Sorrento Completes Successfully the SAD Study and Initiates the MAD Phase 1 Study with STI-1558, An Oral M(pro) Inhibitor as a Standalone Treatment and Prevention of COVID-19 without the Ritonavir as Booster

August 3, 2022

- Single ascending dose (SAD) Phase 1 Study completed in Australia with a maximum dose of 2,000 mg.
- Pharmacokinetics (PK) were dose proportional and PK modeling and preclinical data support a 600 mg twice daily dose.
- There were no serious AEs (SAEs) or severe TEAEs and the maximum tolerated dose (MTD) was not reached.
- Initiation of the multiple ascending dose (MAD) portion of the STI-1558 study has been initiated.

SAN DIEGO, Aug. 03, 2022 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") today announced the completion of the SAD portion of the Phase 1 study of its oral main viral protease (M^{pro}) inhibitor, the STI-1558.

The Phase 1 safety and PK study in healthy volunteers was conducted in Australia. The MPR-COV-101AU study is entitled: “A Randomized, Double-Blind, Placebo-Controlled, Phase I Study to Assess the Safety, Tolerability, and Pharmacokinetics of Single and Multiple Oral Doses of STI-1558 in Healthy Volunteers”. In the SAD portion of the study, 4 dose-escalation cohorts (single oral dose of 300, 600, 1200, and 2000 mg STI-1558 or placebo) with 8 subjects in each cohort randomized 3:1 (except for Cohort 2 for the fasted and fed dosing with 10 subjects randomized 4:1).

Only the preliminary blinded safety and PK data from the SAD portion of the study is available. Overall, there were no changes in vital signs, physical examinations, ECGs or safety clinical labs resulting from study participation. The preliminary overall summary of treatment-emergent adverse events (TEAEs), showed that there were no serious AEs (SAEs) or severe TEAEs and the maximum tolerated dose was not reached. No dose limiting toxicity was noted and there were no premature terminations from the study post treatment and no deaths during the study.

The linear and semi-log plots for doses from 300 mg to 1,200 mg (Cohorts 1-3) are proportional and support a twice daily dose of 600 mg to maintain drug levels in plasma above EC_{90} of the predicted value for viral inhibition. In rats, STI-1558 has showed sufficient lung tissue penetration with 5.8-fold higher drug level in lungs than in plasma, indicating a potential robust antiviral activity in COVID-19 patients.

A high fat meal reduced C_{max} and AUC, therefore it is appropriate to take the STI-1558 capsules on an empty stomach twice daily.

The multiple ascending dose (MAD) study is starting in Australia. A large Phase 2 study is planned in Mexico that could support an Emergency Use Authorization (EUA) in Mexico. Phase 2/3 trials in US and other major regions have also been planned once the MAD part is successfully completed.

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 Abivertinib, 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 COVISHIELD™ and COVI-MSC™; and diagnostic test solutions, including COVIMARK™

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 postherpetic neuralgia (PHN). RTX has been cleared for a Phase II trial for intractable pain associated with cancer and a Phase II trial in osteoarthritis patients. Positive final results from the Phase III Pivotal Trial C.L.E.A.R. Program for SEMDEXA™, its novel, non-opioid product for the treatment of lumbosacral radicular pain (sciatica), were announced in March 2022. 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 Sorrento’s products, technologies and prospects. 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 technologies and prospects, including, but not limited to risks related to safety and efficacy of STI-1558 and seeking regulatory approval for STI-1558; clinical development risks, including risks in the progress, timing, cost, and results of clinical trials and product development programs; risks related to Sorrento’s multiple ascending dose (MAD) Phase 1 Study with STI-1558; 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,

study and trial results, including those for STI-1558, may not be replicated in continuing or 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 Sorrento in the execution of its 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, 2021 and subsequent Quarterly Report 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.

Media and Investor Relations
Contact: Brian Cooley
Email: mediarelations@sorrentotherapeutics.com

Source: Sorrento Therapeutics, Inc.