Castle Biosciences Announces Publication of Clinical Utility, Long-Term Outcomes Data and Meta-Analysis for DecisionDx-UM for Patients with Uveal Melanoma

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Study Published Recently in O*cular Oncology and Pathology*

FRIENDSWOOD, Texas--(BUSINESS WIRE)--Jul. 15, 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 multicenter, prospective study demonstrating that DecisionDx®-UM test results significantly impacted treatment plan recommendations for patients with uveal melanoma (UM).

The article titled, “Gene expression profiling in uveal melanoma: five-year prospective outcomes and meta-analysis,” was published in the peer-reviewed journal *Ocular Oncology and Pathology.*

DecisionDx-UM is Castle’s 15-gene expression profiling (GEP) test developed to identify patients at low risk (Class 1) or high risk (Class 2) of metastasis, based on the unique biology of their primary tumor, and is the current standard of care for UM patients. It is estimated that nearly 8 in 10 patients diagnosed with UM in the U.S. receive the DecisionDx-UM test as part of their diagnostic workup. UM patients face up to a 50% risk of metastasis, despite successful control of the primary tumor.

The multicenter CLEAR Registry Study (Clinical Application of DecisionDx-UM Gene Expression Assay Results) was designed to prospectively evaluate management plans and five-year clinical outcomes for UM patients tested with DecisionDx-UM as part of their clinical care. The median follow-up time for patients who did not develop metastasis was 4.9 years, reflecting the longest follow-up reported to date for any prognostic tool for UM.

“The accurate and reliable identification of a patient’s metastatic risk is critical for clinical planning and decision-making,” commented first author, Thomas Aaberg, Jr., M.D., associate clinical professor at Michigan State University Medical School and ocular oncologist with Retina Specialists of Michigan. “As with previously published studies, the results of the CLEAR study demonstrate the high-level of accuracy of DecisionDx-UM for prediction of metastatic risk and further support its use in guiding patient management.”

Study Background and Highlights:

- Eighty-nine patients with DecisionDx-UM results were prospectively enrolled at four centers. Sample size calculations indicated that 29 patients would be sufficient to demonstrate a statistically significant difference in metastatic rates between Class 1 and Class 2 patients, while 47 patients would be sufficient to detect differences in melanoma-specific mortality.
- Physician-recommended management plans were collected, and clinical outcomes tracked every six months.
- Five-year DecisionDx-UM Class 1 and DecisionDx-UM Class 2 metastasis-free survival rates were 90% and 41% ($p<0.0001$), respectively, and melanoma-specific survival rates were 94% and 63% ($p=0.0007$), respectively.
- In multivariate analysis with clinicopathologic features, including age, ciliary body involvement, largest basal diameter and tumor thickness, the DecisionDx-UM Class 2 result was the only statistically significant predictor of metastasis, with a hazard ratio (HR) of 7.53 ($p<0.0001$).
- A meta-analysis with published cohorts found that patients with a Class 2 result had a HR of 8.70 ($p<0.0001$) for metastasis and 7.21 ($p<0.0001$) for mortality.
- All patients with DecisionDx-UM Class 2 (high-risk) test results were managed with high-intensity surveillance (imaging and/or liver function tests every 3-6 months), while 80% of Class 1 (low-risk) patients were managed with low-intensity surveillance (annual imaging and/or liver function tests, $p<0.0001$).
- The results of this study support that DecisionDx-UM is used to appropriately guide metastatic surveillance in UM patients. High-risk Class 2 patients were managed more intensely, in accordance with an observed metastatic rate of greater than 50%, while low-risk Class 1 patients were managed with low-intensity surveillance, resulting in appropriate utilization of healthcare resources.

About DecisionDx-UM

DecisionDx-UM is a 15-gene expression profile (GEP) test that uses an individual patient’s tumor biology to predict individual risk of metastasis. DecisionDx-UM is the standard of care in the management of uveal melanoma in the majority of ocular oncology practices in the United States. Since 2009, the American Joint Committee on Cancer (AJCC; v7 and v8) Staging Manual for UM has specifically identified the GEP test as a prognostic factor that is recommended for collection as a part of clinical care. Further, the National Comprehensive Cancer Network (NCCN) guidelines for uveal melanoma include the DecisionDx-UM test result as a prognostic method for determining risk of metastasis and recommended differential surveillance regimens based on a Class 1A, 1B, and 2 result. DecisionDx-UM is the only prognostic test for uveal melanoma that has been validated in prospective,

multi-center studies, and it has been shown to be a superior predictor of metastasis compared to other prognostic factors, such as chromosome 3 status, mutational status, AJCC stage and cell type.

It is estimated that nearly 8 in 10 patients diagnosed with uveal melanoma in the U.S. receive the DecisionDx-UM test as part of their diagnostic workup. More information about the test and disease can be found at www.MyUvealMelanoma.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) and uveal melanoma (DecisionDx®-UM, DecisionDx®-PRAME and DecisionDx®-UM*Seq*; 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-CM*Seq*, DecisionDx-UM, DecisionDx-PRAME and DecisionDx-UM*Seq* 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-UM test results to optimize diagnostic 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 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, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, filed with the SEC on May 11, 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.

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