DermTech Announces Positive Topline Results From Trust 2 Study Evaluating the DermTech Melanoma Test (DMT)

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- Trust 2 Study demonstrated powerful clinical utility for the DMT as a rule-out test for melanoma
- Negative predictive value (NPV) higher than 99%

SAN DIEGO--(BUSINESS WIRE)--Jan. 8, 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 its Trust 2 Study, which evaluated the foundational gene expression assay component of the DermTech Melanoma Test (DMT) in a real-world clinical setting.

“The Trust 2 Study results reaffirm the DMT’s real-world clinical utility to rule out melanoma with a negative predictive value (NPV) that is higher than other currently available methods,” said Loren Clarke, M.D., chief medical officer, DermTech. “Importantly, for clinicians and patients, a high NPV delivers assurance that a suspicious pigmented lesion which tests negative is unlikely to be a melanoma. As a non-invasive test that has demonstrated an NPV of 99% or higher in multiple, large studies, the DMT provides actionable genomic information for a suspicious pigmented lesion that a clinician may be hesitant to biopsy for a variety of reasons.”

Dr. Clarke continued, “The DMT may also help clinicians avoid biopsies and other procedures for benign lesions and thereby reduce healthcare costs. Finally, we believe these positive results will support re-engagement with payers as they consider reimbursement for the DMT.”

The Trust 2 Study, initiated in 2021, enrolled over 20,000 patients tested with the DMT in a real-world clinical setting. Follow-up evaluations occurred for more than 5,000 tested lesions, with median and mean follow-up durations of 348 days and 337 days, respectively. Follow-up evaluations included pathology diagnoses for lesions that were biopsied, and visual re-examination for lesions that were monitored rather than biopsied, in which the lesion was classified as either stable/unchanged or changed in a manner concerning for melanoma.

The Trust 2 Study results demonstrated an NPV of 99.7% for the foundational gene expression assay component of the DMT. The NPV of 99.7% was observed (rather than calculated from an assumed prevalence), and was associated with a narrow 95% confidence interval of 99.5% to 99.9%. The Trust 2 Study results also included a sensitivity of 95.8%, a specificity of 69.4% and a positive predictive value (PPV) of 13.4%. The Trust 2 Study results further validate the 99% NPV observed in a similar real-world study (Trust 1) published in 2021, which evaluated the tested lesions of more than 1,500 patients.

“The Trust 2 Study illustrates that a high NPV test such as the DMT can allow physicians to confidently rule out melanoma for their patients,” commented Maral K. Skselvey, M.D., Clinical Professor of Dermatology at Georgetown University’s Medical School and one of the lead Trust 2 Study investigators. “Our clinic at the Dermatologic Surgery Center of Washington in Chevy Chase has used the DMT more than 5,400 times. Patients love the test’s non-invasive sample collection. It’s clear there is a place for the DMT in every dermatologic practice alongside established protocol.”

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 LINCO0518 (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.

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,” “should,” “could,” “would,” “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; and expectations regarding agreements with or reimbursement by or cash collection patterns from government payers (including Medicare) and 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 including 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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