Sorrento Therapeutics Logo

Sorrento Launches Novel I-Cell™ COVID-19 Cellular Vaccine Program

March 25, 2020

- STI-6991 is an I-Cell™ COVID-19 cellular vaccine made of replication-deficient human erythroleukemia K562 cells expressing membrane-bound S1 protein of the SARS-CoV-2 virus
- The I-Cell vaccine is expected to elicit both T cell and B cell immunities against SARS-CoV-2
- Sorrento is in active discussions with the FDA's Center for Biologics Evaluation and Research to gain guidance on rapid development of this novel vaccine (IND# 019724), with a goal to start enrolling in a human clinical trial as early as mid-year 2020
- Sorrento anticipates its existing cGMP cell therapy manufacturing facilities will have the capacity to produce enough drug substance to meet the demand for millions of monthly doses of the final drug product (vaccine), if approved
- The strategic approach that inspired the I-Cell cellular vaccination strategy has been published as a short communication in "Medicine in Drug Discovery" (https://doi.org/10.1016/j.medidd.2020.100026)

SAN DIEGO, March 25, 2020 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") today announced it has been working on a novel decoy cellular vaccine for COVID-19 (STI-6991) and is in active discussions with the FDA's Center for Biologics Evaluation and Research under IND#019724 regarding the required IND-enabling studies, CMC (chemistry, manufacturing and controls), clinical protocol and end-points for potential accelerated approval. Upon receiving guidance from the FDA, Sorrento intends to submit a full package for an IND filing that would enable human clinical trials to start as soon as possible.

The decoy cell strategy (I-Cell™, which means immune-training cells) has been conceptualized and developed by Sorrento scientists utilizing expertise acquired in the fight against cancer. Sorrento expects to utilize a well-known replicating cell line (human erythroleukemia, K562) to incorporate SARS-CoV-2's spike protein or its S1 domain onto the cellular membrane so that the viral antigen is presented on a decoy cell surface to elicit both T cell and B cell immunities. The selected cell line has been used safely in cancer vaccination programs and is well characterized (clinical trials using K562 expressing granulocyte-macrophage colony-stimulating factor have been used as a tumor vaccine). Upon expression of the viral protein as a surface marker, the decoy cell "looks like" the virus to a healthy person's immune system. After irradiation to prevent the replication of the cells, the cells can be administered by intramuscular injection as a vaccine. In the presence of this "look alike" training cell, the recipient may develop a protective immune response and produce corresponding neutralizing antibodies against the SARS-CoV-2 virus. If the vaccinated subject is later exposed to the SARS-CoV-2 coronavirus, his or her T cell immunity and neutralizing antibodies are expected to block the spike protein from attaching to the ACE2 (angiotensin converting enzyme 2) on the normal human cell surface, thus potentially attenuating or preventing the SARS-CoV-2 infection which causes COVID-19 disease.

A short communication explaining this vaccination approach was accepted for publication by Medicine in Drug Discovery (an Elsevier peer reviewed open access journal. The article can be found at https://www.sciencedirect.com/science/article/pii/S2590098620300130?via%3Dihub). Per the publication, "the overall strategy to utilize a viral antigen-expressing, non-replicating cellular system as both a carrier, and as an immunogenic antigen-presenting platform is novel. The view is that this platform will be recognized by the immune system, and a neutralizing antibody response will ensue. The most important aspect of the platform is that it should allow for dendritic cells to recruit T lymphocytes and induce Th1 cell polarization that if feasible will also induce a cytotoxic T cell response and thus clearance of SARS-CoV-2 virus. The strategy should be safe as they are using K562 cell line that is HLA negative. The platform appears to be readily scalable and would appear to provide uniform cell product. One key aspect is that will the vaccine prevent engraftment and proliferation after host implantation; the answer here appears to be yes as the cells will be irradiated post-expansion in order to abolish their replication ability and thus no in vivo cell growth. In sum an intriguing platform is put forth and if viable as it appears to be it could make an impact on the treatment of COVID-19."[1]

Sorrento is currently working to demonstrate I-Cells' ability to generate protective T cell and B cell immunities in an animal model. Sorrento has identified a leading infectious disease contract research organization to support the phase 1 clinical trial and accelerated timelines. Sorrento has begun process development, validation and scaled up manufacturing testing in its state-of-the-art cGMP cell therapy facilities in San Diego in anticipation of registrational clinical trials and commercialization.

