New Data Demonstrates Significant and Risk-Appropriate Clinical Impact of DecisionDx-SCC Test Results on Patient Management Decisions

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FRIENDSWOOD, Texas--(BUSINESS WIRE)--May 19, 2020-- Castle Biosciences, Inc. (Nasdaq: CSTL), a skin cancer diagnostics company providing personalized genomic information to improve cancer treatment decisions, today announced the publication of an intended use survey for DecisionDx®, its prognostic test for patients diagnosed with high-risk cutaneous squamous cell carcinoma (SCC). The test is expected to be launched commercially in the third quarter of 2020.

The article titled, “Impact of a prognostic 40-gene expression profiling test on clinical management decisions for high-risk cutaneous squamous cell carcinoma,” was published in the peer-reviewed journal, Current Medical Research and Opinion (CMRO).

Results of the study demonstrate that integration of DecisionDx-SCC (40-gene expression profile test) results impacted management decisions in a significant and risk-appropriate manner for high-risk SCC patient scenarios, while remaining aligned with national guidelines for patient management.

“It is critical that management and follow-up recommendations for patients diagnosed with high-risk cutaneous squamous cell carcinoma are tailored to individual risk, yet current staging methods are often unable to precisely stratify different risk groups that may have markedly different outcomes,” said principal investigator Darrell Rigel, M.D., M.S., Clinical Professor at New York University School of Medicine. “These results demonstrate that information on tumor biology can impact clinical decisions in a significant, risk-appropriate manner.”

Disease and Study Background

- Approximately 1 million patients are diagnosed with SCC of the skin in the U.S. each year, and the incidence continues to grow; while the majority of patients have a favorable prognosis, approximately 200,000 patients are identified as high risk.
- National Comprehensive Cancer Network (NCCN) guidelines for SCC define treatment pathways based on risk of local recurrence or metastasis. For SCC, there are two clinicopathologically defined categories: low risk and high risk. NCCN defines high risk as SCC patients with one or more of several high-risk clinicopathologic features.
- DecisionDx-SCC stratifies patients into three categories based on risk of metastasis: Class 1 (low-risk), Class 2A (high-risk) and Class 2B (highest-risk). The study objective was to determine the impact of DecisionDx-SCC test results on clinician management decisions and how their choices would align with an NCCN compliant, risk-directed management plan for high-risk SCC.
- 162 clinicians attending a national dermatology conference were presented with DecisionDx-SCC test validation data. They were then asked to rate clinicopathological features and DecisionDx-SCC test results to assess their opinion of how concerning each is to SCC prognosis. When presented with vignettes describing patients with NCCN-defined high-risk features, clinicians were asked to document their treatment plan pre-test (without DecisionDx-SCC results), then, post-test (with DecisionDx-SCC Class 1, 2A, or 2B results) methodology along with corresponding metastasis rates for each test group. Assessed treatment plan modalities included follow-up schedule, sentinel lymph node biopsy, nodal imaging, adjuvant radiation and adjuvant chemotherapy.

Study Findings

- When comparing DecisionDx-SCC risk classes with clinicopathologic risk factors, Class 2B DecisionDx-SCC result, perineural invasion, immunosuppression, invasion beyond subcutaneous fat, and tumor diameter >1cm on the scalp were identified as the features most highly associated with risk of metastasis.
- Adding a DecisionDx-SCC low-risk Class 1 result to clinicopathologic information led to an overall reduction in treatment plan modality intensity by more than 60% when compared to clinicopathological features alone.
- Adding a Decision-SCC Class 2B test result to clinicopathologic information led to an overall escalation in treatment plan modality intensity by more than 90% when compared to clinicopathological features alone.
- More than 95% of the management recommendations were in a risk appropriate direction compared to the DecisionDx-SCC class result, and all changes were within established NCCN-guidelines for patient management.

DecisionDx-SCC is the second skin cancer test discovered, developed and validated by Castle Biosciences.

About Cutaneous Squamous Cell Carcinoma

Cutaneous squamous cell carcinoma (SCC) is one of the most common cancers. Approximately 1 million patients are diagnosed with SCC each year in the U.S. While the majority of patients have a favorable prognosis, approximately 200,000 patients are identified as high risk. National guidelines provide for broad, aggressive treatment plan recommendations relative to low-risk patients. Traditional clinicopathologic based risk-factor staging systems suffer from low positive predictive value; meaning many more patients are classified as high risk than actually develop metastatic disease.
This may lead to over- and under-treatment of a substantial number of cutaneous 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 cutaneous SCC at high risk for metastasis, in order to enable more informed, objective 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®-CMSeq; www.SkinMelanoma.com) and uveal melanoma (DecisionDx®-UM, DecisionDx®-PRAME and DecisionDx®-UMSeq; 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-CMSeq, DecisionDx-UM, DecisionDx-PRAME and DecisionDx-UMSeq 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 anticipated timing for commercial availability of the DecisionDx-SCC test; the ability of DecisionDx-SCC test results to appropriately direct cutaneous 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 Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 10, 2020, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, filed with the SEC on May 11, 2020, 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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