Real-World Study Confirms Long-Term Performance of DecisionDx®-UM for Metastatic Risk Stratification in Uveal Melanoma and Utility of PRAME Biomarker for Refining Risk When Considered with the DecisionDx-UM Class Result

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FRIENDSWOOD, Texas, May 09, 2025 (GLOBE NEWSWIRE) -- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, today announced new data from the first independent validation of the recently published Collaborative Ocular Oncology Group Study No. 2 (COOG2.1) by Harbour et al.[1] The data, from a real-world cohort of 1,297 patients with uveal melanoma (UM), was presented at the Association for Research in Vision and Ophthalmology (ARVO) 2025 Annual Meeting in Salt Lake City. The findings provide further support for adding Preferentially Expressed Antigen in Melanoma (PRAME) gene expression information to the DecisionDx-UM test result to further refine metastatic risk prediction for patients with UM, which is a rare but aggressive eye cancer.

"This real-world validation of the landmark COOG2.1 study both confirms the long-term performance of the DecisionDx-UM test and affirms the clinical value of PRAME as an adjunct biomarker that may further refine a patient's metastatic risk when combined with the DecisionDx-UM class result," said Rebecca Critchley-Thorne, Ph.D., vice-president, research and development, of Castle Biosciences. "This enhanced approach to risk stratification is designed to equip clinicians with more precise information to help guide surveillance strategies and enable more personalized treatment planning with the goal of helping to improve outcomes for patients with UM."

Details regarding Castle's presentation at ARVO are included below. The abstract may be viewed using the ARVO

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2025 **mobile meeting planner**.

- Presentation Number 981: PRAME status as a risk modifier of 15-gene expression profile class: Evidence from a real-world cohort of 1297 uveal melanoma patients
- Presentation Type: Poster Session
- Session Number: 154
- Session Title: Uveal Melanoma
- Summary: An ongoing collaboration with the National Cancer Institute's Surveillance, Epidemiology and End Results (NCI SEER) Program enabled linkage of UM patient records with such patients' DecisionDx-UM and PRAME test results. In a large, real-world, population-based cohort of patients with UM, this study aimed to validate the findings from the prospective COOG2.1 study, which found that adding the reported expression of the PRAME gene to the DecisionDx-UM class result can further refine risk by subdividing Class 1 and Class 2 tumors based on PRAME positive (+) versus negative (-) status. Consistent with the COOG2.1 study, the findings shared at ARVO demonstrate that co-reporting of DecisionDx-UM class and PRAME status provides additional insights into a patient's likelihood of metastasis to better inform treatment pathway decisions.

About DecisionDx-UM

DecisionDx-UM is Castle Biosciences' 15-gene expression profile (GEP) test that uses an individual patient's tumor biology to predict individual risk of metastasis in patients with uveal melanoma (UM). DecisionDx-UM is the standard of care in the management of newly diagnosed UM 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 UM 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 currently the only prognostic test for UM 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 UM in the United States receive the DecisionDx-UM test as part of their diagnostic workup. Learn more at **www.CastleBiosciences.com**.

About Castle Biosciences

Castle Biosciences (Nasdaq: CSTL) is a leading diagnostics company improving health through innovative tests that guide patient care. The Company aims to transform disease management by keeping people first: patients, clinicians, employees and investors.

Castle's current portfolio consists of tests for skin cancers, Barrett's esophagus and uveal melanoma. Additionally, the Company has active research and development programs for tests in other diseases with high clinical need,

including its test in development to help guide systemic therapy selection for patients with moderate-to-severe atopic dermatitis seeking biologic treatment. To learn more, please visit **www.CastleBiosciences.com** and connect with us on **LinkedIn**, **Facebook**, **X** and **Instagram**.

DecisionDx-Melanoma, DecisionDx-CMSeq, i31-SLNB, i31-ROR, DecisionDx-SCC, MyPath Melanoma, TissueCypher, DecisionDx-UM, DecisionDx-PRAME and DecisionDx-UMSeq are trademarks of Castle Biosciences, Inc.

1. Harbour JW, Correa ZM, Schefler AC, et al. 15-Gene Expression Profile and PRAME as Integrated Prognostic Test for Uveal Melanoma: First Report of Collaborative Ocular Oncology Group Study No. 2 (COOG2.1). J Clin Oncol. 2024;42(28):3319-3329. doi:10.1200/JCO.24.00447

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