Quidel Receives FDA Clearance for Solana® Bordetella Complete® Molecular Diagnostic Assay for the Detection of Pertussis (Whooping Cough), Parapertussis Infections

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SAN DIEGO--(BUSINESS WIRE)--Jul. 16, 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 from the United States Food and Drug Administration (FDA) to market its Solana Bordetella Complete Assay, a molecular diagnostic assay to be used with the Solana molecular diagnostic instrument for the qualitative detection and differentiation of *Bordetella pertussis* and *Bordetella parapertussis* nucleic acids isolated from nasopharyngeal swab specimens obtained from patients suspected of having a respiratory tract infection attributable to *Bordetella pertussis* and *Bordetella parapertussis*.

Pertussis, or whooping cough, is a very contagious disease caused by the *Bordetella pertussis* bacteria, which attach to the cilia that line part of the upper respiratory tract, causing inflammation through the release of toxins, which cause airways to swell.[1] Pertussis is spread from person to person through the inhalation of bacteria from an infected person's cough or sneeze. Symptoms, such as a runny nose, low-grade fever, or mild cough usually develop within 5–10 days after exposure, but sometimes appear as long as 3 weeks later. Although whooping cough can cause serious illness in children and adults, it is most dangerous for infants and babies. According to the Centers for Disease Control and Prevention (CDC), about half of infants younger than 1 year of age who get this disease require hospitalization.[2]

The incidence of pertussis has risen steadily over the last few years.[3] Factors that have likely contributed to the increased incidence of pertussis include a decline in vaccine use, waning vaccine-induced immunity in adolescent and adult populations, failure to receive booster shots later in life, and continued circulation of *B. pertussis* in our population.[4-5]

According to the CDC, *B. parapertussis* causes a pertussis-like illness that is generally milder than pertussis, likely because the bacteria do not produce pertussis toxin. Co-infection of *B. pertussis* and *B. parapertussis* can occur but is uncommon.[6] *B. parapertussis* is not easily distinguished from *B. pertussis* infection by symptoms, and unlike *B. pertussis*, usually it is not laboratory confirmed. For these reasons, the epidemiology of illness caused by *B. parapertussis* is poorly recognized.[7]

The Solana Bordetella Complete Assay leverages the Helicase-Dependent Amplification (HDA) technology that is resident in Quidel's AmpliVue® molecular product line to generate a fast and accurate test result on the Solana molecular diagnostic instrument. The assay targets the IS481 and IS1001 sequence of the Bordetella pertussis and Bordetella pertussis genomes, respectively.

The Solana molecular diagnostic instrument can process up to 12 patient samples in each batched run, and provides time-saving workflow advantages to healthcare professionals in moderately complex settings. Solana also comes connected to Virena®, Quidel's data management system, which provides aggregated, de-identified testing data in near real-time.

"We are pleased to receive 510(k) clearance for our Solana Bordetella Complete Assay, as this test rounds out our Solana molecular test offering in the respiratory category," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "Although whooping cough cases can be sporadic, outbreaks are often highly contagious, and we believe that this test can provide healthcare workers with the ability to quickly diagnose whooping cough and *B. parapertussis*. When paired with Quidel's Virena ecosystem, clinicians will be able to see real-time positive cases at the local level, giving them further insights into disease prevalence for both parapertussis and pertussis."

The Solana instrumented system offers a comprehensive set of 510(k)-cleared assays that allows laboratories to quickly process multiple patient samples to diagnose many diseases such as Influenza A+B, Strep Complete (Groups A+C/G), RSV+hMPV, HSV 1+2/VZV, Trichomonas, Group B Strep, and C. difficile.

The commercial introduction of Solana has broadened Quidel's molecular strategy to include instrumented systems, and grown the number of its molecular platforms that are both 510(k) cleared and available commercially. Quidel's other FDA cleared molecular solutions include the AmpliVue® non-instrumented system for lower-volume moderately complex labs, and Lyra® reagents for higher throughput, highly complex laboratories that are compatible with existing PCR infrastructure.

1) http://www.cdc.gov/pertussis/about/causes-transmission.html
2) http://www.cdc.gov/pertussis/about/signs-symptoms.html
3) CDC. Provisional Pertussis Surveillance Report. 2013. http://www.cdc.gov/pertussis/downloads/pertussis-surveillance-report.pdf
4) Versteegh FGA, Schellekens JFP, Fleer A, Roord JJ. Pertussis: a concise historical review including diagnosis, incidence, clinical manifestations and the role of treatment and vaccination in management Rev Med Microbiol 2005; 16 (3): 79-89.
5) Atwell JE, Van Otterloo J, Zipprich J, Winter K, Harriman K, Salmon DA, Halsey NA, Omer SB. Nonmedical vaccine exemptions and pertussis in California, 2010. *Pediatrics* 2013; 132 (4): 624–30.
6) https://www.cdc.gov/vaccines/pubs/surv-manual/chpt10-pertussis.html
7) Mastrantonio P, Stefanelli P, Giuliano M., Herrera Rojas Y, Ciofi Degli Atti M, Anemoa A Tozzi AE. Bordetella pertussis infection in children: epidemiology, clinical symptoms, and molecular characteristics of isolates, 1998. Journal of Clinical Microbiology April 1998: 999-1002.

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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