



FDA clears Abivertinib for Phase 2 safety and efficacy study in hospitalized patients with moderate to severe COVID-19

July 20, 2020

- **Abivertinib is a novel Tyrosine Kinase Inhibitor with dual selective targeting of mutant forms of EGFR and BTK that has completed a registration trial (lung cancer) and been administered to over 600 patients worldwide.**

- **The compound demonstrated in-vitro the ability to simultaneously lower multiple critical inflammatory cytokines associated with cytokine storm and poor prognosis in COVID-19 patients.**

- **It is to be tested next in a Phase 2 trial in moderate to severe COVID-19 patients, hospitalized with developing cytokine storm in the lungs.**

SAN DIEGO, July 20, 2020 /PRNewswire/ -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") today received clearance from the FDA to initiate a Phase 2 trial of Abivertinib in patients with COVID-19 who have moderate to severe pulmonary symptoms.



Abivertinib is a novel small molecule tyrosine kinase inhibitor (TKI) that selectively targets both mutant forms of the epidermal growth factor receptor (EGFR) and Bruton's tyrosine kinase (BTK). On May 21, 2020, Sorrento announced that it had entered into a binding term sheet for an exclusive license to ACEA Therapeutics' Abivertinib across all indications for all territories outside of China. The parties have since entered into an exclusive license agreement.

Abivertinib irreversibly binds to the BTK receptor, preventing the phosphorylation of the receptor. Due to this effect, it has shown potent immunomodulatory activities in vitro by inhibiting key pro-inflammatory cytokine production, including IL-1beta, IL-6 and TNF-alpha. These cytokines are associated with cytokine release syndrome (CRS) or cytokine storm and COVID-19 disease progression with poor outcomes in patients with acute respiratory distress syndrome (ARDS).

Since Abivertinib targets multiple cytokines simultaneously, Sorrento anticipates that the effects of Abivertinib will be incremental to the initial published findings by others for IL-6 inhibitors targeted for COVID-19 trials, and the clinical benefits will be more pronounced given the broader range of anti-cytokine activity.

The trial, titled A Phase 2, Double Blinded, Randomized Study of the Efficacy and Safety of STI-5656 (Abivertinib Maleate) With Standard of Care Versus Standard of Care in Subjects Hospitalized With COVID-19 (NCT04440007), will be initially conducted in centers in the USA.

Abivertinib has been studied in over 600 patients worldwide in various oncologic indications, including one registration trial in non-small cell lung cancer. Most treatment-related adverse events (AEs) were grade 1 or 2, the most common of which were transaminase elevations and diarrhea, which are generally considered common for TKIs. Other common treatment-related AEs included anemia, neutropenia and thrombocytopenia, each of which are generally considered typical AEs with long-term use of TKIs. No unexpected AEs were reported.

About ACEA Therapeutics

ACEA Therapeutics is committed to developing and delivering innovative treatments to improve the lives of patients with life-threatening diseases. ACEA has expanded drug discovery efforts to encompass development in both targeted cancer therapy and immunotherapy areas. Alongside a robust R&D organization, ACEA has established drug manufacturing in China to support its long-term growth. This infrastructure provides ACEA greater control over drug supply chain to make sure products are delivered to patients on-time and at the highest quality. ACEA is well positioned to deliver on its promise to bring innovative treatments to patients living with life-threatening diseases while creating value for shareholders, employees, and society.

For more information visit www.aceatherapeutics.com

About Sorrento Therapeutics, Inc.

Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to treat cancers. 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"), clinical stage immuno-cellular therapies ("CAR-T", "DAR-T™"), antibody-drug conjugates ("ADCs"), and clinical stage oncolytic virus ("Seprehvir™", "Seprehvec™"). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including COVIDTRAP™, ACE-MAB™, COVI-MAB™, COVI-GUARD™, COVI-SHIELD™ and T-VIVA-1

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 ZTlido® (lidocaine topical system) 1.8% for the treatment of post-herpetic neuralgia. RTX is completing a phase IB trial for intractable pain associated with cancer and a phase 1B trial in osteoarthritis patients. 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 its potential ability to lower inflammatory cytokines associated with cytokine storm and poor prognosis in COVID-19 patients, the anticipated effects and clinical benefits of Abivertinib in patients with COVID-19 and the anticipated Phase 2 trial of Abivertinib in patients with COVID-19. 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 conducting clinical trials and seeking regulatory approval of Abivertinib; that prior test results may not be replicated in future studies and trials; conducting and receiving results of clinical trials for Abivertinib; the viability and success of using Abivertinib for the treatment of inflammatory cytokines associated with cytokine storm and poor prognosis in COVID-19 patients; risks related to Sorrento's and its subsidiaries', affiliates' and partners' technologies and prospects and collaborations with partners, including, but not limited to 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 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 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, 2019, 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.

Contact

Alexis Nahama, DVM (SVP Corporate Development)

Email: mediarelations@sorrentotherapeutics.com

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

G-MAB™, COVI-GUARD™, COVI-SHIELD™, COVIDTRAP™, T-VIVA-19™, COVI-MAB™, ACE-M™, COVI-TRACK™, Saving-Life™ and Improving-Life™ are trademarks of Sorrento Therapeutics, Inc.

ZTlido® is a trademark owned by Scilex Pharmaceuticals Inc.

All other trademarks are the property of their respective owners.

© 2020 Sorrento Therapeutics, Inc. All Rights Reserved.

 View original content to download multimedia: <http://www.prnewswire.com/news-releases/fda-clears-abivertinib-for-phase-2-safety-and-efficacy-study-in-hospitalized-patients-with-moderate-to-severe-covid-19-301095327.html>

SOURCE Sorrento Therapeutics Inc.