Sorrento anticipates all IND requirements will be fulfilled in the next few months. Depending on government support and the FDA's response, Sorrento believes it may be in a position to initiate human vaccination trials as early as mid-year 2020.

David Epstein, former CEO of Novartis Pharmaceuticals, a division of Novartis AG, who has been advising Sorrento, said, "This promising vaccination strategy is uniquely suited for rapid scale up and advancement into the clinic. I am hopeful because this novel approach can make a difference in the lives of so many."

"We have developed a novel approach to vaccination that we believe can be a breakthrough in the fight against COVID-19. We believe using a human cell as a training agent is unique and likely to be effective for vaccination," stated Dr Henry Ji, Chairman and CEO of Sorrento Therapeutics. "By utilizing an existing cell line that has previously been used to make cancer vaccines, we know we have a product candidate with a promising safety profile. We are very confident that, if our product candidate is approved, we will have the required capacity in place to produce enough doses to protect millions of people in the near term. Confirming that I-Cell works in humans is our top priority and our most immediate focus."

About Sorrento Therapeutics, Inc.

Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to turn malignant cancers into manageable and possibly curable diseases. 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"), intracellular targeting antibodies ("iTAbs"), antibody-drug conjugates ("ADC"), and clinical stage oncolytic virus ("Seprehvir®"). Sorrento is also

developing potential coronavirus antiviral therapies, including COVIDTRAP™, ACE-MAB™ and I-Cell™.

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. Resiniferatoxin 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 the expected timing for commencing and completing registrational studies and for submitting an IND application for I-Cell™ STI-6991 as a vaccine for the SARS-CoV-2 virus; the therapeutic potential of I-Cell™ STI-6991 as a vaccine for SARS-CoV-2 and COVID-19 disease; I-Cell™ STI-6991's ability to elicit T cell and B cell immunities against SARS-CoV-2; the ability of a contract research organization to support the clinical trial (Phase 1) of I-Cell™ STI-6991; the expected timing of a clinical trial (Phase 1) of I-Cell™ STI-6991; the expected timing of completion of all IND requirements I-Cell™ STI-6991; the expected timing for commencing and completing human vaccination trials of I-Cell™ STI-6991; regulatory approvals of I-Cell™ STI-6991; the development and commercialization of I-Cell™ STI-6991 for SARS-CoV-2 virus and COVID-19; the readiness of Sorrento's cGMP facilities for large-scale production of I-Cell™ STI-6991 for commercialization and Sorrento's expected capacity to produce drug substance; the expected time needed for Sorrento's cGMP facilities to produce doses of I-Cell ™ STI-6991; the safety and efficacy of I-Cell™ STI-6991; and Sorrento's potential position in the vaccine 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 pre-clinical trials and seeking IND regulatory approval for I-Cell™ STI-6991; conducting and receiving results of clinical trials for I-Cell™ STI-6991; the clinical and commercial success of a vaccine against SARS-CoV-2 virus infections using I-Cell™ STI-6991; the viability and success of using I-Cell™ STI-6991 in anti-viral therapeutic areas, including coronaviruses; 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 the company in the execution of its I-Cell™ STI-6991 vaccine strategies; risks related to Sorrento's debt obligations; 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.

Media and Investor Relations

Contact: Alexis Nahama, DVM (SVP Corporate Development)

Telephone: 1.858.203.4120

Email: mediarelations@sorrentotherapeutics.com

---

[1] https://doi.org/10.1016/j.medidd.2020.100026

Source: Sorrento Therapeutics, Inc.