DermTech Announces Positive Topline Results From a Study Evaluating the DermTech Melanoma Test (DMT) Across All Skin Types

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- Study demonstrated the DMT’s effectiveness as a melanoma rule-out test for all skin types
- Negative predictive value (NPV) higher than 99% regardless of skin type

SAN DIEGO--(BUSINESS WIRE)--Jan. 18, 2024-- DermTech, Inc. (NASDAQ: DMTK) (DermTech or the Company), a leader in precision dermatology enabled by a non-invasive skin genomics technology, today reported positive topline results from a study evaluating the foundational gene expression assay component of the DermTech Melanoma Test (DMT) across all skin types in the real-world clinical setting. The peer-reviewed study entitled, “Non-invasive gene expression analysis rules out melanoma with high negative predictive value regardless of skin phototype” was presented at the Winter Clinical Dermatology Conference (January 12-17, 2024).

Using follow-up information and biopsy results from a large registry database that also served as the basis for the Company’s recently completed Trust 2 Study, this study compared the DMT’s performance in patients with Fitzpatrick skin phototypes I-III (n=4,152) to its performance in patients with skin phototypes IV-VI (n=130). As in prior DMT studies, lesions on acral skin (palms, soles and nailbeds) were excluded because the thicker skin on acral sites may interfere with the test’s non-invasive sample collection method.

The negative predictive value (NPV) for both groups (I-III and IV-VI) was greater than 99%, and the 95% confidence interval for the difference in NPV between the groups indicated that there was no significant difference between the skin phototype groups. Additional analysis limited to subjects with re-examination of DMT-negative lesions at least 6 months after testing confirmed the results observed in the full cohort. These data establish that the DMT’s performance does not vary across Fitzpatrick skin types.

“This study demonstrated that regardless of a patient’s skin type, the DMT can help clinicians rule out melanoma non-invasively, with an NPV of over 99%,” said Loren Clarke, M.D., chief medical officer, DermTech. “A high NPV means a suspicious pigmented lesion that tests negative is unlikely to be a melanoma. The DMT provides genomic information that can help guide biopsy decisions for suspicious pigmented lesions across all skin types.”

“This study shows that the DMT can help clinicians improve outcomes for cutaneous melanomas in patients of all skin types,” commented Neal Bhatia, M.D., director of Therapeutics Clinical Research and a co-author of the study. “This is significant progress toward making this test available for patients with Fitzpatrick skin types IV-VI, which is important because ruling out melanoma in individuals with these skin types can be particularly challenging.”

About The DermTech Melanoma Test

DermTech originally marketed its foundational assay under the name Pigmented Lesion Assay (PLA). The PLA assesses pigmented skin lesions, moles or dark skin spots for melanoma. In particular, the PLA detects expression of the LINC00518 (LINC) and preferentially expressed antigen in melanoma (PRAME) genes using reverse transcription-polymerase chain reaction (RT-PCR). The Company introduced an add-on assay to the PLA in 2021, which is designed to identify the presence of mutations in TERT gene promoter region using DNA sequencing. The Company has since branded its PLA and TERT add-on assay as the DermTech Melanoma Test (DMT). The DMT may be ordered with or without the add-on test for TERT. Positive results for LINC, PRAME or TERT correlate with a lesion at higher risk for melanoma. If none of the biomarkers are detected, this result indicates a 99% probability that the mole tested is not melanoma. Effective March 1, 2024, the Company will discontinue the optional TERT promoter mutation add-on assay to simplify the DMT, which will thereafter consist of the foundational gene expression assay for LINC and PRAME.

About DermTech

DermTech is a leading genomics company in dermatology and is creating a new category of medicine, precision dermatology, enabled by its non-invasive skin genomics technology. DermTech’s mission is to improve the lives of millions by providing non-invasive precision dermatology solutions that enable individualized care. DermTech provides genomic analysis of skin samples collected using its Smart Stickers™. DermTech develops and markets products that facilitate the assessment of melanoma. For additional information, please visit DermTech.

Forward-Looking Statements

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,” “runway,” “outlook,” “anticipate,” “intend,” “plan,” “strive,” “may,” “will,” “sustain,” “could,” “should,” “believe,” “predict,” “potential,” “continue,” and similar expressions are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, expectations and evaluations with respect to: the performance, patient benefits, cost- effectiveness, commercialization and adoption of DermTech’s products and the market opportunity for these products; expectations regarding DermTech’s potential growth, scale, patient reach, financial outlook, including its cash runway and future financial performance DermTech’s ability to increase its test volume, revenue and the proportion of reimbursed billable tests and control or reduce cost, expenses and cash burn; and expectations regarding agreements with or reimbursement or cash collection patterns from government payers (including Medicare) or commercial payers and related billing practices or number of covered lives. 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 government payers (including Medicare) and commercial payers; (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 and maintain or improve its
operating efficiency and reduce operating expenses; (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 the “Risk Factors” section of the most recent Annual Report on Form 10-K filed by DermTech with the Securities and Exchange Commission (the “SEC”), and other documents filed or to be filed by DermTech with the SEC, including subsequently filed reports. 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.

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