CAREDX RESPONDS TO CMS PROPOSAL TO CUT ALLOMAP PRICING BY 74%

CareDx engages with local Medicare Contractors to prove that CMS proposal is factually baseless

BRISBANE, Calif., June 29, 2016 (GLOBE NEWSWIRE) -- CareDx, Inc. (Nasdaq: CDNA), a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients, is challenging the recent proposal by Center of Medicare and Medicaid Services (CMS) as being harmful for heart transplant patients.

AlloMap® is a non-invasive blood test for heart transplant recipients to determine the risk of acute cellular rejection. AlloMap is the only alternative to an Endomyocardial Biopsy (EMB), which is more invasive, riskier and costlier for taxpayers.

The current Medicare rate paid for AlloMap is $2,821 per testing service, which is in line with many advanced diagnostic tests. The Clinical Lab Fee Schedule (CLFS) preliminary determination proposed rate is $732.12, a 74% reduction. This proposal is based on data provided by Medicare Administrative Contractors (MACs) that have little to no experience with AlloMap or the value it provides to heart transplant patients. If this proposal stands, CareDx will be unable to provide AlloMap to Medicare patients as the proposed price is far below the cost to provide the test.

Palmetto GBA and Noridian, MACs most experienced in the country with high-value molecular tests, have proposed the current price of $2,821. CareDx asks that other MACs should follow this lead.

“We have already heard from concerned patients and doctors. We are actively reaching out to those MACs that submitted pricing proposals that are the basis for the CMS calculations,” says Peter Maag, President and CEO of CareDx. “We plan to work with the healthcare community to educate CMS on the potentially harmful consequences of its current proposal.”

The company successfully overturned a 2015 proposal to wrongfully price AlloMap under the cross-walk process. The current proposal will be open to public comment until August 10, 2016, with the final determination expected to be published in November 2016, according to the CMS website.

CareDx is actively requesting meetings with the local MACs that have submitted unacceptable pricing proposals for AlloMap. CMS has signaled support in the establishment of an information exchange between companies and MACs to inform pricing proposals.

About CareDx

CareDx, Inc., headquartered in Brisbane, California, is a global molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients. CareDx offers AlloMap®, a gene expression test that aids clinicians in identifying heart transplant patients with stable graft function who have a low probability of moderate to severe acute cellular rejection. CareDx is developing additional products for transplant monitoring using a variety of technologies, including AlloSure™, a proprietary next-generation sequencing–based test to detect donor-derived cell-free DNA after transplantation.

CareDx, with its presence through Olerup, also develops, manufactures, markets and sells high quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. Olerup SSP® is a set of HLA typing used prior to hematopoietic stem cell/bone marrow transplantation and organ transplantation. XM-ONE® is the first standardized test that quickly identifies a patient's antigens against HLA Class I, Class II or antibodies against a donor's endothelium. For more information, please visit: www.CareDx.com.

Media Contact
Molly Martell, CareDx, Inc.
T: +1 415-728-6307
mmartell@caredx.com

Investor Contact
Jamar Ismail, Westwicke Partners
T: +1 415-513-1282
jamar.ismail@westwicke.com

Forward Looking Statements

In addition to historical information, this press release contains forward-looking statements with respect to our business, research, development and commercialization efforts and anticipated future financial results. These forward-looking statements are based upon information that is currently available to us and our current expectations, speak only as of the date hereof, and are subject to numerous risks and uncertainties, including risks related to our ability to complete diagnostic studies, including obtaining sufficient clinical samples and participation of clinical investigators in such studies, the timeline for completion of research efforts, development and commercialization of additional diagnostic solutions including cell-free DNA, which is a lengthy and complex process that may not be successful, our dependence on Medicare for a substantial portion of our revenue, and our dependence on health insurers and other third-party payers to provide coverage for our current test and future tests, if any. These factors, together with those that are described in our filings with the SEC, including the Annual Report on Form 10-K for the fiscal year ended December 31, 2015 filed by us with the SEC on March 29, 2016, may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements. We expressly disclaim any obligation, except as required by law, or undertaking to update or revise any such forward-looking statements.