Castle Biosciences Announces Commercial Launch of DecisionDx-SCC

September 2, 2020

Prognostic gene expression profile test for metastatic risk in cutaneous squamous cell carcinoma now available to clinicians in the U.S.

Conference Call and webcast today at 4:30 p.m. ET

FRIENDSWOOD, Texas--(BUSINESS WIRE)--Sep. 2, 2020-- Castle Biosciences, Inc. (Nasdaq: CSTL), a skin cancer diagnostics company providing personalized genomic information to improve cancer treatment decisions, today announced that DecisionDx®-SCC, its prognostic gene expression profile test for patients diagnosed with high-risk cutaneous squamous cell carcinoma (SCC), is now commercially available.

"We are pleased to offer DecisionDx-SCC, intended for use in adding actionable, patient-specific information to risk assessment and to help guide management decisions in SCC," said Derek Maetzold, president and chief executive officer of Castle. "Using current SCC staging methods, about 200,000 patients annually are classified as high risk based on various clinical and pathological factors. But this relatively broad high-risk category leaves room for over- and undertreatment—a degree of uncertainty that patients and clinicians cannot afford, as death rates from SCC continue to rise. Now with the ability to add DecisionDx-SCC to commonly used clinical and pathological factors, we believe that this important innovation will improve prognostic accuracy and risk-appropriate management planning. We expect to see strong demand for DecisionDx-SCC, as we build upon our success with DecisionDx-UM and DecisionDx-Melanoma and follow our established model for commercialization."

Ashley Wysong, M.D., University of Nebraska Medical Center, Omaha NE stated, "As SCC cancer treatment plans and their outcomes are guided by risk of metastasis, improved prognostic accuracy has direct implications on patient management. By classifying SCC patients with existing risk factors into low, moderate and high biological risk categories, we believe DecisionDx-SCC can contribute positive predictive value to follow-up and management recommendations, potentially changing or narrowing recommendations in line with individual risk. I look forward to integrating tumor biology through DecisionDx-SCC into the clinical care of my patients."

The DecisionDx-SCC test is a qRT-PCR assay of 40 genes that uses a neural network algorithm to classify patients into risk categories. Independent validation was performed in a prospectively designed, multi-center (33 sites) study using archival tissue from 420 patients with known 3-year outcomes. The test's validity and impact are supported by four peer-reviewed publications.

Conference Call and Webcast Details

As previously announced, Castle Biosciences, with guest speaker, Wysong, will hold a conference call on Wednesday, September 2, 2020, at 4:30 p.m. Eastern time to discuss the launch of DecisionDx-SCC.

A live webcast of the conference call can be accessed here: https://edge.media-server.com/mmc/p/ffayujyd or via the webcast link on the Investor Relations page of the Company's website (www.castlebiosciences.com). Slides to be presented during the webcast will also be available on the Investor Relations page of the Company's website. Please access the webcast at least 10 minutes before the conference call start time. An archive of the webcast will be available on the Company's website until September 23, 2020.

To access the live conference call via phone, please dial (877) 282-2581 from the United States and Canada, or +1 (470) 495-9479 internationally, at least 10 minutes prior to the start of the call, using the conference ID 4576527.

There will be a brief Question & Answer session following prepared remarks.

About 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 these patients have a favorable prognosis, approximately 200,000 of these patients are identified as high risk. National guidelines for high-risk patients 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.

About DecisionDx-SCC

DecisionDx-SCC is a 40-gene expression profile test that uses an individual patient's tumor biology to predict individual risk of squamous cell carcinoma metastasis for patients with one or more risk factors. The test result, in which patients are stratified into a Class 1, 2A or 2B risk category, predicts individual metastatic risk to inform risk-appropriate management.

Peer-reviewed publications have demonstrated that DecisionDx-SCC is an independent predictor of metastatic risk and that integrating DecisionDx-SCC with current prognostic methods can add positive predictive value to clinician decisions regarding staging and management.

More information about the test and disease can be found at www.mySCCskincancer.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), cutaneous squamous cell carcinoma (DecisionDx®-SCC, www.mySCCskincancer.com) and uveal melanoma (DecisionDx®-UM, DecisionDx®-PRAME and DecisionDx®-UM*Seq*;

www.MyUvealMelanoma.com). Castle also has products in development for other underserved cancers, the most advanced of which is focused on 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-SCC, DecisionDx-UM, DecisionDx-PRAME and DecisionDx-UM*Seq* and 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 benefits and contributions offered by DecisionDx-SCC, including for risk assessment and patient treatment; usefulness of the information provided by DecisionDx-SCC analysis; and physician adoption of DecisionDx-SCC and related plans for commercialization. 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 effects of the COVID-19 pandemic on our business and our efforts to address its impact on our business and our ability to maintain compliance with the covenants in our debt facility, the timing and amount of revenue we are able to recognize in a given fiscal period, unexpected delays in planned launch of our pipeline products, the level and availability of reimbursement for our products, our ability to manage our anticipated growth and the risks set forth in our Annual Report on Form 10-K for the year ended December 31, 2019, filed on March 10, 2020, our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, filed on August 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/20200902005174/en/

Investor Contact:
Camilla Zuckero
832-835-5158
czuckero@castlebiosciences.com

Media Contact:
Amy Jobe, Ph.D.
LifeSci Communications, LLC
315-879-8192
ajobe@lifescicomms.com

Source: Castle Biosciences