NEWS RELEASE

FDA Accepts Letter of Intent for iBox Scoring System as a Surrogate Endpoint in Pharmaceutical Clinical Trials

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CareDx congratulates C-Path's Transplant Therapeutics Consortium on utilizing iBox to streamline the development of novel transplant drugs

SOUTH SAN FRANCISCO, Calif., June 18, 2020 (GLOBE NEWSWIRE) -- CareDx, Inc. (Nasdaq: CDNA), a leading precision medicine company focused on the discovery, development, and commercialization of clinically differentiated, high-value healthcare solutions for transplant patients and caregivers, congratulates the Critical Path Institute's (C-Path) Transplant Therapeutics Consortium (TTC) on the U.S. Food and Drug Administration (FDA) accepting the iBox Scoring System into the Center for Drug Evaluation and Research's Biomarker Qualification Program.

TTC provided information supporting the qualification of the iBox Scoring System as a reasonably likely surrogate endpoint for clinical trials evaluating immunosuppressive therapies for use in kidney transplant recipients, allowing drug sponsors to purse accelerated approval. FDA indicated in its decision that it supports TTC's intent to pursue biomarker qualification for the iBox Scoring System and invited TTC to submit a Qualification Plan.

CareDx currently offers KidneyCare, which is a prediction tool based on iBox technology, alongside AlloSure and AlloMap, for informing the clinical care and management of transplant patients. "The use of the iBox Scoring System as a reasonably likely surrogate endpoint represents a novel clinical trial design that will ultimately benefit patients by accelerating the development of next generation immunosuppression drug therapy," said Matthew Cooper, M.D., Director of Kidney and Pancreas Transplantation, MedStar Georgetown Transplant Institute.

"As a long-standing member of TTC, we appreciate the work of the consortium, the leadership shown by C-Path,

and the collaborative efforts of all involved," said Peter Maag, Chairman and CEO of CareDx. "CareDx's sole mission is to improve outcomes for transplant recipients, and we believe this decision by the FDA is the first step to bringing novel therapies that can truly improve long-term survival and quality of life."

About CareDx

CareDx, Inc., headquartered in South San Francisco, California, is a leading precision medicine solutions company focused on the discovery, development and commercialization of clinically differentiated, high-value healthcare solutions for transplant patients and caregivers. CareDx offers testing services, products, and digital healthcare solutions along the pre- and post-transplant patient journey, and is the leading provider of genomics-based information for transplant patients. For more information, please visit: **www.CareDx.com**.

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