Castle Biosciences Announces Presentation of Prospective, Multicenter Study Demonstrating Significant Impact of DecisionDx-UM on Treatment Plan Recommendations for Patients with Uveal Melanoma

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Data presented at American Academy of Ophthalmology 2019 Annual Meeting

FRIENDSWOOD, Texas--(BUSINESS WIRE)--Oct. 16, 2019-- Castle Biosciences, Inc. (Nasdaq: CSTL), a skin cancer diagnostics company providing personalized genomic information to improve cancer treatment decisions in skin cancers and uveal melanoma, today announced the presentation of a multicenter, prospective study demonstrating that DecisionDx®-UM test results significantly impacted treatment plan recommendations for patients with uveal melanoma. The study was presented at the American Academy of Ophthalmology 2019 Annual Meeting held October 12-15, 2019, in San Francisco.

The CLEAR II study (Clinical Application of DecisionDx-UM Gene Expression Assay Results) was designed to prospectively evaluate metastatic surveillance regimens for patients with uveal melanoma who were tested with the DecisionDx-UM gene expression profile (GEP) test as part of their diagnostic work-up.

“Treatment planning in uveal melanoma is critical since 30% of patients who are diagnosed with uveal melanoma will experience life-threatening metastasis within five years despite successful control of the primary tumor,” commented study co-author and presenter Amy C. Schefler, M.D., Associate Professor of Clinical Ophthalmology, Weill Cornell Medical College/Houston Methodist Hospital and the University of Texas Health Science Center at Houston, and Retina Consultants of Houston. “The results from the CLEAR II study demonstrate that the DecisionDx-UM test has a significant impact on treatment planning, helping to ensure that patients receive imaging, follow-up and referrals that are appropriate for their individual risk.”

Study Highlights:

- 138 patients from eight centers were enrolled between March 2018 and February 2019.
- 93 patients (67%) had a low-risk Class 1 test result; 45 patients (33%) had a high-risk Class 2 test result.
- Results showed that patients with a Class 2 DecisionDx-UM result were significantly more often followed by medical oncology for surveillance compared to ocular oncology or primary care physicians (p=0.002).
- 95% (42 of 44) of the Class 2 patients who received a referral were referred to medical oncology.
- Patients with a Class 2 result were significantly more likely to receive recommendations for frequent (three or four times a year) abdominal imaging, chest imaging, and liver function testing compared to Class 1 patients (p<0.0001).
- These findings show that treatment plan recommendations are aligned with metastatic risk and consistent with results from previously published studies documenting the impact of DecisionDx-UM on patient management.

About DecisionDx-UM

DecisionDx-UM is a 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. Since 2009, the American Joint Committee on Cancer (AJCC; v7 and v8) has included GEP testing for the identification of Class 1 and 2 as a prognostic factor recommended for clinical care. In 2018, the National Comprehensive Cancer Network (NCCN) published guidelines on uveal melanoma that include the DecisionDx-UM test results of Class 1A, Class 1B and Class 2B as prognostic factors to guide clinical care. DecisionDx-UM is the only prognostic test for uveal melanoma that has been validated in prospective, multi-center studies. In addition, the DecisionDx-UM test result has been shown to be a superior predictor of metastasis compared to chromosome 3 status, mutational status, AJCC stage, and cell type, as demonstrated in multiple studies.

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.

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