Sorrento Announces That COVISTIX™ (COVID-19 Virus Rapid Antigen Detection Test) Has Received a CE Mark and Registration of the Device

October 20, 2021

- COVISTIX has received CE mark and marketing authorization from FAMHP (Federal Agency for Medicines and Health Products) that enables Sorrento to sell this device in all territories that accept the Qarad EC-Rep (Belgium) CE Mark for commercialization.
- Distribution contracts are being negotiated.

SAN DIEGO, Oct. 20, 2021 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") today announced that it has received an official CE Mark for COVISTIX and a Registration Number: BE/CA01/1-17633-00001-IVD. COVISTIX is a sensitive and rapid (approximately 15-minute) diagnostic test for the detection of the SARS-CoV-2 virus nucleocapsid antigen in nasal or nasopharyngeal samples of patients suspected of a SARS-CoV-2 infection.

COVISTIX is currently EUA-cleared in Mexico by COFEPRIS and EUA filings are underway with Canada, Brazil, WHO, and the US. In a large independent study conducted by INMEGEN (The Instituto Nacional de Medicina Genomica, Mexico), COVISTIX demonstrated high accuracy as a general screening for all-comers (i.e. COVID-19 symptomatic and asymptomatic populations), COVISTIX (n=783) has an 81% sensitivity vs. 62% (n=2202) sensitivity by globally leading Panbio rapid antigen test.

Sorrento is currently negotiating with global and regional distributors to ensure rapid distribution of COVISTIX to those countries that access to rapid, accurate and affordable testing.

“This is a significant milestone for Sorrento and we appreciate the cooperation with European authorities to bring our highly sensitive antigen test to help control this pandemic,” stated Dr. Henry Ji, Chairman and CEO of Sorrento. “We are expanding our manufacturing capacity in anticipation of large orders and are ready to deliver tests in the tens of millions of units.”

About Sorrento Therapeutics, Inc.

Sorrento is a clinical and commercial stage biopharmaceutical company developing new therapies to treat cancer, pain (non-opioid treatments), autoimmune disease and COVID-19. Sorrento's multimodal, multipronged approach to fighting cancer is made possible by its extensive immuno-oncology platforms, including key assets such as fully human antibodies (“G-MAB™ library”), immuno-cellular therapies (“DAR-T™”), antibody-drug conjugates (“ADCs”), and oncolytic virus (“Seprehvec™”). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including Abivertinib, COVIGUARD™, COVI-AMG™, COVISHEILD™, COVI-MSG™ and COVIDROPS™; and diagnostic test solutions, inclu CVITRACK™, COVISTIX™ and COVITRACE™.

Sorrento's commitment to life-enhancing therapies for patients is also demonstrated by our effort to advance a first-in-class (TRPV1 agonist) non-opioid pain management small molecule, resiniferatoxin ("RTX"), and SP-102 (10 mg, dexamethasone sodium phosphate viscous gel) (SEMDEXA™), a novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, and to commercialize ZTlido® (lidocaine topical system) 1.8% for the treatment of post-herpetic neuralgia. RTX has completed a Phase IB trial for intractable pain associated with cancer and a Phase 1B trial in osteoarthritis patients. SEMDEXA is in a pivotal Phase 3 trial for the treatment of lumbosacral radicular pain, or sciatica. ZTlido® was approved by the FDA on February 28, 2018.

For more information visit www.sorrentotherapeutics.com.

Forward-Looking Statements

This press release and any statements made for and during any presentation or meeting contain forward-looking statements related to Sorrento Therapeutics, Inc., under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements regarding COVISTIX; the performance capabilities of COVISTIX, including its sensitivity and specificity; the speed at which COVISTIX provides results or is able to provide results; the potential receipt of any approvals in Canada, Brazil and the US, and from WHO; the expected entry into distribution agreements to enable rapid distribution of COVISTIX; Sorrento’s manufacturing capacity and ability to produce and deliver a high volume of COVISTIX tests; and Sorrento’s potential position in the diagnostics and therapeutics industries. Risks and uncertainties that could cause our actual results to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to: risks related to Sorrento's and its subsidiaries’, affiliates’ and partners’ technologies and prospects and collaborations with partners, including, but not limited to risks related to conducting additional studies and seeking regulatory approval for COVISTIX, including the timing for receipt of any such approval; conducting and receiving results of clinical trials associated with cancer and a Phase 1B trial in osteoarthritis patients. SEMDEXA is in a pivotal Phase 3 trial for the treatment of lumbosacral radicular pain, or sciatica. ZTlido® was approved by the FDA on February 28, 2018.

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obligation to update any forward-looking statement in this press release except as required by law.

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