DermTech Announces Topline Results of its TRUST Study: Results Confirm the High Negative Predictive Value of the PLA at 99% and Find No Significant Adverse Outcomes After Long-Term Follow-Up of PLA Negative Tests

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LA JOLLA, Calif.--(BUSINESS WIRE)--Dec. 17, 2020-- DermTech, Inc. (NASDAQ: DMTK) (“DermTech”), a leader in precision dermatology enabled by a non-invasive skin genomics platform, announced today the topline results from its TRUST Study of the company’s non-invasive melanoma rule-out test, the Pigmented Lesion Assay (the “PLA”). The TRUST study is a long-term follow-up study of pigmented skin lesions that tested negative for melanoma with the PLA. It was designed to assess long-term outcomes of PLA negative tests and to further confirm the 99% negative predictive value (“NPV”) of the PLA. Specifically, the study protocol called for reevaluating and retesting lesions that were PLA negative 12 to 24 months prior to each subject’s enrollment in the TRUST Study in order to determine the proportion of true negative lesions among those that tested negative. The PLA enhances early melanoma detection by assessing atypical pigmented lesions (lesions suspicious for melanoma) to help rule out melanoma and the need for surgical evaluation. The PLA detects LINC 518 (long intergenic non-protein coding RNA 518) and PRAME (preferentially expressed antigen in melanoma) as a 2-panel gene expression assay.

The TRUST Study was conducted at five geographically distinct clinical sites in the U.S. that consistently use the PLA to help manage atypical pigmented lesions in their clinical practice. A long-term follow-up cohort of 1,781 lesions with PLA negative tests in a 12 to 24 month period prior to the study’s start were identified and the subjects with such lesions were solicited to return for repeat PLA testing on the same lesion. A total of 302 lesions were evaluated by means of repeat testing with the PLA, meeting the study protocol’s pre-specified enrollment target.

After the enrollment of subjects in the repeat testing arm of the TRUST Study, the NPV and patient outcomes for the full cohort of eligible lesions was established via a prospectively planned chart review for any melanoma diagnoses on the PLA tested lesion, late-stage melanoma diagnoses, and melanoma mortality. Of the 1,781 lesions in the long-term follow-up cohort, there were no melanoma deaths or late-stage melanoma diagnoses reported in the full cohort. Ten lesions from the full cohort had received a melanoma diagnosis after initial testing, with four at Stage 0 (*in situ*) and six at Stage 1a. A subset of the full cohort, representing 1,233 lesions, had confirmed follow-up evaluations from the initial PLA negative test, and from these evaluations we calculate an NPV of 99.2% ($CI_{95\%}$= 98.5 - 99.6).

Of the 302 lesions evaluated by means of repeat testing with the PLA, none (0%) were found to have clinically obvious melanoma upon the subject’s return to the clinic, confirming the results of the initial chart review. Eighty-nine percent of these lesions (268 lesions) were negative on repeat testing with the PLA and 34 (11.2%) were positive. Positive lesions were biopsied and subjected to a single read histopathologic review. Three lesions (1%) that tested positive on repeat testing were diagnosed as Stage 0, in situ. Photographic review of the three Stage 0 cases identified changes in clinical appearance since the initial test. The pathology reports from the remaining biopsied lesions indicated a variety of non-melanoma diagnoses, including compound nevi with mild to moderate atypia. Given the early stage (*in situ*) of the melanomas detected on repeat testing, and length of time from the initial test (an average of 15 months), it is difficult to determine whether these melanomas evolved after the initial test or were present at the time of the initial test. In any case, the finding of three melanomas in a cohort of 302 lesions subjected to repeat testing further confirms an NPV of the PLA of at least 99.0% ($CI_{95\%}$ = 97.1 - 99.8) and is consistent with the results from the full long-term follow-up cohort. These results exemplify how PLA repeat testing of lesions that may have evolved over time after the initial negative PLA test, can identify early-stage melanoma and benefit patients.

“These results further support the PLA’s high negative predictive value in routine -use scenarios and the test’s ability to enhance early melanoma detection. Clinicians should have confidence in the PLA as the long-term follow-up of PLA negative tests observed in the TRUST Study did not reveal any adverse outcomes,” stated Dr. Burkhard Jansen, DermTech’s CMO.

“The TRUST Study illustrates that the PLA can identify melanoma at the earliest stages to maximize patient benefit,” commented Dr. Maral Skelsey, Director of the Mohs Surgery Unit and Clinical Associate Professor of Dermatology at Georgetown University and one of the TRUST study investigators.

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.

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,” “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, cost-effectiveness, commercialization and adoption of DermTech’s products, including the Smart Sticker platform, 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 Quarterly Report on Form 10-Q filed by DermTech with the Securities and Exchange Commission (the “SEC”), and (y) other documents filed or to be filed by DermTech with the SEC. 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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