



NEWS RELEASE

CareDx Accuses Natera of False Advertising Claims That Mislead Medical Personnel and Transplant Patients

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CareDx Files Second Lawsuit Against Natera

BRISBANE, Calif., April 10, 2019 (GLOBE NEWSWIRE) -- CareDx, Inc. (Nasdaq: CDNA), a leading molecular diagnostics company focused on creating diagnostic solutions for organ transplant patients, has filed a second lawsuit against Natera, Inc. in the United States District Court for Delaware. In this suit, CareDx alleges that Natera's comparisons of its kidney transplant technology to CareDx's AlloSure technology are based on numerous unscientific, unreliable, and inappropriate conclusions, and are therefore misleading.

"Natera has begun a false advertising campaign designed to deceive doctors, healthcare professionals, insurance companies, and patients – as well as investors – into believing that Natera's 'me too' test is superior to AlloSure when that has simply not been shown," says CareDx in its complaint. The complaint states several times that the comparisons to AlloSure are false both because the Natera Study is substantially flawed and because the Natera and CareDx study methodologies differ so significantly that comparison claims are precluded.

The complaint points to four specific examples of why Natera's comparisons of its product to AlloSure are unfair and inappropriate:

"...the samples analyzed in the Natera Study are not representative of the real-world kidney transplant population, as they were taken retrospectively from a pre-existing sample archive collected from a single study center...The CareDx Study was a multi-center study, which means that samples analyzed in the CareDx Study were collected from fourteen (14) study centers with biopsies primarily interpreted by the real-world pathologists at each center... the data obtained from Natera's pre-existing sample set cannot reliably be used to extrapolate results for the entire

kidney transplant population.”

“Natera made claims about [its kidney transplant technology’s] performance based on its analysis of 292 samples from 187 patients...Yet, in the Natera Study Publication, the results are based an analysis of only 217 samples[an exclusion of 26% of study samples].”

“‘For cause’ kidney biopsies are conducted on patients for whom a warning sign about possible active organ rejection has been triggered...A ‘protocol’ biopsy is conducted even though the patient has no prior indication of active organ rejection...The Natera Study further biases its sample selection by mixing ‘for cause’ and ‘protocol’ biopsy samples in a manner that inappropriately skews the performance metrics of the Natera Study in Prospera’s favor.”

“The Banff Classification of Allograft Pathology (the “Banff Rules”) is an international consensus classification for the reporting of biopsies from solid organ transplants...Although the Natera Study Publication claims to adhere to the 2017 Banff Rules...the detailed criteria found in the Natera StudyPublication do not consistently comport with the 2017 Banff Rules, especially in classifications of T cell-mediated rejection...”

“Just one of these four instances could be chalked up to innocent mistake or unintentional error,” said CareDx attorney Ed Reines of Weil, Gotshal & Manges LLP. “However, together they suggest a concerted effort by Natera to mislead patients and medical personnel into thinking its study was more credible than it actually was and that it proved Natera’s technology is superior to CareDx’s, which it is not.”

CareDx is seeking all available remedies, including monetary damages.

About CareDx

CareDx, Inc., headquartered in Brisbane, California, is a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant recipients. CareDx offers products along the pre- and post-transplant testing continuum, and is the leading provider of genomics-based information for transplant patients.

For more information, please visit: www.CareDx.com.

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