Quidel Receives CE Mark for TriageTrueTM High Sensitivity Troponin I Test, Its Next-Generation Diagnostic Assay for Aid in Diagnosis of Myocardial Infarction for Use with Quidel's Triage® MeterPro Instrumented System

November 29, 2018

SAN DIEGO--(BUSINESS WIRE)--Nov. 29, 2018-- **Quidel Corporation (NASDAQ: QDEL) ("Quidel"),** a provider of rapid diagnostic testing solutions, cellular-based virology assays and molecular diagnostic systems, announced today that Quidel has received CE Mark for its TriageTrue™ High Sensitivity Troponin I Test for the quantitative determination of troponin I in EDTA anticoagulated whole blood and plasma specimens. The test is to be used as an aid in the diagnosis of myocardial infarction (MI) for use with Quidel's Triage® MeterPro instrumented system.

MI, or heart attack, occurs when a part of the heart muscle doesn't receive enough blood flow. The more time that passes without treatment to restore blood flow, the greater the damage to the heart muscle. According to the World Health Organization (WHO), it is estimated that almost 18 million people die each year from cardiovascular diseases (CVD), and 85% of all CVD deaths are due to heart attacks and strokes.[1]

Troponin I, T and C are protein subunits that make up the troponin complex, which is integral to the regulation of myofibril contraction in skeletal and cardiac muscle cells. Cardiac troponin I assays are commonly used as aids in the diagnosis of MI which is injury to cardiac muscle cells caused by ischemia. When an MI occurs, cardiac troponin I levels rise after the onset of cardiac symptoms, reaching a peak at 12 to 16 hours and can remain elevated for 4 to 9 days. Upon patient presentation, the determination of presence and concentration of troponin levels through serial monitoring at different time points can help diagnose MI and differentiate it from other cardiovascular and non-cardiovascular conditions.

The latest generation of troponin assays can detect and quantitate troponin at lower levels than previous generation assays, giving them higher sensitivity for the detection of MI at the time of patient presentation. This advancement allows for the time interval between baseline measurement and the second measurement of cardiac troponin to be significantly shortened, thereby reducing the time to diagnosis and improving efficiency in the emergency department.

The TriageTrue™ High Sensitivity Troponin I Test is a single-use fluorescence immunoassay device for use with Quidel's Triage® MeterPro instrument and designed to determine the concentration of troponin I in whole blood or plasma specimens, anticoagulated with EDTA. TriageTrue™ features a redesigned cartridge that greatly improves assay sensitivity and precision which are critical to the performance of high sensitivity troponin testing. The assay uses monoclonal antibodies specific to human cardiac troponin I in the detection and quantitation of cardiac troponin I. The results are displayed on the MeterPro screen in <20 minutes from the addition of specimen to the device. All results are stored in the MeterPro memory to display or print when needed. Also, the integrated cartridge design enables a lower total cost per reportable result than standard immunochemistry analyzers in low volume settings. When connected, the MeterPro can transmit results to the laboratory or hospital information system. TriageTrue™ enables hsTnI testing to be performed in the emergency department, urgent care facilities and other decentralized settings.

"We are very pleased to receive the CE Mark for our next-generation Troponin I assay. This accomplishment is truly a team effort, and really speaks to the success of our integration of our Triage team at Summers Ridge," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "We are proud to introduce the world's first Near Patient high sensitivity diagnostic test for Troponin I, and are excited by the positive impact that we can make in accurately providing results in 20 minutes or less to aid in diagnosing a heart attack."

