Sorrento Reports FDA Clearance for the Commencement of a Phase 2/3 Study for Abivertinib in Treatment of Hospitalized Patients With Severe Pneumonia Due to COVID-19

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- Abivertinib is a novel oral small molecule tyrosine kinase inhibitor that selectively targets both mutant forms of the epidermal growth factor receptor (EGFR) as well as Bruton's tyrosine kinase (BTK) and potentially can reduce cytokine storm associated with acute respiratory distress syndrome (ARDS) in severe hospitalized COVID-19 patients.

- Sorrento will be starting a multicenter, multinational Phase 3 study with a Phase 2 run-in to identify the recommended Phase 3 dose (RP3D) and to demonstrate the safety and efficacy of Abivertinib in patients with respiratory compromise due to COVID-19.

- This clearance follows the successful completion of parallel phase 2 studies in the US and Brazil, both of which indicated that a high-risk population of patients requiring oxygen support by non-invasive ventilation or high flow oxygen appeared to be more likely to benefit from Abivertinib therapy than those receiving low flow oxygen in reducing progression of respiratory failure.

SAN DIEGO, March 31, 2022 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento"), announced today that the FDA has given clearance for Sorrento to commence the Phase 3 clinical trial of Abivertinib in severe COVID-19 patients (hospitalized patients with respiratory compromise requiring oxygen supplementation). The clinical trial will be conducted in 2 phases, and the initial run-in will define the RP3D. In October 2021, Sorrento released preliminary results of two phase 2 studies that seemed to show that patients hospitalized with severe pneumonia due to COVID-19, especially those requiring non-invasive ventilation or high flow oxygen supplementation, were up to 5-fold more likely to benefit from Abivertinib therapy than those patients who required low flow supplementation. Such patients represent a high-risk population with few treatment options.

The study will be conducted at multiple sites in the USA, Mexico and Brazil. “We are encouraged by the results from our Phase 2 study, and excited to move Abivertinib to the next stage to help these patients who have no good alternatives,” said Dr. Henry Ji, Chairman and CEO of Sorrento.

Sorrento believes the availability of an oral dosage form to manage inflammatory disease progression is very relevant for severely afflicted patients with COVID-19-induced respiratory failure and potentially non-COVID acute respiratory distress syndrome (ARDS). This treatment has the potential to provide significant benefits across the globe with respect to logistical access, scalability and affordability by potentially providing a treatment in a convenient oral dosage form. Sorrento intends to explore the administration of Abivertinib for severe non-COVID related pneumonia and ARDS patients, as the mechanism of disease progression is very similar and the current medical options for treatment are limited.

About Abivertinib

Abivertinib is a novel dual target, small molecule tyrosine kinase inhibitor (TKI) designed to selectively target mutant forms of the epidermal growth factor receptor (EGFR) and Bruton's tyrosine kinase (BTK).

Abivertinib is a third generation EGFR inhibitor that irreversibly targets mutant forms of EGFR in advanced non-small cell lung cancer (NSCLC) patients resistant to first-line EGFR kinase inhibitor therapies with comparable efficacy and safety. Abivertinib demonstrated different resistant mechanisms with rare occurrence of acquired resistant mutation, C797S and potential inhibition of Osimertinib (Tagrisso) resistant tumors in PDX models.

Abivertinib also irreversibly binds to the BTK receptor, inhibiting the phosphorylation of the receptor required for malignant cell survival such as B lymphocytes and prostate cancer.

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™ 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 post-herpetic 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. 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 Abivertinib and the planned Phase 2/3 clinical trial in severe COVID-19 patients, including the expected phases of the trial and sites for the trial; the preliminary results of the two phase 2 studies that were announced in October 2021; Sorrento's belief that an oral dosage form is very relevant for severely afflicted COVID-19 patients; the potential for Abivertinib to provide significant benefits across the globe with respect to logistical access, scalability and affordability; Sorrento's intention to explore the administration of Abivertinib for severe non-COVID related pneumonia and ARDS patients and Sorrento's 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 additional studies and seeking regulatory approval for Abivertinib, including the timing for receipt of any such approval; conducting and receiving results of clinical studies; clinical development risks, including risks in the progress, timing, cost, and results of clinical studies 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 the company in the execution of its COVID-19 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 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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