NEWS RELEASE

# Castle Biosciences Presents New Data from Collaboration with the National Cancer Institute's (NCI) Surveillance, Epidemiology and End Results (SEER) Program

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Linked data from Castle's ongoing collaboration with the NCI to link testing data with data from the SEER Program's registries showed that DecisionDx®-Melanoma can provide significant risk stratification and identify patients with a low risk of death who may potentially forego unnecessary adjuvant therapies

Analysis of the first set of NCI/SEER-linked uveal melanoma patient data showed that DecisionDx-UM accurately stratified UM patients' risk of death, which is important for guiding management decisions

FRIENDSWOOD, Texas--(BUSINESS WIRE)-- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, today announced new data from two studies demonstrating the potential of DecisionDx®-Melanoma and DecisionDx®-UM to accurately stratify risk of death from melanoma (cutaneous melanoma (CM) and uveal melanoma (UM), respectively) in a group of real-world, unselected and prospectively tested patients. The studies are part of the Company's ongoing collaboration with the National Cancer Institute (NCI) to link DecisionDx-Melanoma and DecisionDx-UM clinical testing data with data from the Surveillance, Epidemiology and End Results (SEER) Program's registries on CM and UM cases, respectively. The data were shared in poster presentations at the 19th International Congress of the Society for Melanoma Research (SMR) in Edinburgh, United Kingdom.

"Castle is committed to providing innovative and clinically actionable tests that can guide more informed and more personalized treatment decisions," said Derek Maetzold, president and chief executive officer of Castle Biosciences.

“We believe our DecisionDx family of GEP tests has clinical value, and the studies that we have done in collaboration with the NCI’s SEER Program provide a unique opportunity to demonstrate their performance, specifically DecisionDx-Melanoma and DecisionDx-UM, in real-world patients with known survival outcomes.”

## DecisionDx®-Melanoma | Poster #: P- 036

Improving patient selection for adjuvant therapy: Considerations for the role of the 31-gene expression profile test

Pembrolizumab (KEYTRUDA®) received expanded FDA approval as an adjuvant therapy for patients with stage IIB-IIC melanoma in late Dec. 2021 but is associated with a high adverse-event rate, suggesting that the benefit-to-risk ratio for patient selection could be improved by identifying patients who would have high survival rates without therapy. The study evaluated the risk stratification performance of DecisionDx-Melanoma in a group of real-world, unselected and prospectively tested patients with stage I-III CM in the SEER registry (n=4,687), including stage IIB-IIC patients who could potentially benefit from better selection for adjuvant therapy.

In the study, DecisionDx-Melanoma was a statistically significant and independent predictor of melanoma-specific survival (MSS), consistent with previously published retrospective and prospective studies. Patients with stage IIB or IIC melanoma and a low-risk (Class 1A) DecisionDx-Melanoma test result had higher three-year MSS than patients with a high-risk (Class 2B) result (Class 1A: 100% vs. Class 2B: 88.3%, p=0.04); similar results were observed for patients with stage III CM (Class 1A: 96.1% vs. Class 2B; 79.6%, p=0.03). Additionally, DecisionDx-Melanoma was a statistically significant and independent predictor of MSS across all stages of disease, with a hazard ratio of 7.00 for the Class 2B result. Overall, the study data show that DecisionDx-Melanoma can identify patients with a low risk of death from CM who could potentially forego unnecessary adjuvant therapies, thereby reducing healthcare costs and adjuvant therapy-related adverse events; conversely, the test can identify patients who are at a much higher likelihood of progressing, potentially enabling more aggressive decisions regarding the use of adjuvant therapy.

The poster may be viewed **here**.

## DecisionDx®-UM | Poster #: P- 035

A collaborative outcome study in uveal melanoma with the National Cancer Institute’s Surveillance, Epidemiology, and End Results Program Registries (NCI SEER): Performance of the 15-gene expression profile test in clinically tested uveal melanoma patients

The study evaluated the risk-stratification performance of DecisionDx-UM in a real-world, unselected, clinically tested cohort of patients with UM (n=615). On behalf of the SEER registries, a third-party honest broker conducted a linkage of all patients with UM from 16 NCI SEER registries to those clinically tested with DecisionDx-UM. The study

included all linked cases diagnosed in 2018 with survival outcome information and a DecisionDx-UM test result. Patients with stage IV disease (evidence of distant metastasis) at initial presentation were excluded from the analysis.

In the study, DecisionDx-UM accurately stratified patient risk of death from UM. Patients with a low-risk (Class 1A) DecisionDx-UM test result had higher 18-month overall survival (OS) and 18-month MSS than patients with a high-risk (Class 2) test result (OS=97.1% vs. 86.2%, P=0.02; MSS= 98.9% vs. 92.7%; P=0.02). Additionally, patients with a high-risk DecisionDx-UM test result had a ten-fold higher risk of death from UM than patients with a low-risk test result (hazard ratio=10.06, p=0.033). Overall, the study data confirm the accurate risk-stratification performance of DecisionDx-UM shown in previously published studies, which is important for guiding management decisions regarding the frequency of follow-up and metastatic surveillance imaging, as well as participation in clinical trials.

The poster may be viewed **here**.

## About DecisionDx®-Melanoma

DecisionDx-Melanoma is a gene expression profile risk stratification test. It is designed to inform two clinical questions in the management of cutaneous melanoma: a patient's individual risk of sentinel lymph node (SLN) positivity and a patient's personal risk of melanoma recurrence and/or metastasis. By integrating tumor biology with clinical and pathologic factors using a validated proprietary algorithm, DecisionDx-Melanoma is designed to provide a comprehensive and clinically actionable result to guide risk-aligned patient care. DecisionDx-Melanoma has been shown to be associated with improved patient survival and has been studied in more than 9,000 patient samples. DecisionDx-Melanoma's clinical value is supported by more than 35 peer-reviewed and published studies, providing confidence in disease management plans that incorporate the test's results. Through June 30, 2022, DecisionDx-Melanoma has been ordered 105,239 times for patients diagnosed with cutaneous melanoma. More information about the test and disease can be found at **www.CastleTestInfo.com**.

## 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. DecisionDx-UM is the standard of care in the management of newly diagnosed 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.CastleTestInfo.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, uveal melanoma, Barrett's esophagus and mental health conditions. Additionally, the Company has active research and development programs for tests in other diseases with high clinical need, including its test in development to predict systemic therapy response in patients with moderate-to-severe psoriasis, atopic dermatitis and related conditions. To learn more, please visit **www.CastleBiosciences.com** and connect with us on **LinkedIn**, **Facebook**, **Twitter** and **Instagram**.



## Forward-Looking Statements

This press release contains forward-looking statements 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 potential of DecisionDx-Melanoma and DecisionDx-UM to accurately stratify risk of death from melanoma and guide more informed and more personalized treatment decisions; and the potential of DecisionDx-Melanoma to provide significant risk stratification that can identify patients with a low risk of death who may potentially forego unnecessary adjuvant therapies, thereby reducing healthcare costs and adjuvant therapy-related adverse events; and the potential of DecisionDx-Melanoma to identify patients who are at a much higher likelihood of progressing, potentially enabling more aggressive decisions regarding the use of adjuvant therapy. The words "can," "could," "may," "potential" 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: subsequent study or trial results and findings may contradict earlier study or trial results and findings or may not support the results obtained in these studies, including with respect to the discussion of DecisionDx-Melanoma and DecisionDx-UM in this press release; actual application of our tests may not provide the aforementioned benefits to patients; and the risks set forth under the heading “Risk Factors” in our Quarterly Report on Form 10-Q for the three months ended June 30, 2022, 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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