NEWS RELEASE

FDA Grants Breakthrough Device Designation to Castle Biosciences' DecisionDx®-Melanoma Test

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FRIENDSWOOD, Texas, July 23, 2025 (GLOBE NEWSWIRE) -- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, today announced that its DecisionDx-Melanoma test has been granted Breakthrough Device designation from the U.S. Food and Drug Administration (FDA). DecisionDx-Melanoma is a gene expression profile (GEP) test that provides comprehensive, personalized results to guide risk-aligned management decisions for patients diagnosed with stage I-III cutaneous melanoma.

"DecisionDx-Melanoma provides valuable biological insights that help inform clinicians' post-diagnosis decision making based on a patient's individual predicted risk of metastasis," said Derek Maetzold, president and chief executive officer of Castle Biosciences. "We believe the clinical performance of our DecisionDx-Melanoma test is unmatched by other tests currently on the market, both in its ability to provide precise and clinically meaningful risk stratification as well as accurate predictions of sentinel lymph node positivity.

"We believe this recognition by the FDA supports DecisionDx-Melanoma's potential to significantly improve melanoma outcomes by delivering personalized care to those who need it most. We expect to submit a device marketing submission to the FDA and look forward to working with the agency to help more patients access these potentially life-changing insights."

The FDA grants Breakthrough Device designation to select qualifying devices that may offer improved treatment or diagnosis of life-threatening or irreversibly debilitating diseases when compared to currently available alternatives. The Breakthrough Devices Program is intended to provide patients and healthcare providers with timely access to medical devices by speeding up development, assessment and review.

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 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 10,000 patient samples. DecisionDx-Melanoma's clinical value is supported by more than 50 peer-reviewed and published studies, providing confidence in disease management plans that incorporate the test's results. The test is currently marketed as a Laboratory Developed Test (LDT), and through March 31, 2025, has been ordered more than 200,000 times for patients diagnosed with cutaneous melanoma. 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 these and 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**.

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: DecisionDx-Melanoma's ability to provide (i) comprehensive, personalized results to guide risk-aligned management decisions for patients diagnosed with stage I-III cutaneous melanoma, (ii) valuable biological insights to help inform clinicians; post-diagnoses decision making and (iii) precise and clinically meaningful risk stratification and accurate predictions of sentinel lymph node positivity; DecisionDx-Melanoma's performance versus other tests currently on the market; Castle's potential plans to seek Premarket Approval for DecisionDx-Melanoma. The words "believe," "can" 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 our tests 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 Annual Report on Form 10-K for the year ended December 31, 2024, our Quarterly Report for the three months ended March 31, 2025, 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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Source: Castle Biosciences Inc.

Source: Castle Biosciences, Inc.