Sorrento Enters Into Letter Of Intent To Acquire SmartPharm And Develop Pipeline Of Gene-Encoded Therapeutic Antibodies, Starting With Neutralizing Antibodies To Treat COVID-19 and Cancer Therapeutics

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-- The combination of SmartPharm's Gene Mab™ gene-encoded in vivo expression system and Sorrento’s SARS-CoV-2 neutralizing antibodies may potentially provide longer-acting, single injection protection against COVID-19.

-- The combination of Sorrento’s proprietary fully human G-MAB™ Antibody Library and SmartPharm’s Gene-Encoded Therapeutics (GET) Platform is expected to provide a vast product pipeline of novel, long-acting therapeutic proteins for treating a broad range of diseases, including cancer.

SAN DIEGO and BOSTON, July 24, 2020 /PRNewswire/ -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") and SmartPharm Therapeutics, Inc. ("SmartPharm") announced today the signing of a letter of intent for Sorrento to acquire SmartPharm, a gene-encoded therapeutics company developing non-viral DNA and RNA gene delivery platforms for COVID-19 and rare diseases, with broad potential for application in enhancing antibody-centric therapeutics, including against COVID-19. The transaction is expected to close in August 2020. Financial terms of the deal were not disclosed.

Sorrento and SmartPharm previously announced a research and development collaboration to encode and express in vivo Sorrento's proprietary SARS-CoV-2 neutralizing monoclonal antibodies utilizing SmartPharm's Gene Mab plasmid nanoparticle platform. Sorrento plans to accelerate the development of multiple candidates for in vivo gene-encoded expression of Sorrento's antibodies, starting with Sorrento's previously announced STI-1499, or COVI-GUARD™, which is currently moving through preclinical and manufacturing requirements with an IND submission targeted for August 2020. The initial clinical trial for STI-1499 is expected to be in ICU patients to ensure safety and potentially allow a preliminary look at efficacy. In vitro results so far have demonstrated STI-1499's ability to completely neutralize SARS-CoV-2 infection at low doses, making STI-1499 Sorrento's lead candidate for potential cost-effective passive protection against COVID-19.

SmartPharm's Gene Mab™ platform delivers to muscles a novel low-immunogenic DNA plasmid encoded with a therapeutic antibody for long-lasting expression in vivo. If clinical trials are successful, a single administration of STI-1499dpi (DNA plasmid injection) could allow the recipient's own muscle cells to produce the antibody for a prolonged period of time after a single injection, potentially providing extended protection against COVID-19 for periods of time that might provide an alternative to vaccines. Manufacturing of DNA plasmids (in bacterial fermenters) can be done with Sorrento's in-house cGMP capabilities for a fraction of the cost associated with traditional antibody manufacturing.

"We are very encouraged by the preclinical data generated thus far by our STI-1499 neutralizing antibody against COVID-19," said Henry Ji, Ph.D., CEO of Sorrento Therapeutics. "We are excited about the prospect of leveraging SmartPharm's Gene Mab platform in combination with our G-MAB library to produce next-generation gene-encoded antibody candidates against a host of pathogens and cancer cell types. Being able to stimulate the body to produce in vivo our most potent antibodies at optimized manufacturing costs will offer an additional competitive advantage as Sorrento transitions from product development to full scale manufacturing and commercialization."

About SmartPharm Therapeutics

SmartPharm Therapeutics, Inc. is a privately held, development stage biopharmaceutical company focused on developing next-generation, non-viral gene therapies for the treatment of serious or rare diseases with the vision of creating "Biologics from Within." SmartPharm is currently developing a novel pipeline of non-viral, gene-encoded proteins for the treatment of conditions that require biologic therapy such enzyme replacement and tissue restoration. SmartPharm commenced operations in 2018 and is headquartered in Cambridge, MA, USA. For more information, please visit www.smartpharmtx.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 the proposed acquisition of SmartPharm; the potential effects that the acquisition of SmartPharm may have on Sorrento's business and product candidate pipeline; the expected timing for the closing of the transaction; the initiation and completion of ongoing studies for COVID-19 using antibodies and gene-encoded antibodies, and data read-outs related thereto; the potency and potential blocking capabilities of STI-1499 and STI-1499dpi and their respective impact on SARS-CoV-2; the expected length of any antiviral protection provided by STI-1499 and STI-1499dpi; the potential administration and applications of STI-1499 and STI-1499dpi, alone or in combination; the timeline and status of preclinical testing for STI-1499 and STI-1499dpi; the expected timing of an IND submission for STI-1499; expectations regarding the initial clinical trial for STI-1499; the potential safety and efficacy of STI-1499 and STI-1499dpi; the therapeutic potential of STI-1499 and STI-1499dpi for SARS-CoV-2 and COVID-19; the potential costs associated with manufacturing STI-1499dpi and other DNA plasmids; Sorrento’s ability to produce antibody candidates against pathogens and cancer cells; Sorrento’s ability to transition from product development to full-scale manufacturing and commercialization; and Sorrento’s potential position in the anti-viral immunity 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 technologies and prospects with newly acquired technologies, including the proposed acquisition of SmartPharm and the utilization of SmartPharm’s Gene-Encoded Therapeutics (GET) platforms for the treatment and prevention of coronavirus infections and other pathogens and cancer cells; risks related to seeking regulatory approvals and conducting clinical trials; the clinical and commercial success of the treatment and prevention of coronavirus infections using monoclonal antibodies and gene-encoded antibodies; the viability and success of using monoclonal antibodies and gene-encoded antibodies for treatments in anti-viral therapeutic areas, including coronavirus; 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 prior study and trial results may not be replicated in future studies and trials; 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 related to seeking regulatory approvals and conducting clinical trials; risks of manufacturing drug product; risks related to leveraging the expertise of its employees, subsidiaries, affiliates and partners to assist the company in the execution of its 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.

Media and Investor Relations

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