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CareDx and Horizon Discovery Group Enter into a Collaboration for Development of Cell-Free DNA Reference Standards

Horizon's Standards to Support Proficiency Testing of CareDx Solid Organ Transplantation Injury Monitoring Diagnostic Assay

BRISBANE, Calif. and CAMBRIDGE, United Kingdom, June 3, 2015 (GLOBE NEWSWIRE) -- CareDx, Inc. (Nasdaq:CDNA), a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value, diagnostic surveillance solutions for transplant recipients and Horizon Discovery Group plc (Horizon), an international life science company supplying reagent tools and services that power genomics research and the development of personalized medicines, today announced they have entered into a collaboration to develop cell-free DNA (cfDNA) reference standards. These HDx™ Reference standards, being developed by Horizon Diagnostics, a division of Horizon, will support proficiency testing of CareDx's solid organ transplant injury monitoring diagnostic tests and will be integrated into CLIA laboratory testing.

HDx Reference Standards offer a source of genetically defined, quantitative, sustainable and independent third party reference material, critical to the validation and routine performance monitoring of CareDx's next generation sequencing (NGS) based donor-derived cfDNA (dd-cfDNA) diagnostic assay. The reference standards mimic plasma cfDNA both in size and abundance in transplant setting and are the first commercially available standards of their kind.

Horizon Diagnostics uses its proprietary genome engineering platforms to precisely engineer highly characterized parental cell lines. Horizon Diagnostics then generates mixtures at very precise allelic frequencies, verified by digital PCR, ranging between 0.1% and 50%.

CareDx's cfDNA test is designed to monitor injury to transplanted organs, in particular heart and kidney in transplant recipients to allow clinicians to better manage patient health outcomes. There are approximately 300,000 solid organ transplant patients living in the US. The assay amplifies approximately 250 loci of the human genome to identify transplant donor-recipient pairs with diverse ancestral heritage as well as those with close familial relationships. The CareDx cfDNA assay offers a simpler alternative to assays requiring donor and recipient genotyping to simplify assay implementation.

CareDx's cfDNA test follows recent guidance for next generation sequencing (NGS) outlined by Association of Molecular Pathology (AMP), American College of Medical Genetics (ACMG) and Clinical Laboratory Standards Institute (CLSI). The targeted assay was recognized in the "What's Hot, What's New" session at the American Transplant Congress in Philadelphia on May 6, 2015.

Dr. Paul Morrill, President, Products Business, Horizon, said: "This new collaboration with CareDx demonstrates the importance of well validated controls when developing clinical assays, especially as technologies such as NGS become more widely adopted for diagnostic use. Horizon is committed and motivated to be working with CareDx on the development of cell-free DNA reference standards within the solid organ transplant field, taking our reference standard technology into a new area beyond Oncology."

Dr. John J. Sninsky, CSO of CareDx, commented: "I have been working with Horizon's scientists for more than five years, and am continually impressed by their understanding of diagnostic requirements. At CareDx, it is our goal to accelerate patient access to clinical data using next generation sequencing technology. This collaboration with Horizon has the potential to advance us to this goal, and demonstrates CareDx's continued quality and regulatory leadership."

About CareDx

CareDx, Inc., based in Brisbane, California, is a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value, non-invasive diagnostic surveillance solutions for transplant recipients. The Company has commercialized AlloMap®, a gene expression test that aids clinicians in identifying heart transplant recipients with stable graft function who have a low probability of moderate/severe acute cellular rejection. CareDx is also pursuing the development of additional products for post-transplant monitoring of other solid organs that use a variety of technologies, including next generation sequencing to detect donor-derived cell-free DNA to monitor the health of organs after transplantation. The Company is currently investigating a research use only donor-derived cell-free DNA-based test for heart transplant recipients. For more information, please visit: www.CareDx.com.

About Horizon Discovery Group plc www.horizondiscovery.com/

Horizon is a revenue-generating life science company supplying research tools to organizations engaged in genomics research and the development of personalized medicines. Horizon has a diverse and international customer base of over 1,000 organizations across nearly 50 countries, including major pharmaceutical, biotechnology and diagnostic companies as well as leading academic research centers. The Company supplies its products and services into multiple markets, estimated to total in excess of £29 billion by 2015.

Horizon's core capabilities are built around its proprietary translational genomics platform, a high-precision and flexible suite of gene editing tools able to alter almost any endogenous gene sequence of human or mammalian cell-lines. Horizon offers over 16,000 products, almost all of which are based on the application of gene editing to generate cell lines that accurately model the disease-causing mutations found in genetically based diseases. These 'patients-in-a-test-tube' are being used by customers to identify the effect of individual or compound genetic mutations on drug activity, patient responsiveness, and resistance, which may lead to the successful prediction of which patient sub-groups will respond to currently available and future drug treatments.

In addition, Horizon provides rAAV, ZFN and CRISPR gene editing tools, custom cell line and *in vivo* model generation services for research and bioproduction applications, quantitative molecular reference standards, *in vivo* disease models, contract research and custom screening services and custom shRNA development services and off-the-shelf validated shRNA (through Horizon's partner Sirion).

Horizon is headquartered in Cambridge, UK, and is listed on the London Stock Exchange's AIM market under the ticker "HZD", for further information please visit: www.horizondiscovery.com.

About Horizon Diagnostics www.horizondx.com

Horizon Diagnostics, a division of Horizon Discovery Group plc, is a leading provider of genetically defined, human genomic reference standards, including FFPE cell line sections and purified genomic DNA. HDx™ Reference Standards offer a sustainable source of reference material to laboratories, proficiency schemes and manufacturers, providing an unprecedented level of control.

Variability in DNA extraction from tumor biopsies and a lack of standardization are currently major sources of error in molecular laboratories. The availability of genetically defined reference materials provides an industry standard for development and quality control of molecular assays, directly improving their accuracy.

Horizon Diagnostics' suite of HDx Reference Standards includes standards for the increasing number of 'rare' mutations being targeted for cancer therapeutics, which by definition are hard to find in clinical samples.

Drawing upon Horizon Discovery's proprietary genome editing platform, Horizon Diagnostics reconstitutes clinically relevant cancer genes in human cell lines, exactly as they occur in patient tumors. Horizon Diagnostics is able to define virtually every characteristic of its reference standards, from the molecular constitution of the genome to the diameter, width and DNA output associated with each product batch. These standards have been made available in a variety of formats including genomic DNA (gDNA) aliquots, Formalin-Fixed Paraffin-Embedded (FFPE) slices, fluorescent in-situ hybridization (FISH) material and immunohistochemistry (IHC) assays.

Forward Looking Statements

This press release contains forward-looking statements including, but not limited to statements regarding the Company's expectations regarding future potential, development and commercial activities. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward looking statements are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in the forward looking statements, including CareDx's limited operating history and experience with developing new markets; risk relating to new partnerships and commercialization of those relationships, as well as other risks stated in CareDx's filings with the SEC located at www.sec.gov. CareDx disclaims any obligation to publicly update or revise any forward looking statements to reflect events that occur or circumstances that exist after the date on which they were made.

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