Sorrento Receives FDA Clearance to Proceed With Phase 2 Study for Sti-3031, an Anti-Pd-L1 Antibody, for Advanced Urothelial Carcinoma

April 27, 2021

- STI-3031 was discovered from Sorrento's fully human G-MAB™ library.
- Currently, six G-MAB antibodies are in Phase 1b through Phase 3 clinical trials in immuno-oncology and COVID-19 indications.
- These clinical and pre-clinical G-MAB antibodies are expected to be the foundation for developing potent antibody drug conjugates (ADCs) and antibody drug nanoparticle albumin-bound (ADNAB) product candidates.
- G-MAB antibodies have also been used for the generation and production of both CAR-T and DAR-T™ cells for treating hematological cancer and solid tumors.

SAN DIEGO, April 27, 2021 (GLOBE NEWSWIRE) -- Over the last several months, Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") and its development partners have advanced into clinical development (Phase 1b through Phase 3 clinical trials) a number of fully human monoclonal antibodies (mAbs) for the treatment of COVID-19 and various cancers. This demonstrates the potential of the deep pipeline generated from Sorrento's proprietary G-MAB™ library, invented by Dr.Henry Ji, the Chairman and CEO of Sorrento. This G-MAB library is based on the use of RNA transcription for amplification of the antibody variable domains from over 600 donors. These donors were from both sexes and of multiple ethnicities, leading to a broad diversity of antibodies. In-depth analysis of deep sequencing DNA data showed that the G-MAB library contains more than 20 quadrillion (10^{16}) distinct antibody sequences. The G-MAB library has fostered the development of several early and late-stage oncology programs that are currently in Phase 2 and Phase 3 clinical trials and neutralizing mAbs currently in a Phase 2 clinical trial directed against the spike protein of COVID-19 viruses.

Two independent anti-PD-L1 mAbs are now in Phase 2 and Phase 3 clinical studies. A PD-L1 mAb (STI-3031, also known as IMC-001) was licensed to ImmuneOncia Therapeutics, Inc. ("ImmuneOncia"), a joint venture between Sorrento and Seoul-based Yuhan Corporation. IMC-001 has completed a Phase 1b study in patients with metastatic or locally-advanced solid tumors and is nearing completion of a Phase 2, open-label, "Neo-Chance" study in patients with resectable gastric cancer, esophageal cancer and liver cancer. ImmuneOncia has also started to enroll patients in a Phase 2 study in relapsed or refractory extranodal NK/T cell lymphoma, nasal type. Sorrento has filed an IND in the U.S. and received clearance from the FDA to proceed with a Phase 2a study for STI-3031 for advanced urothelial carcinoma.

A second antibody, Socazolimab, is licensed to Lee's Pharmaceutical Holdings Limited in the Greater China territory, and has been cleared to begin a multicenter Phase 3 trial as a potential first-line treatment for patients with extensive-stage small-cell lung cancer. Professor Shun Lu (Shanghai Chest Hospital) is the Principal Investigator. Additionally, Phase 1b studies in several other indications have been completed for this product candidate, including: recurrent metastatic cervical cancer, advanced urothelial carcinoma, and high-grade osteosarcoma after adjuvant chemotherapy for maintenance. In addition, a Phase 1b/2 study has been initiated as a potential neoadjuvant treatment option for esophageal carcinoma. For cervical cancer, a pivotal study has been completed with a breakthrough therapy designation granted by the National Medical Products Administration (NMPA) in China. Sorrento intends to open an IND in the U.S. with the intent to have an end-of-phase 3 meeting or pre-NDA discussion with the FDA for various cancer indications.

Sorrento previously announced FDA clearance to commence a Phase 1b study in various relapsed or refractory solid tumors with an anti-CD47 antibody (STI-6643) (a CD-47 checkpoint inhibitor interacting with SIRPα). In preclinical studies, STI-6643 appears to have a beneficial toxicity profile (e.g., reduced hemolysis) without a priming mechanism while maintaining potent anti-tumor activity. Additionally, Sorrento licensed a separate promising anti-CD47 antibody (IMC-002) to ImmuneOncia, which has initiated a Phase 1b study in patients with metastatic or locally-advanced solid tumors and relapsed or refractory lymphomas.

Sorrento previously announced the formation of its subsidiary company - Adnab, Inc.,– which is focused on developing and commercializing ADNAB™ platform products for hematological malignancies and solid tumors based on an exclusive license from the Mayo Clinic. Sorrento intends to combine a variety of its proprietary mAbs in conjunction with the ADNAB technology platform, which was developed by Dr. Svetomir Markovic, M.D., Ph.D., and his research team at Mayo Clinic. This effort will potentially result in multiple next-generation ADNAB products. Since ADNABs can be designed to have one or two mAbs on the external surface, in addition to a chemotherapeutic payload, the cytotoxic payload can potentially be delivered preferentially to targeted cancer cell types. Sorrento expects to develop a number of innovative ADNABs in anticipation of filing INDs for clinical trials later in 2021.

"These are very exciting times for Sorrento," said Dr. Ji. "These therapeutic antibody examples demonstrate that we are leveraging the G-MAB library to bring product candidates rapidly from preclinical development through the IND process and into clinic trials."

About Sorrento Therapeutics, Inc.

Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to treat cancers 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"), clinical stage immuno-cellular therapies ("CAR-T", "DAR-T™"), antibody-drug conjugates ("ADCs"), and clinical stage oncolytic virus ("Seprehvir™"). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including COVIGUARD™, COVI-AMG™, COVISHIELD™, Gene-MAb™, COVI-MSC™ and COVIDROPS™; and diagnostic test solutions, incl 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.

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 potential for any clinical and pre-clinical G-MAB antibodies to be the foundation for developing potent ADC or ADNAB product candidates; the potential for G-MAB antibodies to be used in the generation and production of future CAR-T or DAR-T cells for treating hematological cancer and solid tumors; the ability of the G-MAB library to continue fostering the development of oncology programs and neutralizing mAbs; the initiation of a Phase 2a study for STI-3031; the potential therapeutic benefits of STI-3031, Socazolimab, STI-6643 and IMC-002; the potential for pre-clinical data and results to be replicated in future clinical trials; the safety and efficacy of STI-3031, Socazolimab, STI-6643 and IMC-002; the potential for the safety and efficacy of STI-3031, Socazolimab, STI-6643 and IMC-002 to be replicated in future clinical trials; regulatory approvals of STI-3031, Socazolimab, STI-6643 and IMC-002; the completion of clinical trials of STI-3031, Socazolimab, STI-6643 and IMC-002; the filing of an IND in the US for Socazolimab; Sorrento's ability to combine proprietary mAbs in conjunction with the ADNAB technology platform to create next-generation ADNAB products; the potential for ADNABs to deliver cytotoxic payloads to targeted cancer cell types; the potential for Sorrento to file INDs for clinical trials for ADNAB; the expected timing of any IND filings for ADNABs; Sorrento's intention to open an IND for Socazolimab and have an end-of-phase 3 meeting or pre-NDA discussion with the FDA for various cancer indications; or Sorrento's ability to continue leveraging the G-MAB library to bring product candidates from preclinical development, through the IND process and into clinical trials. 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 STI-3031, Socazolimab, STI-6643, IMC-002 or any ADNAB product candidates; 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

Source: Sorrento Therapeutics, Inc.