



NEWS RELEASE

# DecisionDx®-Melanoma's i31-SLNB: Report from the Largest Prospective Multicenter Study to Date Confirms 2.6% Nodal Positivity in Patients Predicted to Have Less Than 5% Risk

2026-03-09

Study results were recently shared at the Society of Surgical Oncology (SSO) 2026 Annual Meeting in Phoenix.

NCCN Cutaneous Melanoma Guidelines recommend avoiding a sentinel lymph node (SLN) biopsy (SLNB) if the predicted SLN positivity rate is less than 5%. This report shows that patients with a less than 5% predicted risk of SLN positivity by the DecisionDx-Melanoma test had an actual SLN positivity rate of just 2.6%, and only 1.4% in patients with T1b-T2a tumors specifically, again confirming the clinically actionable performance of DecisionDx-Melanoma.

FRIENDSWOOD, Texas, March 09, 2026 (GLOBE NEWSWIRE) -- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, today announced new data from the largest prospective multicenter study to date evaluating DecisionDx-Melanoma's integrated sentinel lymph node biopsy (i31-SLNB) test result. The study data, recently shared at the SSO 2026 Annual Meeting, confirm that the i31-SLNB accurately predicts SLN positivity and identifies low-risk patients who may safely consider forgoing SLNB while maintaining favorable long-term outcomes. These results expand upon earlier publications from the same prospective multicenter clinical study and further strengthen the growing body of evidence supporting the role of DecisionDx-Melanoma in guiding SLNB decision-making.<sup>1-3</sup>

"This study of DecisionDx-Melanoma's i31-SLNB result confirms that the test delivers clear and clinically meaningful separation between low- and high-risk patients in real-world practice," said Timothy Beard, M.D., FACS, lead author

and surgeon at Summit Medical Group in Bend, Oregon. “Importantly, patients identified as low risk not only had very low rates of nodal positivity but also demonstrated high recurrence-free survival over three years. That level of prospective validation can give clinicians and patients greater confidence when deciding whether to proceed with or forgo sentinel lymph node biopsy.”

Current National Comprehensive Cancer Network® (NCCN) Cutaneous Melanoma Guidelines recommend forgoing 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%. DecisionDx-Melanoma’s i31-SLNB algorithm integrates the independently predictive 31-gene expression profile (GEP) score with established clinicopathologic factors, including Breslow thickness, ulceration, mitotic rate, and age. For any GEP test to be clinically meaningful, the molecular score should demonstrate independent predictive value beyond traditional staging, ensuring it contributes distinct biological insight rather than duplicating clinicopathologic criteria. By combining validated tumor biology with select clinicopathologic features, the i31-SLNB algorithm generates a personalized likelihood of SLN positivity to support risk-aligned shared decision-making consistent with NCCN Guideline thresholds.

In this prospective, multicenter study of 912 patients with T1–T4 cutaneous melanoma enrolled across 30 U.S. centers, 430 patients underwent SLNB and 482 did not, allowing for evaluation of both nodal positivity and recurrence outcomes. Among those who underwent SLNB, patients with a less than 5% predicted risk of SLN positivity by the i31-SLNB had an actual SLN positivity rate of 2.6% compared to 21.4% in those with greater than 10% predicted risk.

In the T1b–T2a subgroup, where SLNB decisions often have the greatest clinical uncertainty, risk stratification by the i31-SLNB was particularly pronounced. Only 1.4% (1/74) of patients with less than 5% predicted risk had a positive node. Patients with a high-risk i31-SLNB result (greater than 10% risk) had an 18.5% SLN positivity rate. These patients were 13.2 times more likely to be SLN-positive.

Patients with a low-risk i31-SLNB result (less than 5% risk) demonstrated a 97.8% three-year recurrence-free survival (RFS) rate, indicating a very low risk of recurrence.

Collectively, these results support the ability of the integrated i31-SLNB to more precisely identify patients at low risk of SLN positivity compared with American Joint Committee on Cancer (AJCC) staging criteria and other predictive GEP tests.

Together, the study findings underscore two key conclusions from the prospective study:

- 1) DecisionDx-Melanoma identifies low-risk patients who have favorable outcomes, with very low nodal positivity rates and high three-year RFS.
- 2) DecisionDx-Melanoma also identifies patients at high risk of nodal positivity, providing clear and clinically meaningful separation between low- and high-risk groups.

