Quidel Receives FDA Clearance for Its New Solana(R) Molecular Assay for the Detection of Herpes Simplex Virus 1+2 and Varicella Zoster Virus

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SAN DIEGO, CA -- (Marketwired) -- 11/29/16 -- 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 510(k) clearance from the United States Food and Drug Administration (FDA) to market its Solana® HSV-1+2/VZV Assay for the qualitative detection and differentiation of herpes simplex virus type 1, herpes simplex virus type 2, and varicella-zoster virus DNA isolated and purified from cutaneous or mucocutaneous lesion samples obtained from symptomatic patients suspected of active herpes simplex virus 1, herpes simplex virus 2 and/or varicella-zoster infection.

The Centers for Disease Control and Prevention (CDC) estimates that there are almost 800,000 new cases of herpes in the United States each year, and about 1 in 6 Americans aged 14 to 49 have a genital HSV-2 infection. [1] An estimated 87.4% of 14-49 year olds infected with HSV-2 have never received a clinical diagnosis. According to the CDC, transmission of HSV-2 most commonly occurs from an infected partner who does not have visible sores and who may not know that he or she is infected.

Herpetic lesions can be a result of the primary infection by the virus or from a reactivation of the latent virus, causing recurrent episodes of the disease. HSV-1 and HSV-2 are genetically and antigenically distinct forms of HSV. HSV-2 is the most common cause of genital infections, due to venereal transmission; HSV-1 is commonly associated with other disease locations although both serotypes have been shown to cause disease in all locations of the body.

Varicella-zoster virus (VZV) is a DNA virus of the family Herpesviridae. Primary VZV infection results in chickenpox (varicella), which rarely results in complications including encephalitis or pneumonia. Even when clinical symptoms of chickenpox have resolved, VZV remains dormant in the nervous system of the infected person (virus latency). In approximately 10 to 20% of cases, VZV reactivates later in life, producing shingles.

Quidel's Solana HSV-1+2/VZV Assay detects and differentiates herpes simplex virus type 1, herpes simplex virus type 2, and varicella-zoster virus from cutaneous or mucocutaneous lesion samples obtained from symptomatic patients. Specimens submitted in a broad range of transport media can be tested with the assay.

The Solana HSV-1+2/VZV Assay is an easy-to-use, accurate, molecular diagnostic test that is compatible with many commonly used transport media, requires no upfront extraction of DNA and generates three accurate results in less than an hour.

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 run, and provides time-saving workflow advantages to healthcare professionals in moderately complex settings.

"Quidel has long been a leader in developing innovative Respiratory and Women's Health assays. Our latest product introduction, the Solana® HSV-1+2/VZV assay, broadens our molecular diagnostic offerings for Women's Health assays in the moderately complex setting," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "We believe that the Solana platform will provide the laboratorian with a fast and accurate method to diagnose many Women's Health conditions, including shingles, herpes, and trichomonas infections."

Solana® HSV-1+2/VZV is Quidel's fifth molecular diagnostic test to receive 510(k) clearance from the FDA in the scalable and versatile Solana format. Solana® Strep Complete received 510(k) clearance in October, Solana® Influenza A+B received 510(k) clearance in September, Solana® Trichomonas assay received 510(k) clearance in August, and the Solana® Group A Strep assay was cleared in June 2015.

With the Solana franchise, Quidel has broadened its molecular strategy to include instrumented systems, and grown the number of its molecular platforms that are both FDA 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.

Solana® HSV-1+2/VZV Assay is not intended for use with cerebrospinal fluid or to aid in the diagnosis of HSV or VZV infections of the central nervous system (CNS). The Solana® HSV-1+2/VZV Assay is not intended for use in prenatal screening.

[1] http://www.cdc.gov/std/Herpes/STDFact-Herpes.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 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.

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

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