Sorrento Receives FDA Clearance to Start Clinical Trial of Anti-CD47 Antibody, Discovered from Fully Human G-MAB Library, for Treatment of Multiple Malignancies

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- Internally developed fully human anti-CD47 antibody (STI-6643) cleared for basket trial;
- No complicated titration or priming dose of the antibody is required to reduce toxicity;
- This study will be conducted at the Moffitt Cancer Center in Tampa, FL with Dr. David A. Sallman as the coordinating lead investigator; and
- A second anti-CD47 antibody (IMC-002) discovered from Sorrento's G-MAB™ library was previously cleared by the FDA for clinical trial, and is currently in human testing by ImmuneOncia Therapeutics, LLC, a joint venture between Sorrento (35% ownership) and Yuhan Corporation.

SAN DIEGO, March 02, 2021 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") today announced that the FDA has cleared Sorrento's internally developed anti-CD47 monoclonal antibody, STI-6643, which was discovered from Sorrento's G-MAB™ library, for an initial clinical trial. The initial clinical trial will be a basket trial entitled "*A Phase 1B, Open-Label, Dose-Escalation Study of the Safety and Efficacy of STI-6643, an Anti-CD47 Human Monoclonal Antibody, in Patients with Selected Relapsed or Refractory Malignancies*."

Cluster of differentiation 47 (also known as integrin-associated protein) ("CD47") is a ubiquitously-expressed glycoprotein of the immunoglobulin superfamily that plays a critical role in self-recognition. Various solid and hematologic cancers exploit CD47 expression to evade immunological eradication, and its overexpression is clinically correlated with poor prognoses. One essential mechanism behind CD47-mediated immune evasion is that it can interact with signal regulatory protein-alpha (SIRPα) expressed on myeloid cells, causing phosphorylation of the SIRPα cytoplasmic immunoreceptor tyrosine-based inhibition motifs and recruitment of Src homology 2 domain-containing tyrosine phosphatases to ultimately result in delivering an anti-phagocytic "don't eat me" signal. Given its essential role as a negative checkpoint for innate immunity and subsequent adaptive immunity, the CD47/SIRPα axis has been explored as a new target for cancer immunotherapy and its disruption has demonstrated great therapeutic promise.

In preclinical evaluations, STI-6643 displayed decreased red blood cell binding and hemolysis, while maintaining potent anti-tumor activity in solid tumor disease models. Clinical trials with anti-CD47 mAbs have historically experienced limitations due to significant anemia, hemagglutination, and thrombocytopenia due to CD47 expression on normal red blood cells, ultimately requiring employment of complicated clinical dosing regimens. These issues have not been seen to date with STI-6643 in preclinical studies conducted head-to-head against synthesized versions of other CD47 mAbs. Additionally, STI-6643 showed minimal T, B or NK cell depletion as opposed to other synthesized mAb clones, which could potentially result in improved efficacy by preserving infiltrating anti-tumor immune cells. STI-6643 has the potential to be a "best-in-class" product if these preclinical benefits are able to be reproduced in human trials. Sorrento is also conducting preclinical studies to compare the safety and efficacy of lymphatic delivery of STI-6643 to established parenteral routes of administration using Sorrento's Sofusa™ technology. This study will be conducted at the Moffitt Cancer Center in Tampa, FL with Dr. David A. Sallman as the coordinating lead investigator.

STI-6643 is the second anti-CD47 antibody that has been developed from the G-MAB library. The other anti-CD47 antibody (IMC-002) discovered from the G-MAB library was previously cleared by the FDA, and is currently in Phase 1 human studies sponsored by ImmuneOncia Therapeutics, LLC, a joint venture company between Sorrento (35% ownership) and Yuhan Corporation.

Regarding the recent clearance for a clinical trial for STI-6643 by the FDA, Dr. Henry Ji, Chairman and CEO of Sorrento, commented, "We have seen great performance from STI-6643 in our IND-enabling studies. Our internal anti-CD47 program has now yielded two clinical candidates, a signal of our continued commitment to the development of innovative, safe and efficacious cancer treatments in addition to our commitment to fighting COVID-19."

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, inclu 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 initiation of a phase 1B basket trial for STI-6643; the therapeutic efficacy of targeting the CD47/SIRPα axis for cancer immunotherapy; the potential therapeutic benefits of STI-6643; the potential for pre-clinical data and results to be replicated in future clinical trials; the safety and efficacy of STI-6643; the potential for the safety and efficacy of STI-6643 to be replicated in future clinical trials; the potential for clinical trials with STI-6643 to not experience limitations that other anti-CD47 mAbs clinical trials have experienced, including anemia, hemagglutination, thrombocytopenia and complicated dosing regimens; the potential for STI-6643 to be a “best-in-class” product; regulatory approvals of STI-6643; and the completion of clinical trials of STI-6643. 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 pre-clinical studies and seeking regulatory approval for STI-6643, including the timing for receipt of any such approval; conducting and receiving results of clinical trials; 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 the company in the execution of its cancer, anti-tumor and G-MAB antibody 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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