Castle Biosciences to Present Data on DecisionDx®-Melanoma, DecisionDx® DiffDx™-Melanoma at 18th Annual Winter Clinical Dermatology Conference

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FRIENDSWOOD, Texas--(BUSINESS WIRE)--Jan. 20, 2021-- Castle Biosciences, Inc. (Nasdaq: CSTL), a skin cancer diagnostics company providing personalized genomic information to improve cancer treatment decisions, today announced poster presentations with data on two of its skin cancer gene expression profile tests at the 18th Annual Winter Clinical Dermatology Conference, taking place virtually from Jan. 15 – 24, 2021.

President and chief executive officer, Derek Maetzold, will also participate in the meeting’s “2021 View for Dermatology Industry Panel,” scheduled to take place on Saturday, Jan. 23, from 2:10 p.m. – 2:50 p.m. Eastern time.

Poster information is as follows:

**DecisionDx®-Melanoma:**

The virtual poster is entitled, “Identifying predictors of sentinel lymph node metastasis in cutaneous melanoma patients using molecular and clinicopathologic high-risk features.”

DecisionDx-Melanoma is Castle's 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 (SLN) positivity, independent of traditional staging factors.

**Study methods and findings:**

- For 3,093 patients with T1-T4 cutaneous melanoma, authors used decision tree analysis to determine which molecular and clinicopathologic features best stratify SLN positivity risk.
  - DecisionDx-Melanoma was the most important factor in distinguishing between high and low SLN-positivity rates (p<0.001).

**DecisionDx® DiffDx™-Melanoma**

The virtual poster is entitled, “Performance of a 35-gene expression profile test in suspicious pigmented lesions of the head and neck.”

DecisionDx DiffDx-Melanoma is designed to aid dermatopathologists in characterizing difficult-to-diagnose melanocytic lesions.

“Melanomas of the head or neck need special consideration with respect to staging and treatment decisions, as many have inconclusive diagnoses upon presentation based on the histological and pathological factors normally used,” said study author, Sarah I. Estrada, M.D., FCAP, laboratory director of Affiliated Dermatology. “We welcome the use of a gene expression profile test to help refine melanoma diagnoses of cases of indeterminate status. The study results demonstrate that DecisionDx DiffDx-Melanoma maintains its performance in this delicate sub-population of potential melanoma cases, and the utilization of this objective tool in clinical practice has the potential to improve subsequent management decisions.”

**Study methods and findings:**

- As melanoma of the head and neck often require special consideration with respect to staging and treatment decisions, early and accurate detection is especially critical for these lesions. This study evaluated DecisionDx DiffDx-Melanoma’s accuracy in classifying pigmented lesions on the head and neck.
- DecisionDx DiffDx-Melanoma was used to independently assess 105 lesions located on the head and neck in adults age 18 and up.
- DecisionDx DiffDx-Melanoma classified these lesions as benign (n=54, 51.4%), malignant (n=48, 45.7%), and intermediate-risk (n=3, 2.9%) with accuracy metrics of 98.0% sensitivity, 100% specificity, 100% PPV and 98.2% NPV.
- The test’s performance in the head and neck lesion population is similar to its performance in pigmented lesions in the rest of the body in the overall adult population.
- DecisionDx DiffDx-Melanoma demonstrated its ability to be an effective tool for refining melanoma diagnoses on the head and neck and therefore improving downstream management decisions, as indicated by its high sensitivity and specificity in this study.

**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 5,700 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 six prospective risk of recurrence studies including more than 1,600 patients. Prediction of the likelihood of sentinel lymph node positivity has also been validated in two prospective multicenter studies that included more than 3,000 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. Through September 30, 2020, DecisionDx-Melanoma has been ordered more than 64,560 times for use in patients with cutaneous melanoma.

More information about the test and disease can be found at www.CastleTestInfo.com.

About DecisionDx DiffDx-Melanoma

DecisionDx® DiffDx™-Melanoma is designed to aid dermatopathologists in characterizing difficult-to-diagnose melanocytic lesions. Of the approximately 2 million suspicious pigmented lesions biopsied annually in the U.S., Castle estimates that approximately 300,000 of those cannot be confidently classified as either benign or malignant through traditional histopathology methods. DecisionDx DiffDx-Melanoma classifies these lesions as: benign (gene expression profile suggestive of benign neoplasm); intermediate-risk (gene expression profile cannot exclude malignancy); or malignant (gene expression profile suggestive of melanoma). Interpreted in the context of other clinical, laboratory and histopathologic information, DecisionDx DiffDx-Melanoma is designed to add diagnostic clarity and confidence for dermatopathologists while helping dermatologists deliver more informed patient management plans.

More information about the test and disease can be found at www.CastleTestInfo.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®-CMSeq), cutaneous squamous cell carcinoma (DecisionDx®-SCC), suspicious pigmented lesions (DecisionDx® DiffDx™-Melanoma) and uveal melanoma (DecisionDx®-UM, DecisionDx®-PRAME and DecisionDx®-UMSeq). For more information about Castle's gene expression profile tests, visit www.CastleTestInfo.com. Castle also has active research and development programs for tests in other dermatologic diseases with high clinical need. 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-SCC, DecisionDx DiffDx-Melanoma, DecisionDx-UM, DecisionDx-PRAME and DecisionDx-UMSeq 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 ability of DecisionDx DiffDx-Melanoma to characterize difficult to diagnose melanocytic lesions and accurately differentiate between benign and malignant pigmented lesions in order to add diagnostic clarity and confidence for dermatopathologists and help dermatologists better understand the clinical implications for more informed patient care, the ability of DecisionDx-Melanoma test results to help identify patients with low probability of sentinel lymph node positivity, and statements concerning each of their impact to influence treatment plans and optimize or improve treatment decisions. 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, 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, 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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