Quidel Receives FDA Clearance, CLIA Waiver for Its Point-of-Care Sofia® 2 Lyme Fluorescent Immunoassay for Use with Sofia® 2 Instrument from Finger-Stick Whole Blood Specimens

August 30, 2018

SAN DIEGO--(BUSINESS WIRE)--Aug. 30, 2018-- **Quidel Corporation (NASDAQ: QDEL) ("Quidel"),** a provider of rapid diagnostic testing solutions, cellular-based virology assays and molecular diagnostic systems, announced today that it has received 510(k) clearance and Clinical Laboratory Improvement Amendments (CLIA) waiver from the United States Food and Drug Administration (FDA) to market its Sofia 2 Lyme FIA to be used with the Sofia 2 Fluorescent Immunoassay Analyzer for the rapid differential detection of human IgM and IgG antibodies to *Borrelia burgdorferi* from finger-stick whole blood specimens from patients suspected of *B. burgdorferi* infection. The test is intended for use with the Sofia 2 analyzer to aid in the diagnosis of Lyme disease.

Sofia 2 is Quidel's next-generation version of its best-selling Sofia instrumented system. Sofia 2 utilizes the original Sofia's fluorescent chemistry design while improving upon the graphical user interface and optics system to provide an accurate, objective and automated result in as few as 3 minutes. Sofia 2 also integrates wireless connectivity and its barcode scanner within a smaller footprint than the legacy Sofia instrument. The next-generation Sofia 2 system also comes connected to Virena®, Quidel's data management system, which provides aggregated, de-identified testing data in near real-time.

Lyme disease is the most common tickborne disease in North America and Europe[1]. In the United States, Lyme disease is caused by the bacterium, *Borrelia burgdorferi*, transmitted through the bite of an infected blacklegged tick[1,2]. Patients infected with *B. burgdorferi* may experience symptoms associated with three stages: early localized disease, early disseminated disease, and late persistent disease[1]. The most characteristic symptom of early localized disease is the appearance of erythema migrans (EM) on the skin[1,3]. EM may also be accompanied by flu-like symptoms days or weeks after infection[3]. In the second stage, early disseminated disease, untreated patients may begin to see neurological and rheumatological manifestations, and less commonly, dermatological, cardiac, or ophthalmological manifestations. These symptoms generally appear weeks to months after infection[1]. If the disease continues to be left untreated, late persistent disease may also follow months or years later with continued progression of manifestations in the joints, heart, skin, and nervous system[2,3].

Early detection and treatment of Lyme disease can help resolve symptoms and prevent progression of the disease[1]. The primary means of identifying *B. burgdorferi* infection is detection of the body's IgM and IgG antibody response by way of immunoassay [3]. Detection of IgM antibodies to *B. burgdorferi* is generally most significant in the earlier stages of the disease. Conversely, detection of IgG antibodies has proven to be significant for longer periods, as the antibodies may remain detectable years after infection.

The Sofia 2 Lyme FIA uses a bi-directional test strip format to detect both IgM and IgG antibodies to *B. burgdorferi* from a single finger-stick whole blood sample. One side of the test strip detects IgM antibodies to *B. burgdorferi* and the other side of the test strip detects IgG antibodies to *B. burgdorferi*.

The Sofia 2 Lyme FIA is also novel in that it can process samples from less invasive finger-stick whole blood specimens instead of blood samples collected though venipuncture, the traditional method of sample collection for Lyme testing. The assay's whole blood sample processing technology speeds the time to diagnosis, is less invasive to the patient, and allows the test to be CLIA waived by the FDA.

CLIA waiver for the Sofia 2 Lyme FIA markedly expands the available market for the Sofia 2 test system, which allows the test to be run in physician offices, as well as in several thousand hospitals, medical centers, smaller clinics, and alternate sites (e.g., urgent care centers, free standing emergency departments, retail clinics, etc.) in the United States.

"The Sofia 2 Lyme FIA's 510(k) clearance and CLIA Waiver for use on the Sofia 2 instrument will allow healthcare workers to generate a result in a single office visit, accelerating the time to diagnosis and potential treatment of Lyme Disease for the patient. This is another example of our ability to provide simple, cost-effective solutions for physician offices and hospitals that previously had to wait several days for send-out results," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "We expect that this new product introduction will increase the value of our Sofia 2 platform, and could create incremental instrument placement opportunities in traditional healthcare institutions that are closer to the patient, as well as in the rapidly growing alternate site segment of point of care."

The Sofia 2 Lyme FIA is the fourth Sofia test for use on the Sofia 2 system that has been 510(k) cleared and CLIA waived by the FDA: the Sofia Influenza A+B FIA, the Sofia RSV FIA, and the Sofia Strep A+ FIA were 510(k) cleared and CLIA waived by the FDA in 2017. Quidel also markets the moderately complex Sofia Lyme FIA in the US, as well as Sofia Legionella FIA and Sofia S. pneumoniae FIA in Europe.

1. Wormser, G. P., Dattwyler, R. J., Shapiro, E. D., Halperin, J. J., Steere, A. C., Klempner, M. S., Nadelman, R. B. (2006). The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America. Clinical Infectious Diseases, 43(9), 1089-1134.
2. CDC. http://www.cdc.gov/lyme/diagnosistesting/LabTest/TwoStep/index
3. Aguero-Rosenfeld, M. E., Wang, G., Schwartz, I., & Wormser, G. P. (2005). Diagnosis of Lyme Borreliosis. Clinical Microbiology Reviews, 18(3), 484-509.

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 healthcare providers with 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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