NEWS RELEASE

Castle Biosciences Announces Publication of a Study Evaluating Incorporation of DecisionDx-SCC into Management of High-Risk Cutaneous Squamous Cell Carcinoma

5/5/2020

PDF Version

Published Recently in Current Medical Research and Opinion

FRIENDSWOOD, Texas--(BUSINESS WIRE)--May 5, 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 a clinical utility model for its cutaneous squamous cell carcinoma (SCC) prognostic test, DecisionDx®-SCC, for patients diagnosed with high-risk cutaneous SCC. The test is expected to launch commercially in the second half of 2020.

The article titled, “Integrating gene expression profiling into NCCN high-risk cutaneous squamous cell carcinoma management recommendations: impact on patient management,” was published in the peer-reviewed journal, Current Medical Research and Opinion (CMRO).

This publication proposes a framework for integration of DecisionDx-SCC into existing management pathways for a risk-appropriate approach in high-risk cutaneous SCC patients (as defined by having one or more high-risk factors and consistent with the National Comprehensive Cancer Network (NCCN) guidelines).

“Castle’s DecisionDx-SCC test is designed to stratify risk of regional or distant metastasis in high-risk cutaneous SCC patients,” said Aaron Farberg, M.D., first author, Icahn School of Medicine at Mount Sinai, New York and Arkansas

Dermatology Skin Cancer Center, Little Rock, Arkansas. “This manuscript proposes a framework for clinical use of this test, along with current risk stratification tools within established management pathways. The expectation is that the test will enable more informed clinical decisions about adjuvant therapy and other management options.”

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.
- 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.
- The study objective was to integrate gene expression profiling into the management of high-risk SCC within NCCN guidelines to improve risk-aligned management recommendations.
- 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).This study was designed to evaluate possible changes in management for 300 NCCN high-risk cutaneous SCC patients, when considering DecisionDx-SCC test results.

Study Findings

- Combining DecisionDx-SCC class with American Joint Committee on Cancer T stage identified a group of 159 low-risk patients (Class 1, T1-T2) with a 7.5% rate of metastasis. Similarly, combining test results with Brigham and Women’s Hospital staging identified 173 patients with a metastasis rate of 8.1%. Rates in both groups approached the metastasis rate of 6% observed for the general cutaneous SCC patient population.
- By comparison, Class 2B patients in the study (n=24) had rates of metastasis equal to or surpassing 50%, regardless of the staging system with which the Class 2B result was combined, a rate that may warrant an NCCN-defined, high intensity management plan.
- Following incorporation of DecisionDx-SCC results with T stage for 300 patients with NCCN high-risk features, more than 50% would have been recommended a low intensity management plan, while 34-39% would be recommended for a moderate intensity plan and only 8% for a high intensity plan.

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) 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 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, 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.

View source version on **businesswire.com**: **https://www.businesswire.com/news/home/20200505005416/en/**

Media and Investor Contact:

Camilla Zuckero
832-835-5158
czuckero@castlebiosciences.com

Source: Castle Biosciences, Inc.

PDF Version