recommendations regarding the SLNB surgical procedure in line with national melanoma clinical practice guidelines.

The study titled, "Identification of T1-T2 melanoma patients at low risk for a positive sentinel lymph node using the 31-gene expression profile test," was presented during an Oral Abstract session at the 8th International Congress on Cancer Metastasis (ICCM) in San Francisco, October 25-27.

<u>Study Background:</u>

- National guidelines recommend the SLNB surgical procedure to assess prognosis of melanoma patients whose tumor features suggest at least a 5% likelihood of sentinel lymph node (SLN) positivity. The guidelines do not recommend the procedure if a patient has a likelihood of SLN positivity of less than 5%.

- Among all patients with T1-T2 melanoma (tumor depth of 2 mm or less), only 5-10% have a positive SLNB, with the likelihood of a positive SLN decreasing with age.

- The DecisionDx-Melanoma test is a 31-gene expression profile prognostic test for cutaneous melanoma that predicts 5-year risk of metastasis as low risk (Class 1, 1A lowest risk) or high risk (Class 2, 2B highest risk), as well as metastasis to the sentinel lymph node.

- The DecisionDx-Melanoma test has been previously validated to identify patients with T1-T2 melanoma with SLN positivity rates below 5%, thus helping guide SLNB discussions and recommendations.

- This study was designed to further evaluate the ability of the DecisionDx-Melanoma test to identify T1-T2 melanoma patients with low risk for a positive SLN, using the combination of the previously published cohort with a novel cohort, totaling 1,905 prospectively tested consecutive T1-T2 melanoma patients. The cohort had a median age of 64 years, median Breslow depth of 1.2 millimeters and 13% had ulceration present.

<u>Key Findings:</u>

- In patients with T1-T2 tumors of any age (DecisionDx-Melanoma intended use population) and a Class 1A test result, SLN positivity was 4.9%, significantly less than patients with a Class 1B-2A result (p<0.01) or a Class 2B result (p<0.0001) and below the 5% threshold at which guidelines do not recommend the procedure.

- In SLNB-assessed patients with T1-T2 tumors 65 years of age or older and a Class 1A test result, SLN positivity was 2.7%, significantly less than patients with a Class 1B-2A (p<0.01) or Class 2B result (p<0.0001), and below the 5% threshold at which guidelines do not recommend the procedure.

- In SLNB-assessed patients with T1 tumors (tumor depth of 1 mm or less) 65 years of age or older and a Class 1A test result, SLN positivity was 1.0%, significantly less than patients with a Class 1B-2A (p<0.01) or a Class 2B result (p<0.001), and below the 5% threshold at which guidelines do not recommend the procedure.

- Use of the DecisionDx-Melanoma test to guide SLNB decisions in patients with T1-T2 melanoma could reduce SLNB surgical procedures by 58% in patients 65 years of age or older, as 367 of 629 patients who underwent this procedure had a Class 1A result.

- In a multi-center, retrospective dataset of 576 T1-T2 patients with long-term follow-up (median 7.5 years) Class 1A patients with T1-T2 melanoma had melanoma-specific survival of 99.7%, overall survival of 97.3%%, distant metastasis-free survival of 94.9% and recurrence-free survival of 92.9% at five years, supporting that this population can safely avoid the SLNB surgical procedure.

- In a multi-center, prospective dataset of 246 T1-T2 patients with long-term follow-up (median 3.2 years), Class 1A patients

with T1-T2 melanoma had overall survival of 99.4%, distant metastasis-free survival of 98.7% and recurrence-free survival of 96.6% at three years, adding further support that this population can safely avoid the SLNB surgical procedure.

"The data presented at the ICCM show the DecisionDx-Melanoma test, in combination with patient age and clinical features, can identify T1-T2 melanoma patients who are at low risk for a positive sentinel lymph node and can avoid the SNLB surgical procedure, based on thresholds established by national clinical melanoma guidelines," said Federico A. Monzon, M.D., FCAP, chief medical officer at Castle Biosciences. "Additionally, T1-T2 melanoma patients with a DecisionDx-Melanoma Class 1A result show very low rates of metastatic recurrence and melanoma specific death."

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 study cohorts 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.

DecisionDx-Melanoma, DecisionDx-CM*Seq*, DecisionDx-UM, DecisionDx-PRAME and DecisionDx-UM*Seq* are trademarks of Castle Biosciences, Inc.

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 DecisionDx-Melanoma to identify T1-T2 patients at low risk for SLN positivity and the potential for DecisionDx-Melanoma test results to guide SLNB recommendations and discussions. 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 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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