Castle Biosciences Announces Publication of Clinical Validation and Utility Data for DecisionDx® DiffDx™-Melanoma for Suspicious Pigmented Lesions

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Two Companion Articles Recently Published in SKIN: The Journal of Cutaneous Medicine

FRIENDSWOOD, Texas--(BUSINESS WIRE)--Nov. 17, 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 two studies in *SKIN: The Journal of Cutaneous Medicine*, which demonstrated that DecisionDx® DiffDx™-Melanoma adds significant diagnostic clarity for physicians when characterizing difficult-to-diagnose melanocytic lesions and establishes clinical utility with the potential to improve patient care.

The development and validation study, authored by Dr. Sarah I. Estrada, et al., is titled, “Development and Validation of a Diagnostic 35-Gene Expression Profile Test for Ambiguous or Difficult-To-Diagnose Suspicious Pigmented Skin Lesions.” This study describes the development and clinical validation of the DecisionDx DiffDx-Melanoma test, which is designed to refine the diagnoses of suspicious pigmented lesions.

The clinical utility study, authored by Dr. Aaron S. Farberg, et al., is titled, “A 35-Gene Expression Profile Test for Use in Suspicious Pigmented Lesions Impacts Clinical Management Decisions of Dermatopathologists and Dermatologists.” This study documents the influence of DecisionDx DiffDx-Melanoma test results on subsequent clinical management decisions, potentially leading to decreased unnecessary procedures while correctly identifying at-risk patients.

Estrada et al. Study Background and Results:

- The purpose of this study was to develop and validate DecisionDx DiffDx-Melanoma, including the test’s ability to accurately differentiate between benign and malignant pigmented lesions.
- Discovery started with the assessment of 76 genes with quantitative reverse transcription polymerase chain reaction (RT-PCR); artificial intelligence methods were then employed for diagnostic gene selection and algorithm development using 200 benign nevi and 216 melanomas for training. The final algorithm included 32 discriminant and 3 control genes. To reflect the complex biology of melanocytic neoplasia, the DecisionDx DiffDx-Melanoma test was developed to include an intermediate-risk zone.
- The results of the study showed that the DecisionDx DiffDx-Melanoma test:
    - Had a technical success rate of 97%, meaning that a test result was successfully generated;
    - Achieved accuracy statistics of: Sensitivity = 99.1%, Specificity = 94.3%, Positive Predictive Value = 93.6%, Negative Predictive Value = 99.2%; with an intermediate-risk result in 3.6% of the cases.
- Conclusions: DecisionDx DiffDx-Melanoma was developed to refine diagnoses of melanocytic neoplasms by providing clinicians with an objective tool. A test with these accuracy metrics could alleviate uncertainty in difficult-to-diagnose lesions leading to decreased unnecessary procedures while appropriately identifying at-risk patients.

Farberg et al. Study Background and Results:

- The purpose of this study was to evaluate DecisionDx DiffDx-Melanoma’s clinical utility.
- Dermatopathologists and dermatologists were surveyed regarding diagnostic challenges and patient management strategies in 60 difficult-to-diagnose melanocytic neoplasms. Participants reviewed each lesion twice, once without a DecisionDx DiffDx-Melanoma result and once with. Responses were evaluated for consistent trends in the utilization of the DecisionDx DiffDx-Melanoma test result.
- Dermatopathologists utilized the DecisionDx DiffDx-Melanoma result to refine their diagnoses in lesions receiving a benign vs. malignant result (82.3% diagnostic downgrade vs. 94.9% diagnostic upgrade, respectively).
- Diagnostic confidence was increased (51%), while additional diagnostic work-up requests were decreased in cases with a benign DecisionDx DiffDx-Melanoma result (72.1%) and increased with a malignant DecisionDx DiffDx-Melanoma result (45.6%).
- Conclusions: The diagnosis of challenging melanocytic neoplasms and subsequent clinical management decisions were influenced by DecisionDx DiffDx-Melanoma results in alignment with the test result. The utility of the test may provide the opportunity for clinicians to deliver more informed patient management plans.

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®-CM*Seq),* cutaneous squamous cell carcinoma (DecisionDx®-SCC), suspicious pigmented lesions (DecisionDx®DiffDx™-Melanoma) and uveal melanoma (DecisionD®-UM, DecisionDx®-PRAME and DecisionDx®-UM*Seq*). 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-CM*Seq*, DecisionDx-SCC, DecisionDx DiffDx-Melanoma, 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 ability of DecisionDx DiffDx-Melanoma to 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 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, 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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