1. http://www.who.int/cardiovascular_diseases/en/

About Quidel Corporation

Quidel Corporation serves to enhance the health and well-being of people around the globe through the development of diagnostic solutions that can lead to improved patient outcomes and provide economic benefits to the healthcare system. Marketed under the Sofia®, QuickVue®, D3® Direct Detection, Thyretain®, Triage® and InflammaDry® leading brand names, as well as under the new Solana®, AmpliVue® and Lyra® molecular diagnostic brands, Quidel's products aid in the detection and diagnosis of many critical diseases and conditions, including, among others, influenza, respiratory syncytial virus, Strep A, herpes, pregnancy, thyroid disease and fecal occult blood. Quidel's recently acquired Triage® system of tests comprises a comprehensive test menu that provides rapid, cost-effective treatment decisions at the point-of-care (POC), offering a diverse immunoassay menu in a variety of tests to provide diagnostic answers for quantitative BNP, CK-MB, d-dimer, myoglobin, troponin I and qualitative TOX Drug Screen. Quidel's research and development engine is also developing a continuum of diagnostic solutions from advanced immunoassay to molecular diagnostic tests to further improve the quality of healthcare in physicians' offices and hospital and reference laboratories. For more information about Quidel's comprehensive product portfolio, visit quidel.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, our reliance on sales of our influenza diagnostic tests; fluctuations in our operating results resulting from the timing of the onset, length and severity of cold and flu seasons, seasonality, government and media attention focused on influenza and the related potential impact on humans from novel influenza viruses, adverse changes in competitive conditions in domestic and international markets, the reimbursement system currently in place and future changes to that system, changes in economic conditions in our domestic and international markets, lower than anticipated market penetration of our products, the quantity of our product in our distributors' inventory or distribution channels, changes in the buying patterns of our distributors, and changes in the healthcare market and consolidation of our customer base; our development and protection of proprietary technology rights; our development of new

technologies, products and markets; our reliance on a limited number of key distributors; intellectual property risks, including but not limited to, infringement litigation; our need for additional funds to finance our capital or operating needs; the financial soundness of our customers and suppliers; acceptance of our products among physicians and other healthcare providers; competition with other providers of diagnostic products; adverse actions or delays in new product reviews or related to currently-marketed products by the U.S. Food and Drug Administration (the "FDA") or other regulatory authorities or loss of any previously received regulatory approvals or clearances; changes in government policies; our exposure to claims and litigation, including litigation currently pending against us; costs of or our failure to comply with government regulations in addition to FDA regulations; compliance with government regulations relating to the handling, storage and disposal of hazardous substances; third-party reimbursement policies; our failure to comply with laws and regulations relating to billing and payment for healthcare services; our ability to meet demand for our products; interruptions in our supply of raw materials; product defects; business risks not covered by insurance; our exposure to cyber-based attacks and security breaches; competition for and loss of management and key personnel; international risks, including but not limited to, compliance with product registration requirements, exposure to currency exchange fluctuations and foreign currency exchange risk sharing arrangements, longer payment cycles, lower selling prices and greater difficulty in collecting accounts receivable, reduced protection of intellectual property rights, political and economic instability, taxes, and diversion of lower priced international products into U.S. markets; changes in tax rates and exposure to additional tax liabilities or assessments; risks relating to the acquisition and integration of the Triage and BNP Businesses; Alere's failure to perform under various transition agreements relating to our acquisition of the Triage and BNP Businesses; that we may incur substantial costs to build our information technology infrastructure to transition the Triage and BNP Businesses; that we may have to write off goodwill relating to our acquisition of the Triage and BNP Businesses; that we our ability to manage our growth strategy; the level of our indebtedness; the amount of, and our ability to repay, renew or extend, our outstanding debt and its impact on our operations and our ability to obtain financing; that substantially the Senior Credit Facility is secured by substantially all of our assets; our prepayment requirements under the Senior Credit Facility; the agreements for our indebtedness place operating and financial restrictions on the Company; that an event of default could trigger acceleration of our outstanding indebtedness; our inability to settle conversions of our Convertible Senior Notes in cash; the effect on our operating results from the trigger of the conditional conversion feature of our Convertible Senior Notes; that we may incur additional indebtedness; increases in interest rate relating to our variable rate debt; dilution resulting from future sales of our equity; volatility in our stock price; provisions in our charter documents, Delaware law and the indenture governing our Convertible Senior Notes that might delay or impede stockholder actions with respect to business combinations or similar transactions; and our intention of not paying dividends. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," "plan," "intend," "goal," "project," "strategy," "future," and similar words, although some forward-looking statements are expressed differently. The risks described in reports and registration statements that we file with the Securities and Exchange Commission (the "SEC") from time to time, should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this press release. Except as required by law, we undertake no obligation to publicly release the results of any revision or update of these forward-looking statements, whether as a result of new information, future events or otherwise.

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