



New Blood Tests to Soon Replace Painful Bone Marrow Biopsies for Leukemia and Lymphoma Patients

January 24, 2005

- Quest Diagnostics is granted an exclusive license from The University of Texas M. D. Anderson Cancer Center to use proprietary technology based on blood proteins -

TETERBORO, N.J., Jan. 24 /PRNewswire-FirstCall/ -- Quest Diagnostics Incorporated (NYSE: DGX), the nation's leading provider of diagnostic testing, information and services, announced today that The University of Texas M. D. Anderson Cancer Center in Houston has granted the company exclusive use of five proprietary blood testing methods, which, once available in the form of laboratory diagnostic tests, may eliminate the need for painful and expensive bone marrow and other tissue extractions. The methods are the subjects of two U.S. patent applications. The tests are intended to provide a safer, less painful tool for the diagnosis, treatment and monitoring of leukemia and lymphoma in cancer patients. The initial tests are expected to be available following validation, which could be as early as the end of this year. Additional terms of the licensing transaction were not disclosed.

Current diagnostic and monitoring tests for leukemia and lymphoma patients often require patients to undergo painful procedures, such as bone marrow biopsies which require extraction of tissue with a bone-piercing, large-gauge needle. The new tests are in development at Quest Diagnostics' research and development center, Nichols Institute in San Juan Capistrano, Calif. They have the potential to provide a more clinically useful assessment of prognosis, disease progression, and therapeutic success, which could enable oncologists to advance the efficacy of therapies.

"Our research has shown that testing for tumor constituents in the blood provides a more clinically useful assessment of a patient's disease status because it shows what is happening in the entire body, compared with biopsies where a tissue sample only provides information about a specific area," said Michael J. Keating, M.D., Professor of Medicine and Deputy Department Chairman for the Department of Leukemia at M. D. Anderson Cancer Center. "It also offers a less painful and more cost-effective way to monitor patients. As a result, the new blood tests may allow oncologists to assess patients more frequently and thus provide more clinically relevant monitoring of their progress."

Quest Diagnostics is developing new tests, based on the M. D. Anderson technology, that are designed to detect certain proteins that are expressed on the surface of tumor cells, as well as molecular targets from the tumor cells. The assays will look for the proteins, called CD20, CD33 and CD52, as well as tumor-specific DNA and RNA in blood plasma. The tests are intended to help doctors diagnose lymphoma and leukemia, assess patient response to cancer treatment and monitor the patient post-treatment. By measuring tumor constituents in the blood, as opposed to assessing a tissue sample, physicians might one day replace the current bone marrow biopsies that are painful for patients to endure.

"We are very excited about this opportunity to develop new tests to help patients with lymphoma and leukemia," said Surya N. Mohapatra, Ph.D., Chairman and Chief Executive Officer of Quest Diagnostics. "We hope to provide physicians with tests that avoid the pain associated with bone marrow biopsies."

The technology underlying the new tests was developed under the leadership of Maher Albitar, M.D., Medical Director for Hematopathology at Quest Diagnostics. Prior to joining Quest Diagnostics in 2003, Dr. Albitar was a tenured professor at M. D. Anderson, where he served as Chief of the Leukemia Section in the Department of Hematopathology, with a joint appointment in the Department of Leukemia. Dr. Albitar is a co-inventor of the two current U.S. patent applications by M. D. Anderson and is the lead author on numerous publications on this subject(1). He is a recipient of a Physician Scientist Award from the National Institutes of Health.

The new concept that Dr. Albitar and his team at M. D. Anderson observed is that in hematologic diseases, tumor cells pour into circulation their DNA, RNA, and proteins, and these components can be detected in plasma. The common assumption had been that only proteins that were secreted (made by the tumor cell and then transported to the surface and released into plasma) could be present in the plasma. Most proteins are not secreted but rather embedded in the cell surface or inside the cell. The breakthrough was finding that non-secreted cell-surface proteins as well as their DNA and RNA are actually in the plasma and available for detection.

Quest Diagnostics will validate the testing technology by comparing the new tests that are based on peripheral blood plasma with conventional methods using bone marrow biopsies in patients with leukemia and lymphoma. Some of these studies are planned in coordination with M. D. Anderson researchers.

About Quest Diagnostics

Quest Diagnostics Incorporated is the nation's leading provider of diagnostic testing, information and services, providing insights that enable healthcare professionals to make decisions that improve health. The company offers the broadest access to diagnostic testing services through its national network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is the leading provider of esoteric testing, including gene-based medical testing, and provides advanced information technology solutions to improve patient care. Additional company information is available at: <http://www.questdiagnostics.com>.

The statements in this press release which are not historical facts or information may be forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause actual results and outcomes to be materially different. Certain of these risks and uncertainties may include, but are not limited to, competitive environment, changes in government regulations, changing relationships with customers, payers, suppliers and strategic partners and other factors described in the Quest Diagnostics Incorporated 2003 Form 10-K and subsequent filings.

(1) Numerous studies have been published recently demonstrating the value of testing CD52 and CD20 in the blood as an indicator of disease progression and response to treatment. Citations include:

- * Albitar M, Do KA, Johnson MM, Giles FJ, Jilani I, O'Brien S, Cortes J, Thomas D, Rassenti LZ, Kipps TJ, Kantarjian HM, Keating M. Free circulating soluble CD52 as a tumor marker in chronic lymphocytic leukemia and its implication in therapy with anti-CD52 antibodies. *Cancer*. 2004 Sep 1;101(5):999-1008.
- * Giles FJ, Vose JM, Do KA, Johnson MM, Manshoury T, Bociek G, Bierman PJ, O'Brien SM, Keating MJ, Kantarjian HM, Armitage JO, Albitar M. Circulating CD20 and CD52 in patients with non-Hodgkin's lymphoma or Hodgkin's disease. *Br J Haematol*. 2003 Dec;123(5):850-857.
- * Rogers A, Joe Y, Dey A, Jilani I, Giles F, Estey E, Freireich E, Keating M, Kantarjian H, Albitar M. Relative increase in leukemia-specific DNA in peripheral blood plasma from patients with acute myeloid leukemia and myelodysplasia. *Blood*. 2004 Apr 1;103(7):2799-801. Epub 2003 Oct 23
- * Ahmed M, Giles F, Joe Y, Weber DM, Jilani I, Manshoury T, Giralt S, Lima MD, Keating M, Albitar M. Use of plasma DNA in detection of loss of heterozygosity in patients with multiple myeloma. *Eur J Haematol*. 2003 Sep;71(3):174-8.
- * Manshoury T, Do KA, Wang X, Giles FJ, O'Brien SM, Saffer H, Thomas D, Jilani I, Kantarjian HM, Keating MJ, Albitar M. Circulating CD20 is detectable in the plasma of patients with chronic lymphocytic leukemia and is of prognostic significance. *Blood*. 2003 Apr 1;101(7):2507-13. Epub 2002 Nov 21.

SOURCE Quest Diagnostics

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