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Pathwork® Tissue of Origin Test Cost-Effective For Increasing Cancer Patient Survival

Study Presented at AACR – IASLC Joint Conference

Redwood City, CA, January 9, 2012 – Pathwork Diagnostics, Inc., a pioneer in creating genomics-based diagnostics in oncology utilizing their proprietary informatics platform, announced today that results from a study involving its Pathwork® Tissue of Origin Test will be presented this week at the American Association for Cancer Research (AACR) - International Association for the Study of Lung Cancer (IASLC) Joint Conference on The Molecular Origins of Lung Cancer: Biology, Therapy and Personalized Medicine (January 8-11, 2012, San Diego).

The Pathwork Tissue of Origin Test is the only FDA-cleared, Medicare-covered molecular diagnostic for identifying tissue of origin. It uses a tumor's own genomic information to help pathologists and oncologists diagnose challenging cancer cases such as those that are metastatic or that have a complex clinical history.

In the study, use of chemotherapy regimens consistent with guidelines for the final tumor-site diagnosis increased significantly from 42% to 65%, a gain of 23%. Overall survival was projected to increase from 15.9 months to 19.5 months, a mean gain of 3.6 months overall survival. The average increase in survival adjusted for quality of life was 2.7 months and the average cost per quality-adjusted life year (QALY) gained was $46,858.

“The Tissue of Origin Test significantly altered clinical practice patterns for treating metastatic cancer,” explained John Hornberger, M.D., M.S., CEO/President of Cedar Associates LLC and Principal Investigator of the study. “We saw an increase in overall survival and quality-adjusted life years, resulting in an expected cost per QALY of less than $50,000 per patient, which is within the generally accepted threshold of <$100,000 for cost-effectiveness in the United States.”[1,2]

The retrospective, observational study examined treatment changes made in patients by physicians who received Tissue of Origin Test results. Changes in planned chemotherapy, surgery, radiation therapy, blood tests, imaging and referral to hospice care before and after test results were recorded. Estimates of the effect of changes in chemotherapy on survival were based on National Comprehensive Cancer Network (NCCN) and other treatment guidelines. Costs were estimated based on data from NCCN and Centers for Medicare and Medicaid Services (CMS) fee schedules. Changes in overall survival, costs, and cost per quality-adjusted life year (QALY) gained were estimated.

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QALY is a measure used in cost-utility analysis. It estimates the dollar value of a medical intervention, based on the number of years of life that would be added by the intervention, taking into account both the quality and the quantity of life lived.

The study, "Cost-effectiveness of gene-expression profiling for tumor-site origin," was authored by John Hornberger, Irina Degtiar, Hialy Gutierrez, Ashwini Shewade, W. David Henner, Shawn Becker and Stephen Raab (poster presentation at the AACR-IASLC Joint Conference on Tuesday January 10, 4:30 – 6:30 pm, San Diego Marriott Hotel & Marina, San Diego).

About the Pathwork Tissue of Origin Test
The Pathwork Tissue of Origin Test, available through the Pathwork Diagnostics Laboratory, measures gene expression levels of 2,000 genes and uses proprietary algorithms to compare the tumor's gene expression pattern to that of 15 tumor types, representing 58 morphologies and 90% of all solid tumors. The test provides objective genomic information to help the physician diagnose what type of cancer the patient has. An accurate diagnosis allows oncologists to match therapy to the cancer.

The Pathwork Tissue of Origin Test has been extensively evaluated in multiple independent studies involving more than 1,100 patient specimens, including large validation studies published in the *Journal of Clinical Oncology* and the *Journal of Molecular Diagnostics*.

A retrospective study of 111 cases from 66 academic and community oncology practices illustrates the use of the test in management of cancer patients. Over two thirds of the cases reviewed showed cancer management changed after the Pathwork Tissue of Origin Test result was received. The majority of the oncologists identified the Tissue of Origin Test results as influencing the decision to make a change in therapy.

About Pathwork Diagnostics
Pathwork Diagnostics created its proprietary informatics platform to develop and commercialize high-value, medically important diagnostics aimed at helping guide cancer care. Pathwork has commercialized its Pathwork Tissue of Origin product line, and has a robust pipeline and growing portfolio of pharmaceutical partners. Pathwork is privately held and based in Redwood City, CA. For more information call toll-free (877) 808-0006 or visit www.pathworkdx.com.

1. Greenberg D, Earle C, Fang CH, Eldar-Lissai A, Neumann PJ. When is cancer care cost-effective? A systematic overview of cost-utility analyses in oncology. J Natl Cancer Inst. 2010 Jan 20;102(2):82-8. Epub 2010 Jan 7. Review.

2. Lee CP, Chertow GM, Zenios SA. An empiric estimate of the value of life: updating the renal dialysis cost-effectiveness standard. Value Health. 2009 Jan-Feb;12(1):80-7.

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