Sorrento Receives FDA IND Clearance to Initiate a Phase I Clinical Trial of its CD38 Antibody-Drug Conjugate (ADC) STI-6129 for Patients with Amyloidosis

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SAN DIEGO, May 26, 2020 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") today announced it has received clearance from the U.S. Food and Drug Administration (FDA) for its investigational new drug (IND) application for STI-6129, a CD38-targeting antibody drug conjugate (ADC). STI-6129 utilizes several technology platforms that are under development by Sorrento Therapeutics, including a CD38 specific antibody identified from its fully human G-MAB™ antibody library, its proprietary drug payload Duostatin 5 and its site-specific C-LOCK conjugation technology.

“That the FDA cleared our STI-6129 IND application to proceed to human trials is another important milestone for Sorrento,” stated Dr. Henry Ji, Chairman and CEO of Sorrento Therapeutics. “Together with our CD38 CAR-T program, this has the potential to provide additional therapeutic options for patients in need. We are looking forward to further evaluating the safety and efficacy of STI-6129 in clinical trials.”

Sorrento intends to initiate a phase I multicenter, open-label, dose-escalation clinical trial in patients with advanced relapsed and/or refractory systemic amyloid light chain (AL) amyloidosis with a primary objective to identify a phase 2 dose for STI-6129 based on its safety, preliminary efficacy and pharmacokinetic profile.

“This is Sorrento’s first ADC utilizing our site-specific C-LOCK conjugation technology that is advancing into clinical evaluation,” said Dr. Hui Li, head of Sorrento’s ADC business unit, Levena Biopharma. “STI-6129 demonstrated an improved therapeutic index in animal models, as compared to traditional non-selective conjugates, and we look forward to potentially expanding its utilization into additional ADC programs.”

About Sorrento Therapeutics, Inc.

Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to turn malignant cancers into manageable and possibly curable diseases. 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”), clinical stage immuno-cellular therapies (“CAR-T”, “DAR-T”), antibody-drug conjugates (“ADC”), and clinical stage oncolytic virus (“Seprehvir®”). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including COVIDTRAP™, ACE-MAB™, COVI-MAB™, COVI-GUARD™, COVI-SHIELD™ and COVI-KILLE

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 ZTlido® (lidocaine topical system) 1.8% for the treatment of post-herpetic neuralgia. Resiniferatoxin is completing a phase IB trial for intractable pain associated with cancer and a phase 1B trial in osteoarthritis patients. 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 the potential therapeutic benefits of STI-6129; the planned phase I clinical trial for STI-6129 and the objectives thereof; regulatory approvals of STI-6129; the safety and efficacy of STI-6129; and the completion of clinical trials of STI-6129. 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 and receiving results of clinical trials for STI-6129; the clinical and commercial success of the treatment of the advanced relapsed and/or refractory systemic amyloid light chain (AL) amyloidosis using STI-6129; the viability and success of using STI-6129 for treatments in therapeutic areas, including amyloid light chain (AL) amyloidosis; clinical development risks, including risks in the progress, timing, cost, and results of clinical trials and product development programs; risk of difficulties or delays in obtaining regulatory approvals; risks that clinical study results may not meet any or all endpoints of a clinical study and that any data generated from such studies may not support a regulatory submission or approval; risks of manufacturing and supplying drug product; risks related to leveraging the expertise of its employees, subsidiaries, affiliates and partners to assist the company in the execution of its therapeutic product candidates strategies; risks related to Sorrento’s debt obligations; risks related to the global impact of COVID-19; and other risks that are described in Sorrento's most recent periodic reports filed with the Securities and Exchange Commission, including Sorrento's Annual Report on Form 10-K for the year ended December 31, 2019, and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission, including the risk factors set forth in those filings. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release and we undertake no obligation to update any forward-looking statement in this press release except as required by law.

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