Quidel Announces the Availability of Triage® PLGF Assay for Use with Quidel's Triage® MeterPro Instrumented System

December 13, 2018

SAN DIEGO--(BUSINESS WIRE)--Dec. 13, 2018-- **Quidel Corporation (NASDAQ: QDEL) ("Quidel"),** a provider of rapid diagnostic testing solutions, cellular-based virology assays and molecular diagnostic systems, announced today that the manufacturing of Quidel Triage® PLGF Test is set to resume in 2019 and be commercially available outside the US for clinical use in Q1 2019. Knowledge of maternal circulating concentration of Placental Growth Factor (PLGF), a biomarker for placental dysfunction, aids in the early and accurate diagnosis of preterm pre-eclampsia and helps clinicians to accurately risk-stratify pregnant women resulting in more efficient use of healthcare resources and the potential for cost-saving to the healthcare system.

In Quidel's acquisition of the Triage ® business from Alere Inc., ownership of the Triage PLGF product, together with the continued supply of product into key clinical studies, transferred to Quidel. Quidel has completed an internal review of unmet clinical needs in the management of pre-eclampsia and the strength of clinical evidence and has concluded that Quidel Triage PLGF Test is a competitive and medically necessary diagnostic test.

Current antenatal detection of pre-eclampsia relies on clinical markers, blood pressure and urinalysis for protein, which have low sensitivity and specificity, and poor prognostic ability. A low PLGF concentration in the maternal circulation identifies pregnancies likely to develop placentally-driven complications, such as preterm pre-eclampsia and fetal growth restriction. In May 2016, the UK National Institute for Health and Care Excellence (NICE) developed a national guidance for NHS England on PLGF-based testing[1] to help clinicians diagnose pre-eclampsia in women suspected of having the condition. NICE recommends the use of PLGF-based tests, including Triage PLGF, to help rule-out pre-eclampsia in pregnant women who are between 20 weeks and 34 weeks plus 6 days' gestation and have signs or symptoms of pre-eclampsia.

Uniquely, Quidel's PLGF measurements are performed on the Quidel Triage MeterPro, a small low-cost benchtop analyzer that enables near patient testing and provides results in about 15 minutes. Quidel Triage MeterPro can connect to laboratory information systems and has built-in quality control features. Quidel's MeterPro platform offers end-users a more cost-efficient and expedient testing platform than central laboratory analyzers.

"We are happy to re-introduce Quidel Triage PLGF into the marketplace, thereby assisting healthcare workers in ruling out pre-eclampsia, and protecting our most vulnerable patients," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "Longer term, we believe that clinicians will find that the test has additional clinical value in evaluating placental health."

Quidel's Triage PLGF product is currently CE Marked, and only available for sale outside the United States.

[1] PLGF-based testing to help diagnose suspected pre-eclampsia (Triage PLGF test, Elecsys immunoassay sFlt-1/PLGF ratio, DELFIA Xpress PLGF 1-2-3 test, and BRAHMS sFlt-1 Kryptor/BRAHMS PlGF plus Kryptor PE ratio). National Institute for Health and Care Excellence (NICE) Diagnostics guidance [DG23] Published date: May 2016.

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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