



NEWS RELEASE

Use of Castle Biosciences' DecisionDx®-Melanoma Test Significantly Reduces Unnecessary SLNB Procedures, Latest Findings from Prospective, Multicenter DECIDE Study Presented at Dermato-Onco2024

2024-11-06

Study shows a 25% reduction in unnecessary sentinel lymph node biopsy (SLNB) procedures performed when patient's DecisionDx-Melanoma test results were integrated into clinical decision-making

Among patients electing to have an SLNB, no positive nodes were identified among those with low-risk DecisionDx-Melanoma test results (i.e., predicted sentinel lymph node (SLN) positivity risk of less than 5%), supporting use of the tests' results to safely inform decisions to forego the procedure

FRIENDSWOOD, Texas--(BUSINESS WIRE)-- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, today announced the latest data from its prospective, multicenter DECIDE study exploring the impact of integrating DecisionDx-Melanoma test results into SLNB decision-making for patients recently diagnosed with melanoma. The updated findings demonstrate the power of the test's results to accurately identify patients with a low risk of metastasis who can safely forgo SLNB, thereby reducing unnecessary SLNB procedures and the associated costs and risks of complications that accompany them. The data was presented in a poster and oral presentation at The European Congress on Dermato-Oncology (Dermato-Onco2024) recently held in Vienna, Austria.

"We continue to share data from our DECIDE study highlighting the performance of the DecisionDx-Melanoma test



in providing precise predictions of SLN positivity, earlier this year at SSO 2024 and now at Dermato-Onco2024, with close to 50% more patients in the study cohort,” said J. Michael Guenther, M.D., surgeon at St. Elizabeth Physicians in Edgewood, Kentucky. ¹ “As supported by the study data, clinicians can have confidence in decisions made with their patients when discussing a possible SLNB procedure when DecisionDx-Melanoma test results are a part of the conversation.”

Details regarding Castle’s oral presentation at Dermato-Onco2024 are included below:

DecisionDx-Melanoma

- Title: Clinical use of the i31-GEP for SLNB for T1-T2a cutaneous melanoma significantly and safely reduces unnecessary procedures
- Presenting Author: J. Michael Guenther, M.D.

Study highlights

SLNB is an invasive surgical procedure used at the time of diagnosis to determine whether melanoma has spread to nearby lymph nodes. The procedure returns a surgical result that is negative for metastasis in approximately 88% of patients, illuminating the need for additional prognostic information to inform SLNB decisions. The DecisionDx-Melanoma test addresses this need by integrating a patient’s tumor biology with their personal clinicopathologic factors to provide their individual risk of SLN positivity.

Current National Comprehensive Cancer Network (NCCN) guidelines suggest foregoing SLNB when the likelihood of finding a positive SLN is less than 5%, considering SLNB when the risk is between 5-10% and offering the surgery when the likelihood of positivity is above 10%. As such, decision-making for patients whose staging-based-risk falls within or around the 5-10% threshold (i.e., patients with T1a tumors with high-risk features, T1b and T2a tumors) can be the most challenging. The data shared at Dermato-Onco2024 included 471 patients with these tumor stages whose decision to pursue or forgo SLNB surgery was informed by DecisionDx-Melanoma test results.

The study showed that integrating DecisionDx-Melanoma test results into SLNB decisions resulted in 25% fewer SLNBs performed compared to a matched patient cohort ($p < 0.001$). Further, no patients with a DecisionDx-Melanoma-predicted risk of SLN positivity of less than 5% who decided to have an SLNB had a positive SLN (0/58 patients). Further, 9.8% of patients with a DecisionDx-Melanoma-predicted risk of SLN positivity of 5% or more who had the procedure did have a positive SLN. These study results provide further evidence that the DecisionDx-Melanoma test can safely reduce the number of SLNBs performed in patients with a low risk of SLN metastasis while identifying patients for whom the risk of nodal positivity is sufficient to warrant consideration of the procedure.

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. Through Sept. 30, 2024, DecisionDx-Melanoma has been ordered approximately 183,000 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, mental health conditions 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, psoriasis and related conditions. To learn more, please visit www.CastleBiosciences.com and connect with us on [LinkedIn](#), [Facebook](#), [X](#) and [Instagram](#).

DecisionDx-Melanoma, DecisionDx-CM Seq, i31-SLNB, i31-ROR, DecisionDx-SCC, MyPath Melanoma, DiffDx-Melanoma, TissueCypher, IDgenetix, DecisionDx-UM, DecisionDx-PRAME and DecisionDx-UM Seq are trademarks of Castle Biosciences, Inc.

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: (i) the ability of the DecisionDx-Melanoma test to accurately identify patients with a low risk of metastasis who can safely forego SLNB, thereby reducing unnecessary SNLB procedures; (ii) the ability of the DecisionDx-Melanoma test to increase confidence of clinicians in decisions made when discussing a possible SLNB

procedure; and (iii) the ability of the DecisionDx-Melanoma test to identify patients with sufficient risk of nodal positivity to consider SLNB . The words “believe,” “can,” “could,” “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 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, 2023 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.

1. Society of Surgical Oncology SSO 2024 Annual Meeting. *Ann Surg Oncol* 31 (Suppl 1), 1–294 (2024).

<https://doi.org/10.1245/s10434-024-15179-y> : **view presentation**

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