



## **New Data from Phase III Lung Cancer Trial Show VeriStrat® Identifies Patients Likely to Respond to Erlotinib**

Broomfield, Colorado – April 30, 2010 – Results from the VeriStrat biomarker analysis of a multicenter Phase III trial were presented today at the 2<sup>nd</sup> European Lung Cancer Conference currently being held in Geneva, Switzerland. Results showed that the VeriStrat test identified patients who were likely to have a survival benefit from treatment with erlotinib, a commonly prescribed oral therapy for advanced non-small cell lung cancer (NSCLC). Following treatment with erlotinib, patients in the group classified as “VeriStrat Good” had a median survival of 10.5 months compared to 4.0 months in the group classified as “VeriStrat Poor.”

The study retrospectively applied the VeriStrat proteomic analysis to a subset of the patient population from the NCIC Clinical Trials Group study BR.21, a Phase III, multicenter trial of erlotinib versus placebo in previously treated patients with NSCLC. The VeriStrat analysis involved 441 of 729 patients from the BR.21 study and classified patients as either “VeriStrat Good” or “VeriStrat Poor” based on a proteomic profile. The data suggest that with a VeriStrat Good classification a patient is likely to receive therapeutic benefit from treatment with erlotinib and with a VeriStrat Poor classification, a patient is likely to derive little therapeutic benefit.

VeriStrat Good patients treated with erlotinib had a significant improvement in survival of 10.5 months compared to 6.6 months on placebo (hazard ratio=0.63; p-value=0.002). VeriStrat Poor patients treated with erlotinib had a median survival of 4.0 months compared to 3.1 months on placebo and showed no statistically significant difference between treatment groups (hazard ratio=0.77; p-value=0.11). VeriStrat Good patients also had a significantly higher tumor response rate than VeriStrat Poor patients (11.5% vs. 1.0%, p=0.002). VeriStrat status did not correlate with other biomarkers analyzed in the study.

“The era of personalized medicine requires that we can have biomarkers to select therapy, that these can be easily obtained, and that the results are available in a short time frame. Analysis of a serum protein profile such as VeriStrat meets these criteria,” stated Paul Bunn, MD, James Dudley Chair in Cancer Research at the University of Colorado Denver. “Several therapies such as erlotinib, docetaxel or pemetrexed are approved in either the maintenance setting, the 2<sup>nd</sup> or 3<sup>rd</sup> line setting or both and it has been difficult to determine which of these therapies might be best for an individual, especially an individual without an EGFR mutation. The data presented suggest that a positive VeriStrat test can pick those patients most likely to benefit from erlotinib.”

About NSCLC: As reported by the American Cancer Society, lung cancer is the leading cause of cancer death in the US. NSCLC represents approximately 87% of lung cancer. An estimated 215,000 new cases of lung cancer and 162,000 deaths due to lung cancer occurred in the US in 2008. Treatment options include surgery, radiation therapy, chemotherapy and targeted biological therapies such as bevacizumab (Avastin®) and erlotinib (Tarceva®). Less than 5% of advanced NSCLC patients survive for 5 years, emphasizing the need for improved patient selection to maximize drug efficacy.

About VeriStrat: VeriStrat is a pretreatment, serum test for patients with advanced NSCLC. The test identifies patients who are likely to have good or poor outcomes after treatment with epidermal growth factor receptor inhibitors (EGFRIs). Samples are processed in Bionodesix' CLIA accredited laboratory and results are typically reported within 72 hours of sample shipment. VeriStrat has been validated in clinical studies with over 1000 patients. Bionodesix is engaging in additional studies to further validate the test and to explore the clinical utility of VeriStrat in other solid epithelial tumors and with other EGFRIs. For more information on VeriStrat or to order VeriStrat, visit [www.VeristratSupport.com](http://www.VeristratSupport.com) or call the VeriStrat Support Hotline at 1-866-432-5930.

About Bionodesix: Bionodesix is a fully integrated molecular diagnostic company developing products that support excellence in clinical decision making and improve patient care. The Company's goal is to give physicians more information to understand the patient and their disease. Understanding the clinically meaningful information contained within each patient's molecular profile leads to better care and better outcomes. The Company's unique approach is based on ProTS®, proprietary technology which exploits the power of mass spectrometry and enables the discovery of specific molecular profiles that can be used to better characterize the patient and their disease. Bionodesix collaborates with investigators to address key clinical questions, and partners with biotechnology and pharmaceutical companies for development of companion diagnostics and improved targeting of therapies in clinical trials. For more information about Bionodesix, please visit the Company's website at [www.Bionodesix.com](http://www.Bionodesix.com).

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