Sorrento Therapeutics Announces the FDA IND Clearance of STI-1558, An Oral M(pro) and Cathepsin L Inhibitor to Treat COVID-19

July 19, 2022

- STI-1558, an oral SARS-CoV-2 main protease inhibitor which can block viral replication, is specifically designed as a standalone treatment of COVID-19.
- Studies to date indicate that STI-1558 does not require the co-administration of ritonavir as a booster for CYP3A4 inhibition.
- STI-1558 is also a Cathepsin L inhibitor, which can block effective viral entry into host cells and provides a dual mechanism of action in conjunction with protease inhibition to further protect against COVID-19.
- Patients have been dosed in the previously announced Phase 1 Study of STI-1558 in Australia with 300 mg, 600 mg and 1,200 mg, and dosing is currently ongoing with 2,000 mg.
- The FDA has cleared the Investigational New Drug (IND) application for a pharmacokinetic (PK) study in patients with impaired renal and hepatic function.

SAN DIEGO, July 19, 2022 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") today announced the FDA clearance of a Phase 1 study of its oral main viral protease (M^{pro}) inhibitor, STI-1558, in patients with impaired renal and hepatic function.

A previously announced Phase 1 study of STI-1558 evaluating single ascending doses (SAD), multiple ascending doses (MAD) and food effect is proceeding in Australia, and the drug has been dosed in patients in the first 3 cohorts with doses of 300, 600 and 1,200 mg. The study is currently dosing the final cohort in the study at a dose of 2,000 mg per patient. STI-1558 has been well tolerated to date with only a few related adverse events, all of which have been transient, mild in severity and required no treatment.

To date, the PK profile has matched the predicted values based on the animal studies, confirming that STI-1558 is readily absorbed by humans with high bioavailability and indicating that there is no need for ritonavir, a potent cytochrome P450 3A4 inhibitor, to block metabolic clearance to maintain effective blood levels. Avoiding coadministration of ritonavir significantly reduces the potential for drug-drug interactions. PK modeling suggests that a dose of 600 mg twice daily will maintain blood levels well above the range necessary to effectively inhibit viral replication.

The Phase 1 study cleared by the FDA will examine the PK in patients with moderate renal and hepatic impairment. Two doses of STI-1558 (300 mg and 600 mg) will be studied in 12 subjects across 3 cohorts, 12 normal subjects, 12 renally-impaired subjects and 12 hepatically-impaired subjects, using a cross-over design. This is a required study in the approval process and is expected to enable Sorrento to proceed with the remaining studies that may be required to apply for an Emergency Use Authorization for STI-1558 for the treatment of COVID infections.

As soon as the SAD/MAD study is completed, Sorrento will prepare for a global Phase 2 study in subjects with acute onset of symptoms due to COVID-19. “STI-1558 has the potential to be a highly effective antiviral treatment for acute COVID-19 and we look forward to seeing how it performs in the Phase 1 study and the planned Phase 2/3 study,” stated Henry Ji, Ph.D., Chairman, President and CEO of Sorrento.

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, 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

STI-1558, including the potential antiviral profile of STI-1558 with respect to SARS-CoV-2 and its variants; the preclinical testing of STI-1558; the potential safety and efficacy of STI-1558; the potential that no co-administration will be required with STI-1558; the bioavailability of STI-1558; the potential success of the FDA-cleared Phase 1 trial and the ongoing Phase 1 trial in Australia; the studies required to an Emergency Use Authorization; the expected timing of a global Phase 2/3 trial; STI-1558's and Sorrento's position in the antiviral industry; the expected formulation, dosing and/or route of administration for STI-1558; and the preparation of a global commercial supply of STI-1558. 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; 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 PK modeling and predicted values obtained therefrom, may not be replicated in, or consistent with, 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.

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Source: Sorrento Therapeutics, Inc.