Quidel Receives FDA Clearance for Its New Solana(TM) Molecular System and Solana(TM) Molecular Assay for Diagnosis of Group A Streptococcal Infections

June 23, 2015

SAN DIEGO, CA -- (Marketwired) -- 06/23/15 -- ***Quidel Corporation*** (NASDAQ: QDEL), 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 Quidel's new instrumented molecular system -- Solana -- and for the Solana Group A Strep Assay (Solana GAS Assay) for the rapid, qualitative detection of β-hemolytic, Group A Streptococcus (*Streptococcus pyogenes*) nucleic acids isolated from throat swab specimens from patients with signs and symptoms of pharyngitis, such as sore throat.

The Solana molecular platform 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. Solana can process up to 12 patient samples in each 30-minute run, thereby providing time-saving workflow advantages to healthcare professionals in moderately complex settings.

The Solana Group A Strep Assay is an easy-to-use, rapid molecular diagnostic test that has superb clinical accuracy and does not require culture confirmation of negative results. The assay requires no upfront extraction of DNA and generates an accurate result in approximately 30 minutes.

Group A streptococci are Gram-positive bacteria, primarily residing in the nose, throat and skin; these bacteria are responsible for several illnesses, ranging from comparatively mild illnesses (e.g., strep throat, otitis media, or skin infections) to severe illnesses (e.g., necrotizing fasciitis and streptococcal toxic shock syndrome).[1] Strep throat (streptococcal pharyngitis) is the most common illness caused by Group A streptococcal infections. These bacteria are spread through contact with airborne droplets from an infected person's cough, sneeze or via contaminated items such as eating utensils.[2]

"We are very pleased to receive FDA clearance for the Solana system," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "We believe that Solana is uniquely positioned in the marketplace because it offers customers the ability to batch the more commonly-run assays, provides superb clinical accuracy, and can also serve as an elegant batch method for confirmation of rapid immunoassay results when needed."

With the 510(k) clearance of Solana, Quidel now offers three molecular platforms -- AmpliVue, Lyra, and Solana -- that are designed to meet the unique needs of customers in different market settings. Combined, they provide for the enhanced diagnosis of fourteen (14) different infectious diseases, including those caused by Influenza A, Influenza B, hMPV, RSV, Group A Strep, Groups C/G Strep, Group B Strep, C. difficile, Bordetella pertussis (whooping cough), adenovirus, parainfluenza virus, HSV 1, HSV2, and Trichomonas.

1. http://www.cdc.gov/groupAstrep/about/faqs.html
2. http://www.cdc.gov/Features/strepthroat/

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 QuickVue®, D3® Direct Detection and Thyretain® leading brand names, as well as under the new Sofia®, AmpliVue® and Lyra® 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 research and development engine is also developing a continuum of diagnostic solutions from advanced lateral-flow and direct fluorescent antibody 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.

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, fluctuations in our operating results resulting from seasonality, the timing of the onset, length and severity of cold and flu seasons, 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, changes in sales levels as it relates to the absorption of our fixed costs, lower than anticipated market penetration of our products, the reimbursement system currently in place and future changes to that system, and changes in economic conditions in our domestic and international markets, 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 intellectual property; our development of new technologies, products and markets; our reliance on a limited number of key distributors; our reliance on sales of our influenza diagnostics tests; our ability to manage our growth strategy, including our ability to integrate companies or technologies we have acquired or may acquire; intellectual property risks, including but not limited to, infringement litigation; limitations and covenants in our senior credit facility; our need for additional funds to finance our operating needs; volatility and disruption in the global capital and credit markets; 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"); changes in government policies; compliance with other government regulations, such as safe working conditions, manufacturing practices, environmental protection, fire hazard and disposal of hazardous substances; third-party reimbursement policies; our ability to meet demand for our products; interruptions in our supply of raw materials; product defects; business risks not covered by insurance and exposure to other litigation claims; interruption to our computer systems; 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; our significant debt service requirements; the possibility that we may incur additional indebtedness; our ability 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; dilution resulting from future sales of our equity; volatility in our stock price; provisions in our charter documents, Delaware law and 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. We undertake no obligation to publicly release the results of any revision or update of these forward-looking statements, except as required by law.

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