Sorrento Announces FDA IND Filing Today for COVI-AMG Neutralizing and High Potency Antibody Against SARS-CoV-2

November 9, 2020

- IND filing today for STI-2020 (COVI-AMG™) for the treatment of COVID-19 in patients with mild symptoms and a separate safety and pharmacokinetic study in healthy volunteers.
- These initial trials are expected to be followed by pivotal trials with a goal of potentially receiving an EUA (Emergency Use Authorization).
- Animal model data (golden Syrian hamsters infected with SARS-CoV-2) demonstrated a highly effective neutralizing profile.
- This antibody has been engineered for ultra-high potency, with an expected effective dose in humans to be much lower than current known antibodies being assessed by others in active trials, which would allow for a simple IV-push administration that is suitable in the outpatient setting.
- This antibody has been engineered and validated in preclinical studies to avoid antibody-dependent enhancement (ADE) to potentially increase the safety profile.
- Additional *in vitro* experiments demonstrated the complete virus neutralizing property of STI-2020 against the highly contagious D614G SARS-CoV-2 variant.
- Sorrento has initiated cGMP manufacturing to produce 100,000 doses, expected to be available early next year, in anticipation of a potential EUA.

SAN DIEGO, Nov. 09, 2020 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, “Sorrento”) announced today that it is filing an investigational new drug application (IND) for intravenous (IV) COVI-AMG (STI-2020) to treat COVID-19 patients with mild symptoms and to evaluate safety and pharmacokinetics in healthy volunteers.

Sorrento has previously submitted an IND for COVI-GUARD™ (STI-1499), the parent antibody for COVI-AMG. That submission was cleared by the FDA in September. Sorrento has built on the knowledge from the prior IND requirements to file this new IND, including information and data about Sorrento’s affinity maturation process that further enhanced the potency of this antibody.

As Sorrento previously announced, in preclinical studies, STI-2020 demonstrated a 100% neutralizing effect (both *in vitro* and *in vivo*) and at a very low dose prevented SARS-CoV-2 from infecting healthy cells and causing COVID-19-like disease in golden Syrian hamsters.

The high potency of the antibody may potentially translate to more doses per bioreactor manufacturing run, lower cost per dose, and allow for rapid deployment and availability to patients. Sorrento has initiated cGMP manufacturing to produce 100,000 doses, expected to be available early next year, in anticipation of a potential EUA.

In order to speed up development toward EUA submission, Sorrento is also planning on initiating dosing in a healthy population in order to rapidly generate safety and pharmacokinetic results.

The STI-2020 antibody has been evaluated in preclinical studies against multiple strains of SARS-CoV-2, including the highly contagious D614G variant, the current dominant strain globally.

The STI-2020 antibody has been engineered and demonstrated in preclinical studies to avoid ADE (antibody-dependent enhancement) which may be associated with the serious side effects of some other neutralizing antibodies and vaccines.

More information about the phase 1 clinical trial can be found on www.clinicaltrials.gov (NCT# NCT04584697).

About Sorrento Therapeutics, Inc.
Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to treat cancers. 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 ("ADCs"), and clinical stage oncolytic virus ("Seprehvir®"). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including COVI-GUARD™, COVI-AMG™, COVI-SHIELD™ and COVI-DROPS™; and diagnostic test solutions, including COVI-TRACK™, COVI-STIX™ and COVI-TRAC

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 the potency and potential neutralizing profile of STI-2020 and the impact on SARS-CoV-2; the preclinical testing of STI-2020; the safety, pharmacokinetics and efficacy of STI-2020; the potential for STI-2020 to avoid antibody-dependent enhancement side effects; the expectation of the commencement of any pivotal trials for STI-2020; the potential receipt of an EUA for STI-2020 and expected timing for any receipt thereof; the expected availability of doses of STI-2020 and the timing thereof; the belief that the IND addresses all questions and recommendations from the FDA; the predictive value of the animal model used in preclinical studies; the proposed dosages in the phase 1 clinical trial; the potential potency of STI-2020; the expected effective dose in humans; the expected administration method of STI-2020; the potentially faster manufacturing speed, availability and potential lower cost for STI-2020; and Sorrento's potential position in the antiviral industry. 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 pre-clinical studies and seeking IND regulatory approval for STI-2020; conducting and receiving results of clinical trials for STI-2020; the clinical and commercial success of STI-2020 against preventing and treating SARS-CoV-2 virus infections; the viability and success of STI-2020 in anti-viral therapeutic areas, including coronaviruses; 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 that prior test results may not be replicated in future studies and trials; 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 COVID-19 therapeutic product candidates strategies; 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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