# Castle Biosciences Presents Data at the ASDP 56th Annual Meeting Supporting DecisionDx-Melanoma Test's Ability to Identify T1 Melanoma Patients at Low Risk for a Positive Sentinel Lymph Node

October 18, 2019

FRIENDSWOOD, Texas--(BUSINESS WIRE)--Oct. 18, 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 the ability of the DecisionDx®-Melanoma gene expression profile (GEP) test to identify T1 (tumor depth of 1 mm or less) melanoma patients at low risk for a positive sentinel lymph node (SLN) at the American Society of Dermatopathology (ASDP) 56th Annual Meeting in San Diego from October 17-20.

The study titled, "Identification of T1 melanoma patients at low risk for a positive sentinel lymph node (SLN) using a 31-gene expression profile (31-GEP)" (Abstract #262), will be presented as a poster at the meeting.

**Study Background:**

- Current guidelines recommend that clinicians discuss the sentinel lymph node biopsy (SLNB) procedure with patients who have greater than 5% likelihood of SLN positivity; the guidelines do not recommend the procedure for patients with less than 5% likelihood of SLN positivity. Patients with T1 melanoma tumors have a 5.4% risk of SLN positivity overall.
- The DecisionDx-Melanoma test is a 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).
- The DecisionDx-Melanoma test has been previously validated to guide SLNB decisions, as patients with T1-T2 melanoma (tumor depth of 2 mm or less) with a Class 1A result had very low rates of SLN positivity.
- This study was designed to evaluate the ability of the DecisionDx-Melanoma test to identify T1 melanoma patients with low risk for a positive SLN, using the combination of the previously published cohort with a novel cohort, totaling 910 consecutively tested T1 melanoma patients collected prospectively or retrospectively under IRB-approved protocols.

**Key Findings:**

- For patients with T1 tumors of any age and a Class 1A test result, SLN positivity was 3.5%, significantly less than patients with a Class 1B-2B result (p=0.0005), and below the 5% threshold at which guidelines do not recommend the procedure.
- For patients with T1 tumors 55 years of age or older and a Class 1A test result, SLN positivity was 2.3%, significantly less than patients with a Class 1B-2B result (p=0.002), 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 melanoma could reduce SLNB surgical procedures by 80% in patients 55 years of age or older, as 272 of 339 patients who underwent this procedure had a Class 1A result.
- Class 1A patients with T1 melanoma had recurrence free survival of 96.9% and distant metastasis-free survival of 97.3% on a retrospective dataset of 345 T1 patients with long-term follow-up, supporting that this population can safely avoid the SLNB surgical procedure.

"The study results show that use of the DecisionDx-Melanoma test can identify T1 patients who are at low risk for a positive sentinel lymph node and can guide sentinel lymph node biopsy discussions," said Federico A. Monzon, M.D., FCAP, chief medical officer at Castle Biosciences. "Furthermore, the identification of patients who are unlikely to benefit from sentinel lymph node biopsy can reduce unnecessary surgical procedures and have a positive impact on the allocation of healthcare resources."

**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 three 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 patients at low risk for SLN positivity; and the potential for DecisionDx-Melanoma test results to guide SLNB recommendations, reduce the number of unnecessary SLNB surgical procedures and correspondingly improve the allocation of healthcare resources. 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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