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Caris Life Sciences Introduces Research Showing Time-To-Next Treatment as Effective Surrogate Outcome Measure in Retrospective Study of 4729 Cancer Patients Undergoing Panomic Profiling

IRVING, Tex., June 7, 2016 – Caris Life Sciences®, a leading biotechnology company focused on fulfilling the promise of precision medicine, today announced the presentation of a retrospective study introducing time-to-next treatment (TNT) as a surrogate measure predicting outcomes in patients with advanced cancer at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting. Panomic profiling from Caris Life Sciences was used in the study to predict the outcome of systemic therapy in 4,729 patients with solid tumors.

Researchers found a clinically relevant and statistically significant increase in overall survival (OS) in association with broadly based panomic profiling used for the prediction of treatment response. “To our knowledge, this is the first large clinical series that has shown a statistically significant increase in OS in patients undergoing panomic profiling and who received treatments in line with molecular profiling recommendations,” said lead author Dr. John Marshall, director, Otto J. Ruesch Center for the Cure of Gastrointestinal Cancer at Georgetown Lombardi Comprehensive Cancer Center and chief of the hematology/oncology division at MedStar Georgetown University Hospital. Marshall is also a member of Caris’ Scientific Advisory Board. He continued, “In addition, while further validation is needed, our study demonstrates that time-to-next-treatment is a meaningful surrogate endpoint correlated to overall survival for biomarker selected treatments.”

The study included data from 1,180 patients with solid tumors from the Caris Registry who were referred for testing between 2009 and 2015, as well as data from IntrinsiQ Specialty Solutions for over 3700 additional patients. All of these patients underwent Caris Molecular Intelligence’s multiplatform genomic and proteomic testing which included protein expression analysis using immunohistochemistry (IHC), gene copy number analysis using chromogenic or fluorescence in situ hybridization (FISH), fragment analysis, and gene sequencing using pyrosequencing and next-generation sequencing (NGS). The patients were retrospectively classified into Matched (M) or Unmatched (U) cohorts depending on whether they received treatments in line with the predictions of their molecular profile. For the creation of TNT data, the classification into M and U cohorts was performed based on the first treatment administered after collection of the panomic analysis sample while all treatments received were taken into account for correlation with OS data.

The study results pointed to an improved OS (p < 0.001, hazard ratio [HR] = 0.69) of patients in the M cohort (1069 days), with a median increase of more than one year compared to the patients in the U cohort (686 days). In addition, the results based on the full data set of 4729 patients pointed to statistically significant changes (p = 0.00036, hazard ratio [HR] = 0.87) in TNT values between the M and U cohorts, reflecting the changes seen in OS.
“Our research demonstrates a novel approach that integrates molecular profiling, clinical treatment and patient outcome data over a large case volume to evaluate the utility of panomic testing. By following Caris’ recommendations, our evidence has shown that patients live up to one year longer and have to undergo 1.2 fewer lines of therapy,” said David D. Halbert, founder and CEO of Caris Life Sciences. “We are confident that Caris will continue to be a leader in this evolving field of research, and the evidence will continue to emphasize the importance of integrating the knowledge of predictive biomarkers into treatment selection for cancer patients worldwide.”

About Caris Life Sciences®
Founded by David D. Halbert in 2008, Caris Life Sciences® is a leading biotechnology company focused on fulfilling the promise of precision medicine through quality and innovation. Caris Molecular Intelligence®, the company’s comprehensive and patented tumor profiling product, with more than 90,000 patients profiled, provides oncologists with the most clinically actionable treatment options available to personalize cancer care today. Using a variety of advanced profiling technologies to assess relevant biological changes in each patient’s tumor, Caris Molecular Intelligence connects biomarker data generated from a tumor with biomarker-drug associations supported by evidence in the relevant clinical literature. Since 2009, Caris Life Sciences has tracked clinical and outcome data for certain patients undergoing tumor profiling, and has observed that patients treated with drugs consistent with their tumor profile show a significant increase in overall survival. The company is also developing its ADAPT Biotargeting System™, a revolutionary and unbiased profiling platform with applications across therapy development, drug delivery, advanced diagnostics and disease monitoring. Currently being developed for cancer and other complex diseases, the ADAPT Biotargeting System is able to simultaneously measure millions of molecular interactions within complex biological systems in their natural state(s). Headquartered in Irving, Texas, Caris Life Sciences offers services throughout the U.S., Europe, Australia and other international markets. To learn more, please visit www.CarisLifeSciences.com.

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