“The strength of these prospective data clearly differentiates the risk prediction provided by DecisionDx-Melanoma from staging criteria and other predictive GEP tests and reinforces our leadership in precision risk assessment for patients with melanoma,” said Derek Maetzold, president and chief executive officer of Castle Biosciences. “By integrating DecisionDx-Melanoma’s independently validated 31-GEP score with key clinicopathologic factors, the i31-SLNB result provides clinicians with a more comprehensive, accurate and clinically grounded foundation to guide more confident SLNB decision-making.”

This study has been accepted for publication at Future Oncology and will be available online soon.

#### About DecisionDx-Melanoma

DecisionDx-Melanoma is a gene expression profile (GEP) test designed to analyze tumor biology to deliver a personalized risk assessment for patients with stage I–III cutaneous melanoma, enhancing risk stratification beyond American Joint Committee on Cancer (AJCC) staging alone. By combining molecular insights with select clinicopathologic features, the test provides two distinct outputs: a personalized risk of sentinel lymph node (SLN) positivity and a personalized risk of recurrence and/or metastasis. This clinically actionable information is designed to help guide risk-aligned patient management decisions, including SLN biopsy consideration, follow-up intensity, imaging and referrals.

DecisionDx-Melanoma is supported by more than 50 peer-reviewed publications, including prospective studies and meta-analyses, and was developed in collaboration with more than 100 leading U.S. institutions. The test has been clinically validated in more than 10,000 patient samples, ordered more than 220,000 times since launch, and has been shown to be associated with improved patient survival. Learn more at [www.CastleBiosciences.com](http://www.CastleBiosciences.com).

#### About Castle Biosciences

Castle Biosciences (Nasdaq: CSTL) is a leading diagnostics company improving health through innovative tests that guide patient care. With a primary focus in dermatologic and gastroenterological disease, we develop personalized, clinically actionable solutions that help improve disease management and patient outcomes.

We put people first—empowering patients and clinicians and informing care decisions through rigorous science and advanced molecular tests that support more confident treatment planning. To learn more, visit [www.CastleBiosciences.com](http://www.CastleBiosciences.com) and connect with us on [LinkedIn](#), [Instagram](#), [Facebook](#) and [X](#).

DecisionDx-Melanoma, DecisionDx-CMSeq, i31-SLNB, i31-ROR, DecisionDx-SCC, MyPath Melanoma, AdvanceAD-Tx, TissueCypher, DecisionDx-UM, DecisionDx-PRAME and DecisionDx-UMSeq 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: the ability of DecisionDx-Melanoma’s i31-SLNB test to (i) generate a personalized likelihood of SLN positivity to support risk-aligned shared decision-making consistent with NCCN guideline thresholds; and (ii) identify patients at both low and high risk of nodal metastasis. The words “designed,” “may”, “can”, and similar expressions are intended to identify forward 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 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 certain 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, 2025, and our subsequent Quarterly Reports on Form 10-Q, each as filed or to be filed with the SEC, 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) Yamamoto M, Sickel-Santanello B, Beard T, et al. The 31-gene expression profile test informs sentinel lymph node biopsy decisions in patients with cutaneous melanoma: results of a prospective, multicenter study. *Curr Med Res Opin.* 2023;39(3):417-423. doi:10.1080/03007995.2023.2165813

2) Guenther JM, Ward A, Martin BJ, et al. A Prospective, Multicenter Analysis of Recurrence-Free Survival After Sentinel Lymph Node Biopsy Decisions Influenced by the 31-GEP. *Cancer Med.* 2025;14(7):e70839. doi:10.1002/cam4.70839

3) Guenther JM, Ward A, Martin B, et al. A prospective, multicenter analysis of the integrated 31-gene expression profile test for sentinel lymph node biopsy (i31-GEP for SLNB) test demonstrates reduced number of unnecessary SLNBs in patients with cutaneous melanoma. *World J Surg Oncol.* 2025 Jan 3;23(1):5. doi: 10.1186/s12957-024-03640-x

Investor Contact:

Camilla Zuckero

**czuckero@castlebiosciences.com**

Media Contact:

Allison Marshall

**amarshall@castlebiosciences.com**

Source: Castle Biosciences, Inc.