Quidel Receives CE Mark for Its Point-of-Care Sofia® Quantitative Vitamin D Assay for Use With Sofia Instrument

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SAN DIEGO--(BUSINESS WIRE)--Dec. 19, 2018-- **Quidel Corporation (NASDAQ: QDEL)**, a provider of rapid diagnostic testing solutions, cellular-based virology assays and molecular diagnostic systems, announced today it has received CE Mark for its Sofia Quantitative Vitamin D FIA for use with the Sofia fluorescent immunoassay analyzer for the quantitative determination of total 25-OH vitamin D from serum samples. The test is intended for use with the Sofia analyzer to aid in the assessment of Vitamin D sufficiency and is the first quantitative assay on Sofia.

Sofia is the brand name for Quidel's flagship product, an instrumented immunoassay system. The easy-to-use first-generation Sofia analyzer and its companion assays combine unique software and fluorescent chemistry to yield an automatic, objective result that is readily available on the instrument's screen, in a hard-copy printout, and in a transmissible electronic form that can network via an LIS system to hospital and medical center databases. The Sofia analyzer along with the Sofia Quantitative D FIA provide reliable diagnostic results within 10 minutes of processing the patient's serum sample.

Vitamin D is a fat-soluble vitamin that helps maintain serum calcium and phosphate concentrations and plays an important role in bone mineralization. Vitamin D also facilitates cell growth modulation, neuromuscular function, immune function and alleviates inflammation.[1] Consequently, vitamin D deficiency has been correlated with increased risk of various health problems including, but not limited to, cancer, bone disease, cardiovascular diseases, and hypertension.[2,3,4,5] Children ages birth to 18 years with vitamin D deficiency may experience rickets which results in a marked decrease in growth and bone development, including a negative impact on both density and peak bone mass.[6] During the adolescent puberty years where rapid growth spurts occur, there is a marked increase in the need for vitamin D to maintain the metabolic requirements for growth.[6]

Prevalence of vitamin D inadequacy in humans worldwide is high. Major causes of vitamin D inadequacy include lack of direct exposure of skin to sun without sun protection such as clothing or sunscreen, limited number of foods naturally containing vitamin D, and inadequacy of foods fortified with vitamin D to satisfy vitamin D requirements.[2,3]

Total 25-OH vitamin D is the best indicator of vitamin D status. It reflects vitamin D produced cutaneously, obtained from food and supplements,[7] and has a fairly long circulating half-life of 15 days.[8] Vitamin D made endogenously in the skin, or obtained from dietary sources, is metabolized to 25-OH vitamin D in the liver. Finally, in the kidneys, it is converted to its biologically active form, 1,25-$(OH)_2$ vitamin D. In contrast to 25-OH vitamin D, circulating 1,25-$(OH)_2$ vitamin D is not a good indicator of vitamin D status because it has a short half-life of 15 hours and serum concentrations are closely regulated by parathyroid hormone, calcium, and phosphate.[8] Levels of 1,25$(OH)_2$ vitamin D do not typically decrease until vitamin D deficiency is severe.[9,10]

"We are pleased to have received approval for our Sofia Vitamin D product and are excited about the opportunity to expand Sofia's international footprint," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "This also demonstrates our ability to develop quantitative assays on Sofia and Sofia 2 – greatly expanding the potential pipeline and market opportunity for both products."

CE mark allows Quidel to launch the Vitamin D assay on the Sofia analyzer in Europe and in other locations outside of the United States. The product is currently not for sale in the U.S.

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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, a final determination that some of the provisions of our contractual arrangement with Beckman Coulter are unenforceable or otherwise not valid; 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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