Castle Biosciences Announces Level of Evidence Review on DecisionDx-Melanoma Published in Latest Issue of American Journal of Clinical Dermatology

December 30, 2019

FRIENDSWOOD, Texas--(BUSINESS WIRE)--Dec. 30, 2019-- Castle Biosciences, Inc. (Nasdaq: CSTL) today announced that results from a study designed to perform a systematic review of the literature and establish the level of evidence for the Company's DecisionDx®-Melanoma gene expression profile test were published in the December 2019 issue of the American Journal of Clinical Dermatology. The results show that the DecisionDx-Melanoma test achieves a higher level of evidence than determined by major organizations that publish guidelines on melanoma management.

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. In this independent study by Dubin, et al. titled, “Level of Evidence Review for a Gene Expression Profile Test for Cutaneous Melanoma,” the researchers conducted a review of seven development and validation studies for the DecisionDx-Melanoma test. They then applied attributes of each study to the level of evidence criteria for the American Joint Committee on Cancer (AJCC), National Comprehensive Cancer Network (NCCN) and American Academy of Dermatology (AAD). The AJCC, NCCN and AAD are considered major authoritative organizations that many dermatologists rely upon to provide skin cancer guidelines, and each employs a unique ranking system to assign a level of evidence to the management of melanoma.

Key Findings:

- The evaluation of seven development and validation studies led the authors to classify DecisionDx-Melanoma as level I/II, I–IIIB and IIA according to AJCC, NCCN and AAD criteria, respectively, which are higher than the official unrated status conferred by the AJCC and NCCN and the II/IIIC rating designated by the AAD in the latest version of their melanoma guidelines.
- The authors note that the differences between the study’s findings and official published ratings may be attributed to chronological issues, as many of the studies were not yet published when the organizations conducted their reviews. There was also difficulty in applying the National Comprehensive Cancer Network criteria to this prognostic test, as their guidelines were intended for evaluation of therapeutic response markers.
- Based on current published data, the authors find integration of the DecisionDx-Melanoma test to be useful for patients with invasive melanoma, particularly older patients with T1/T2 (tumor depth of 2 mm or less) melanomas:
  - For patients with invasive melanoma, DecisionDx-Melanoma may help guide the frequency of skin examinations and utilization of a sentinel lymph node biopsy (SLNB) surgical procedure or imaging following diagnosis of melanoma.
  - DecisionDx-Melanoma may benefit patients aged older than 65 years diagnosed with T1/T2 melanomas in the assessment of the risks and benefits of a SLNB surgical procedure.

Three additional prospective peer-reviewed clinical validity studies published in 2019 were not included in the Dubin study, due to publication after the systematic review was completed.

The full published study can be accessed at the journal’s website.

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 3,900 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 five prospective risk of recurrence studies including more than 780 patients. Prediction of the likelihood of sentinel lymph node positivity has also been validated in two prospective multicenter study cohorts that included more than 2,000 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.

More information about the test and disease can be found at www.SkinMelanoma.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; 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.
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 regarding DecisionDx-Melanoma achieving a higher level of evidence than is currently recognized by the AJCC, NCCN and AAD, the usefulness of DecisionDx-Melanoma for patients with invasive melanoma and older patients with T1/T2 melanomas, including with respect to the assessment of risks and benefits of, and guidance for the frequency of examinations and use of, a SNLB surgical procedure. 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 September 30, 2019, filed with the SEC on November 12, 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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Source: Castle Biosciences, Inc.

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