

New Study Shows Combining TERT Mutation Analyses With DermTech's PLA Provides Improved Sensitivity for Detecting Melanoma With Non-invasive Patches

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Genomic test can objectively identify skin lesions with risk for melanoma at earlier stages

Combining TERT mutation analyses with DermTech PLA improves test sensitivity from 91% to 97% expanding actionable information for clinicians assessing patient risk for melanoma

LA JOLLA, Calif.--(BUSINESS WIRE)-- DermTech, Inc. (NASDAQ: DMTK) ("DermTech"), a leader in precision dermatology enabled by a non-invasive skin genomics platform, today announced that SKIN, the official journal of the National Society for Cutaneous Medicine, has published data showing that combining TERT DNA mutation analyses with DermTech's Pigmented Lesion Assay (the "DermTech PLA") improved the test sensitivity for detecting melanoma to 97%, up from a sensitivity of 91% without TERT.

"Clinicians average 15-25 biopsies before a single melanoma diagnosis is made," said the lead author on the study, Stephanie Jackson Cullison, MD, PhD, Dermatology, University of Pittsburgh. "Biopsies cause discomfort and scarring for patients, and there is still a 17% chance of missing melanoma with this approach. Non-invasive analysis of gene expression and TERT mutations provides insight into the biological risk of a pigmented lesion without putting patients through potentially unnecessary procedures."

"This study points to the value of having additional genetic information and objective diagnostic tools to assess disease risk beyond what can be ascertained visually," said Laura K. Ferris, M.D., PhD, associate professor, Dermatology, University of Pittsburgh.

The study assessed 103 pigmented skin lesions clinically suspicious for melanoma with the objective of evaluating the expression of LINC, PRAME and select melanoma driver mutations. Samples from clinically concerning lesions, with one or more ABCDE criteria, represent both clinically-challenging borderline lesions as well as lesions at both ends of the severity spectrum. Lesions were first sampled using the DermTech PLA non-invasive adhesive patch test, and then each lesion was surgically biopsied immediately afterwards for standard histopathological diagnoses. The study shows that:

- In this study, combining TERT mutation analyses with DermTech PLA gene expression (LINC00518 and PRAME) increased sensitivity to 97%. The sensitivity of the PLA in this study was 93%
- 61% of PLA-positive lesions that were not diagnosed as melanoma were found to have severe histologic atypia
- PLA-positive lesions histopathologically diagnosed as melanomas harbored TERT mutations in 70% of cases, while both severely dysplastic nevi and non-melanoma lesions including nevi without severe histologic atypia harbored TERT mutations in only 4% of cases

"This study supports the addition of TERT to the PLA test to improve sensitivity of the test. TERT by itself has been shown by other investigators to provide a reasonable sensitivity and high specificity in differentiating benign from malignant lesions.¹ The PLA *plus* TERT can serve as an important test to spare patients unnecessary biopsies and excisions all while enabling the detection of melanoma at the earliest stages," said John Dobak, M.D., Chief Executive Officer of DermTech.

About DermTech:

DermTech is the leading genomics company in dermatology and is creating a new category of medicine, precision dermatology, enabled by our non-invasive skin genomics platform. DermTech's mission is to transform the practice of dermatology through more accurate diagnosis and treatment, and the elimination of unnecessary surgery, leading to improved patient care and lower costs. DermTech provides genomic analysis of skin samples collected non-invasively using an adhesive patch rather than a scalpel. DermTech markets and develops products that facilitate the early detection of skin cancers, and is developing products that assess inflammatory diseases and customize drug treatments. For additional information on DermTech, please visit DermTech's investor relations site at: www.dermtech.com.

This press release includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. The expectations, estimates, and projections of DermTech may differ from its actual results and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "continue," and similar expressions are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, expectations with respect to the performance, patient benefits and cost-effectiveness of the DermTech PLA and the market opportunity therefor. These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside of the control of DermTech and are difficult to predict. Factors that may cause such differences include, but are not limited to: (1) the outcome of any legal proceedings that may be instituted against DermTech; (2) DermTech's ability to obtain additional funding to develop and market its products; (3) the existence of favorable or unfavorable clinical guidelines for DermTech's tests; (4) the reimbursement of DermTech's tests by Medicare and private payors; (5) the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for DermTech's products; (6) DermTech's ability to grow, manage growth and retain its key employees; (7) changes in applicable laws or regulations; (8) the market adoption and demand for DermTech's products and services together with the possibility that DermTech may be adversely affected by other economic, business, and/or competitive factors; and (9) other risks and uncertainties included in (x) the "Risk Factors" section of the most recent Annual Report on Form 10 -K filed with the Securities and Exchange Commission (the "SEC") by the company, and (y) other documents filed or to be filed with the SEC by the company. DermTech cautions that the foregoing list of factors is not exclusive. You should not place undue reliance upon any forward-looking statements, which speak only as of the date made. DermTech does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions, or circumstances on which any such statement is based.

¹The Genetic Evolution of Melanoma from Precursor Lesions" 12 Nov. 2015, <u>https://www.nejm.org/doi/full/10.1056/NEJMoa1502583</u>.

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