Quidel Receives Simultaneous FDA Clearance and CLIA Waiver for Its Sofia(R) Strep A+ Fluorescent Immunoassay (FIA) via the FDA's New Dual Submission Program

December 17, 2014

SAN DIEGO, CA -- (Marketwired) -- 12/17/14 -- ***Quidel Corporation*** (NASDAQ: QDEL), a provider of rapid diagnostic testing solutions, cell-based virology assays and molecular diagnostic systems, announced today that it has received marketing clearance and CLIA waiver by the United States Food and Drug Administration (FDA) for its Sofia Strep A+ Fluorescent Immunoassay (FIA) for the rapid detection of infections by Group A Streptococcus bacteria. These bacteria are the most common cause of bacterial pharyngitis and can also cause rheumatic fever and other potentially serious illnesses.

Sofia is the brand name for Quidel's next-generation, immunoassay system. The Sofia Analyzer and Sofia Strep A+ FIA combine unique immunofluorescence chemistry, advanced lateral flow technology, and failure alert and fail-safe systems designed to ensure reliable, objective, highly accurate, diagnostic results within five (5) minutes of application of the patient's specimen.

The linked-FDA clearance and CLIA waiver represent the first such achievement of any manufacturer under the FDA's new Dual Submission Program. This program requires a Pre-submission, and allows for simultaneous review of the 510(k) and CLIA waiver applications, substantially reducing the time and effort required for the FDA's review of 510(k) and CLIA waiver submissions that previously required two independent sequential submissions. Successful passage through the Dual Submission Program thus allows the diagnostic industry to pursue its commercial goals sooner, while also more quickly bringing new products to the marketplace where they can serve both physicians and patients.

The CLIA waiver designation for the Sofia Strep A+ FIA allows Quidel to sell the assay to all CLIA categories of laboratories in the United States, including the CLIA-waived segment of the market that is comprised of approximately 30,000 physician offices laboratories and 5,000 hospital emergency departments. It is anticipated that the clearance and CLIA waiver of the Sofia Strep A + FIA will further expand the placement of new Sofia instruments -- a process that has accelerated throughout 2014.

"We are pleased and very proud to receive the first joint clearance and CLIA waiver designation under the FDA's new Dual Submission Program. We can now provide our CLIA-waived customers with a highly accurate, quick and easy-to-use solution for the diagnosis of Strep A infections in our best-in-class Sofia format," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "Our customers love the Sofia platform, and because Strep A is our highest-volume product, we believe that our Sofia Strep A+ FIA has the potential to increase Sofia system installations and utilization well into 2015."

The Sofia Analyzer was 510(k) cleared in October of 2011, and Quidel's first Sofia FIA, the Sofia Influenza A+B FIA, received Clinical Laboratory Improvement Amendments (CLIA) waiver by the FDA in April of 2012. In addition to the Sofia Influenza and Sofia Strep A FIAs, Quidel also markets the CLIA-waived Sofia Respiratory Syncytial Virus (RSV) FIA and the Sofia hCG FIA. Quidel now provides a broad spectrum of FDA-cleared Strep A diagnostic assays that cover the full spectrum of market needs for this pathogen, including two assays on the Sofia platform (one CLIA-waived), three different assays on the QuickVue platform (two CLIA-waived), and two new molecular assays -- AmpliVue Strep A Assay and Lyra Direct Strep Assay (for Streptococcus pathogens of Groups A and C&G).

About Quidel Corporation

Quidel Corporation serves to enhance the health and wellbeing 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™ brandsQuidel's products aid in the detection and diagnosis of many critical diseases and conditions, including, among others, influenza, respiratory syncytial virus, Strep, 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; the reimbursement system currently in place and future changes to that system; changes in economic conditions in our 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 quantity of our product in our distributors' inventory or distribution channels, changes in the buying patterns of our distributors and changes in the health care 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; that we may incur significant additional indebtedness; 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 product reviews 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 of 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 US markets; volatility in our stock price; dilution resulting from future sales of our equity; and provisions in our charter documents and Delaware law that might delay stockholder actions with respect to business combinations or the election of directors. 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.

Quidel Contact:
Quidel Corporation
Randy Steward
Chief Financial Officer
(858) 552-7931

Media and Investors Contact:
Quidel Corporation
Ruben Argueta
(858) 646-8023
Email Contact

Source: Quidel