Biodesix Confirms Prognostic Value of VeriStrat Testing in Phase 3 Study of Patients with Advanced Lung Cancer

The Oncologist Publishes Results of 1,048 Patient Study

BOULDER, Colo., August 28, 2018 – A new study published in The Oncologist demonstrates the objective prognostic value of the Biodesix VeriStrat® test in patients with non-small cell lung cancer (NSCLC). Researchers utilized samples from the Phase 3 MARQUEE trial and found that the VeriStrat (VS) test was a significant predictor of outcomes, independent of ECOG Performance Status categories, patient EGFR (epidermal growth factor receptor) mutation status, treatment received, and other clinical variables.

“The present data confirm that VeriStrat results provide information that can impact treatment decisions for both EGFR mutated and non-mutated patient populations. Additionally, VeriStrat results can be combined with performance status to create a stronger prognostic indicator for forming treatment strategies. While further validation studies are needed, this data adds to the growing body of evidence supporting the utility of VeriStrat results in patients with NSCLC,” said Giorgio V. Scagliotti, M.D., Ph.D., principal investigator of the study. Dr. Scagliotti is chief of the Medical Oncology Division at the San Luigi Hospital, Orbassano and former head of the Department of Oncology at the University of Torino, Italy.

The study of 1,048 patients, entitled “Retrospective assessment of a serum proteomic test in a Phase 3 study comparing erlotinib plus placebo to erlotinib plus tivantinib (MARQUEE) in previously treated patients with advanced NSCLC,” demonstrated that patients with VS Poor results and a better ECOG PS (PS 0) have worse OS compared to VS Good patients with a worse PS (PS 1). Additionally, VS is applicable to predicting response differences in EGFR mutation-positive patients as well as those that are EGFR wild-type.

In the EGFR mutation-positive subgroup, patients with a VS Good result experienced improved overall survival as compared to patients with a VS Poor result when treated with a single-agent EGFR-tyrosine kinase inhibitor (EGFR-TKI). When the combination of two EGFR-TKI therapies was used, patients with VS Good results still outperformed those with VS Poor results, but those with VS Poor results performed better on the combination therapy than on erlotinib alone, thus indicating the need for an alternative treatment strategy, which may include novel combination therapies. In contrast, the patients with a VS Good result did not receive significant benefit from the additional agent.

“This analysis provides further evidence that VeriStrat testing can enhance the prognostic evaluation of patients with advanced NSCLC and guide patients and physicians in making effective treatment decisions,” said Linda Traylor, Ph.D., vice president of Clinical Development and Medical Affairs for Biodesix. “The study also indicates VeriStrat testing may be used as an additional prognostic tool for EGFR-mutated patients. Results suggest that patients with an EGFR mutation and a VS Poor result may benefit from an alternative, potentially more aggressive treatment strategy. This is the second published study to indicate that TKI combination therapy may salvage patients with a VS Poor result. Further research in this patient population is a high priority for Biodesix.”
VeriStrat is a multivariate, mass-spectrometry based test that measures circulating proteins in the blood serum or plasma of patients with NSCLC. Test results assign a good (VS Good) or poor (VS Poor) classification to patient samples. Multiple studies support that patients with a VS Good result have a better prognosis than patients with a VS Poor result, independent of current clinical prognostic indicators and treatment choice.

**About Biodesix**

Biodesix is a molecular diagnostics company advancing the development of innovative, multi-omic blood tests in oncology to enable precision medicine. Biodesix discovers, develops and commercializes multivariate protein and genomic liquid biopsy tests, including the GeneStrat® and VeriStrat® tests, that deliver results within 72 hours. The company is changing the standard of care by providing physicians with diagnostic tests and with the Biodesix Lung Reflex™ testing strategy, for better therapeutic guidance, more accurate prognosis and enhanced disease monitoring to improve patient outcomes. At the forefront of personalized medicine, Biodesix is developing new tests to identify patients who may benefit from immunotherapies. In addition to developing novel diagnostics independently, the company partners with biotechnology and pharmaceutical companies to develop companion diagnostics for use with therapeutic agents.

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