



## Sorrento Announces Enrollment of First Subject in Brazil Phase 2 Study of COVI-MSC for Treatment of COVID-19 Associated Acute Respiratory Distress in ICU Patients

September 2, 2021

- First patient enrolled at first site in Phase 2 placebo-controlled study conducted in Brazil.
- Second site scheduled to start enrolling within one week, with multiple additional sites coming online within one month.

SAN DIEGO, Sept. 02, 2021 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") announced today the start of enrollment in its Phase 2 efficacy study of human allogeneic adipose-derived mesenchymal stem cells (COVI-MSC™) for patients suffering from COVID-19-induced acute respiratory distress (ARD) or acute respiratory distress syndrome (ARDS) in Brazil. This study (MSC-COV-202BR) is a multi-arm, randomized, placebo-controlled Phase 2 study of the efficacy and safety of three infusions of COVI-MSC administered on varying schedules in the setting of standard of care treatments for COVID-19 in 100 subjects. The primary objective of this study is to evaluate the efficacy of COVI-MSCs in patients with COVID-19-induced ARD or ARDS.

Additionally, Sorrento will soon begin enrollment for two additional Phase 2 studies with COVI-MSC:

1. A parallel Phase 2 placebo-controlled Phase 2 safety study to be conducted across multiple sites in the United States.
2. A pulmonary long-hauler Phase 2 safety and efficacy study across multiple sites in Brazil.

Dr. Henry Ji, Chairman and CEO of Sorrento Therapeutics, stated, "It brings us great pleasure to see our MSC treatments for COVID-19-induced ARD/ARDS and post-COVID pulmonary long-haul syndrome rapidly move forward in clinical trials and towards a potential emergency approval of this promising therapy globally. We believe that COVI-MSC can help save lives, which is our primary goal at Sorrento."

More information on the three Phase 2 trials can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT04903327, NCT04905836 and NCT04992247).

Mesenchymal stem cells have been demonstrated to support resolution of symptoms in multiple disease settings and have the potential to reduce the long-term effects associated with pulmonary tissue damage. More information on the potential use and benefits of MSCs for patients with COVID-19 can be found in the recently published review at: <https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-020-02380-2>.

*Personalized Stem Cells, Inc. (PSC) is Sorrento's GMP manufacturing partner for COVI-MSC.*

### 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 immunoncology 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™, COVISHIELD™, COVI-MSC™ and COVIDROPS™; and diagnostic test solutions, including COVITRACK™, 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](http://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 clinical testing of a human allogeneic adipose-derived MSC product candidate (COVI-MSC) in a Phase 2 placebo-controlled study in Brazil; the continued enrollment of the Phase 2 clinical trial at multiple sites in Brazil for COVI-MSC; the plans to conduct additional Phase 2 studies across multiple sites in the US and Brazil; 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 technologies and prospects, including, but not limited to risks related to seeking regulatory approval for COVI-MSC in the US and Brazil; 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 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 Sorrento in the execution of its therapeutic antibody product candidate 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, 2020, 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.

**Media and Investor Relations Contact**

Alexis Nahama, DVM (SVP Corporate Development)

Email: [mediarelations@sorrentotherapeutics.com](mailto:mediarelations@sorrentotherapeutics.com)

Sorrento® and the Sorrento logo are registered trademarks of Sorrento Therapeutics, Inc.

G-MAB™, DAR-T™, SOFUSA™, COVIGUARD™, COVI-AMG™, COVISHIELD™, COVIDROPS™, COVI-MSC™, COVITRACK™, COVITI and COVISTIX™ are trademarks of Sorrento Therapeutics, Inc.

SEMDEXA™ is a trademark of Semnur Pharmaceuticals, Inc.

ZTlido® is a registered trademark owned by Scilex Pharmaceuticals Inc.

All other trademarks are the property of their respective owners.

©2021 Sorrento Therapeutics, Inc. All Rights Reserved.



Source: Sorrento Therapeutics, Inc.