Brazilian Health Regulatory Agency (ANVISA) Authorizes Sorrento Phase 2 Clinical Trial of COVI-MSC in COVID-19 Patients With Persistent Pulmonary Compromise After Recovery (Long-Hauler)

January 18, 2022

- Brazil Phase 2 Pulmonary Long-Hauler clinical trial of COVI-MSC is now authorized to proceed.
- The study will compare therapy using mesenchymal stromal cells to placebo (and standard of care) in 60 COVID-19 patients with persistent compromised respiratory function following recovery from a prior COVID infection.
- Stromal Cells are adaptive in their mode of action and have been shown to be effective in modulating pulmonary inflammation and tampering long-term fibrosis in multiple publications in animal models.
- It is estimated that up to 30% of patients recovering from COVID infections might suffer long-hauler syndrome with compromised respiratory function, fatigue, depression and difficulty performing daily tasks among other issues. The clinical study should determine the potential of COVI-MSC in addressing persistent COVID related health issues.

SAN DIEGO, Jan. 18, 2022 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, “Sorrento”) today announced receipt of clearance from the Brazilian regulatory agency (ANVISA) to proceed with a PHASE 2A RANDOMIZED, PLACEBO-CONTROLLED STUDY OF INTRAVENOUS ALLOGENEIC ADIPOSE-DERIVED MESENCHYMAL STROMAL CELLS TO TREAT POST COVID-19 “LONG HAUL” PULMONARY COMPROMISE (NCT04992247).

Recent epidemiologic studies in the US and Britain cite that over 1 in every 3 COVID-19 patients might have lingering symptoms long past the time that they’ve recovered from the initial stages of COVID-19 illness. Often referred to as “Long COVID” syndrome, the symptoms in “long haulers” can include fatigue, shortness of breath, persistent cough, “brain fog”, sleep disorders, fevers, gastrointestinal symptoms, anxiety, and depression, and can persist for months and range in level of severity from mild to incapacitating. In some cases, new symptoms arise well after the time of infection or evolve over time. While still being defined, these effects can be collectively referred to as Post-Acute Sequelae of a SARS-CoV-2 infection.

The Brazil study is a Phase 2, multi-center, randomized, controlled study to evaluate the safety and efficacy of up to three infusions of COVI-MSC™, administered every other day, to patients experiencing respiratory difficulty recovering from a COVID-19 infection at least 3 months prior to enrollment.

The study is expected to enroll 60 patients (in 4 dosing regimen cohorts) in about six months from the date of first enrollment. The primary outcome measure will be improvement in the 6-Minute Walk Distance (6MWD) test at Day 60 post-treatment.

Sorrento expects this projected pace of enrollment due to the prior extensive COVID-19 disease burden in Brazil, Sorrento’s partnership with a leading local clinical research organization (Synova Health), and existing relationships with high quality medical centers throughout the country. The current partnership with Synova Health leverages high quality clinical trial sites in addition to a dozen centers that have already participated in other acute COVID-19 studies with Sorrento (Abivertinib and MSC).

“We are very satisfied with the progress made in Brazil so far, and we have developed very strong local relationships in support of multiple studies,” stated Dr. Henry Ji, Chairman and CEO of Sorrento. “We expect this next Phase 2 study to confirm the clinical benefits for long-hauler patients. Long-hauler syndrome is likely to be the next major challenge for medical systems in a post-COVID era, and we intend to be the leaders in addressing this future unmet need.”

The study is referenced with ANVISA (Brazilian authority) under **Process nº 25351.986743/2021-44, Expediente 3229927/21-4 COMUNICADO ESPECIAL (CE) Nº 0001/22 – GSTCO/DIRE2/Anvisa.**

Details of the Brazilian Clinical Study can be found at:
Study of Allogeneic Adipose-Derived Mesenchymal Stem Cells to Treat Post COVID-19 "Long Haul" Pulmonary Compromise - Full Text View - ClinicalTrials.gov

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, COVI-AMG™, COVISHIELD™, COVI-MSC™ and COVIDROPS™; and diagnostic test solutions, including COVITRACK™ COVISTIX™.

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 (PHN). RTX has cleared for Phase II trial for intractable pain associated with cancer and a Phase II trial in osteoarthritis patients. SEMDEXA announced highly statistically significant positive top-line results from its Phase III Pivotal Trial C.L.E.A.R Program for its novel, non-opioid product for the treatment of lumbosacral radicular pain (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 initiation of a Phase 2 study for COVI-MSC; the expected number of patients to be enrolled in the Phase 2 study; the expected timing for commencing and completing enrollment of the Phase 2 study; Sorrento's expectation to utilize its partnership with Synova Health and other existing relationships with medical centers throughout Brazil to facilitate enrollment of the Phase 2 study; Sorrento's ability to use centers enrolling COVID-19 patients for its Phase 2 clinical trial of Abivertinib for enrollment of patients in the Phase 2 clinical trial for COVI-MSC; the potential for the Phase 2 study to be considered for expansion as a global trial; the potential for Sorrento to recruit patients for the Phase 2 study in the U.S. and Brazil; the potential for additional studies to receive clearance in parallel or immediately following the Phase 2 study; Sorrento's ability to implement synergistic programs that answer safety and efficacy questions related to product candidates; Sorrento's expectation that the Phase 2 study will confirm clinical benefits initially observed in Sorrento's open label Phase 1b study of COVI-MSC; the potential therapeutic benefits of COVI-MSC; and Sorrento's ability to establish a plan for development and manufacturing commitments needed for emergency use approval if clinical benefits of COVI-MSC are confirmed. 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 seeking regulatory approval for COVI-MSC; 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 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, 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.

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Source: Sorrento Therapeutics, Inc.