Quidel Receives FDA Clearance for Its Solana(R) Trichomonas Assay for Diagnosis of Trichomoniasis

August 17, 2016

SAN DIEGO, CA -- (Marketwired) -- 08/17/16 -- ***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 clearance from the United States Food and Drug Administration (FDA) to market its Solana® Trichomonas assay for the detection of nucleic acids isolated from clinician-collected vaginal swabs and female urine specimens obtained from symptomatic or asymptomatic females to aid in the diagnosis of trichomoniasis, a sexually transmitted disease attributable to infection from the *Trichomonas vaginalis* parasite. The Solana® Trichomonas Assay is intended for use only with the Solana® instrument.

According to the Centers for Disease Control and Prevention (CDC), an estimated 3.7 million people in the United States have trichomoniasis. This disease is more common in women and, because only about 30% of those infected develop symptoms of trichomoniasis, most infected persons do not know that they carry the parasite.[1] In pregnant women, Trichomonas infection is often associated with preterm delivery and low body weight in newborns. Genital inflammation is often associated with disease and can facilitate infection by other sexually transmitted pathogens, including HIV. Importantly, trichomoniasis can be cured with a single dose of antibiotics, emphasizing the need for rapid, highly sensitive tests that can detect this parasite and prompt immediate treatment.

The Solana Trichomonas assay is an easy-to-use, rapid molecular diagnostic test that has superb clinical accuracy. The assay requires no upfront extraction of DNA and generates an accurate result in approximately 30 minutes.

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.

"We are pleased to receive clearance for our Solana Trichomoniasis assay, as it has shown excellent performance with vaginal swab and urine samples from both symptomatic and asymptomatic patients. We believe that our test can play a vital role in quickly diagnosing this disease in the moderately complex setting, thereby creating opportunities for patient treatment and limiting its spread," said Douglas Bryant, president and chief executive officer of Quidel Corporation.

The Solana Trichomonas assay received CE Mark in June, and is Quidel's second molecular infectious disease diagnostic test to receive 510(k) clearance from the FDA in the scalable and versatile Solana format. Solana Group A Strep assay for the diagnosis of Group A Strep infections received 510(k) clearance from the FDA in June 2015.

1. http://www.cdc.gov/std/trichomonas/stdfact-trichomoniasis.htm

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 and Thyretain® leading brand names, as well as under the new Solana®, AmpliVue® and Lyra® molecular diagnostic assay 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; 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 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 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