Castle Biosciences Presents Clinical Validation Study for its Cutaneous Squamous Cell Carcinoma Prognostic Test at the American Society for Dermatologic Surgery (ASDS) 2019 Annual Meeting

October 29, 2019

FRIENDSWOOD, Texas--(BUSINESS WIRE)--Oct. 29, 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 a development update and validation data for its cutaneous squamous cell carcinoma (SCC) prognostic test, DecisionDx®-SCC.

The study titled, “Development and validation of a prognostic gene expression profile (GEP) for stratification of cutaneous squamous cell carcinoma (SCC) patients by 3-year risk of regional or distant metastases,” was presented during an Oral Abstract session at the American Society for Dermatologic Surgery (ASDS) Annual Meeting, October 24-27 in Chicago.

Study Background

- Approximately 1 million patients are diagnosed with SCC in the U.S. each year, and the incidence continues to grow.
- Many patients with SCC will have a favorable prognosis, but an estimated 15,000 people in the U.S. die from SCC each year, surpassing the number of U.S. deaths from cutaneous melanoma estimated to be as high as 9,000.
- National guidelines define different treatment pathways and follow-up schedules for low-risk and high-risk SCC patients, but the low positive predictive value (PPV) of available staging systems means that the majority of high-risk patients do not develop metastases. Thus, many high-risk patients may be over-treated with radiation, chemotherapy or other interventions even when they may not be needed.
- There is a clear need for more accurate methods to identify high-risk SCC patients to appropriately direct work-up and treatment plans.

To address this need, Castle Biosciences has developed DecisionDx-SCC, a proprietary 40-gene prognostic test. The test was designed to improve upon existing clinicopathologic staging systems and identify SCC patients who are classified as high risk based upon clinicopathologic staging, but who are actually at a low biological risk for metastasis, and thus, can be considered for de-escalation in their treatment plan. Conversely, the test is also designed to identify a biologically high-risk group that has a significantly higher risk of metastasis than would be determined by clinicopathologic staging alone.

Study Findings

- Successful development of a 40-gene signature that identifies three groups of patients with significantly different risk for regional/distant metastasis using a training set of 122 patients.
- The multicenter validation study included 321 patients, of which 93% had one or more high-risk features and 52 patients experienced metastasis.
- Patients with a Class 1 result (n=203; lowest risk group) had a 91.6% 3-year metastasis-free survival (MFS) rate, significantly better than the MFS rate for patients with a high-risk Class 2A (80.6%; n=93) or highest risk Class 2B (44%; n=25) test result ($p<0.0001$).
- The negative predictive value (NPV) for the DecisionDx-SCC Class 1 was 91.1%. Among all patients in the study, 63% had a Class 1 (lowest risk) result. This group could be considered for de-escalation in their treatment plan.
- The PPV for DecisionDx-SCC Class 2B was 60% compared to the PPV for Brigham and Women’s Hospital (BWH) staging of 35.3% and American Joint Committee on Cancer (AJCC version 8) staging of 20.9%.
- DecisionDx-SCC demonstrated strong independent prognostic value in multivariate analyses compared to the BWH and AJCC v8 staging systems. Specifically, when compared to the BWH staging system, DecisionDx-SCC Class 2B had a hazard ratio (HR) of 8.9 ($p<0.001$) compared to an HR of 1.9 for BWH high risk ($p<0.05$). Similarly, when compared to the AJCC v8 staging system, DecisionDx-SCC Class 2B had an HR of 9.8 ($p<0.001$) compared to an HR of 2.6 for AJCC high risk ($p<0.001$).

“Clinical validation of this prognostic test for SCC demonstrates significant progress towards improved identification of high-risk patients beyond currently available staging systems,” commented Ashley Wysong, M.D., University of Nebraska Medical Center, Omaha NE, study investigator and presenter. “Clinical application of this test may allow us to de-escalate care in patients identified as low risk by tumor biology, as well as provide us objective data to guide implementation of adjuvant radiation, chemotherapy and clinical trial recommendations for those at actual high risk.”

Additional DecisionDx-SCC performance studies are currently underway, including a prospective study. The DecisionDx-SCC test is the second skin cancer test discovered, developed and validated by Castle Biosciences.

About Cutaneous Squamous Cell Carcinoma

Cutaneous squamous cell carcinoma (SCC), a nonmelanoma skin cancer, is one of the most common cancers. Approximately 1,000,000 patients are diagnosed with SCC each year in the U.S. Most patients have a favorable prognosis, but a subset of patients will develop metastasis and up to 15,000

patients each year die from their disease, exceeding the number of deaths from cutaneous melanoma. As current staging parameters have a low positive predictive value, many more patients are considered high risk than actually develop metastatic disease. Conversely, many patients who develop metastatic disease are misidentified as low risk. This may lead to over and undertreatment of a substantial number of SCC patients. To address this clinical need, Castle Biosciences has developed a gene expression profile test designed to improve upon current staging systems and identify patients with SCC at high risk for metastasis or recurrence, in order to enable more informed clinical decisions regarding adjuvant therapy and other management options.

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-SCC test results to appropriately direct SCC patient work-up and treatment plans; the ability of DecisionDx-SCC to improve upon existing staging systems and accurately classify patient risk; and expectations of DecisionDx-SCC to enable de-escalation of care in patients identified as high risk by traditional staging and provide objective data to implement proper recommendations for actual high risk patients. 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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