



## **SORRENTO THERAPEUTICS ANNOUNCES COVISHIELD (STI-9167), A BROAD-SPECTRUM NEUTRALIZING ANTIBODY, POTENTLY NEUTRALIZES OMICRON AND OMICRON (+R346K) VARIANTS OF SARS-COV-2**

January 21, 2022

- **COVISHIELD (STI-9167) neutralizing antibody (nAb) was discovered by scientists from the Icahn School of Medicine at Mount Sinai ("Icahn Mount Sinai") and further optimized and engineered by Sorrento scientists.**
- **Sorrento has obtained worldwide exclusive license rights from Icahn Mount Sinai as previously announced on March 9, 2021 (<https://investors.sorrentotherapeutics.com/news-releases/news-release-details/sorrento-andmount-sinai-health-system-enter-exclusive-license>).**
- **Compared to available published literature and head-to-head experiments, STI-9167 nAb is a potentially "Best-in-Class" nAb against the Omicron variant of SARS-CoV-2 and the first reported nAb with high potency against Omicron (+R346K mutation) and has demonstrated highly potent neutralization activities in vitro (IC<sub>50</sub> of 25 ng/mL for Omicron live virus, 14.8 ng/mL and 23.9 ng/mL for Omicron and Omicron (+R346K mutation) pseudovirus, respectively), in addition to potent neutralizing activities against the SARS-CoV-2 virus and all of its variants of concern (VOCs).**
- **STI-9167 nAb demonstrated strong protection in vivo following Omicron virus challenge in a preclinical model of COVID-19, preventing weight loss and reducing virus titers in the lungs to levels below the limit of detection.**
- **GMP drug product manufacturing in support of large clinical development is in place at Sorrento GMP facilities.**
- **Sorrento is evaluating in-house GMP manufacturing and is in negotiations with major global CMOs for commercial scale manufacturing to secure capacity to manufacture and supply tens of millions of doses. Sorrento currently has in-hand sufficient cGMP drug substance for 100,000's of doses at the projected intranasal dose of STI-9199, the intranasal formulation of STI-9167.**
- **INDs to be submitted in the US, UK and Mexico within a month for use as either a small volume intravenous push or intranasal instillation.**

SAN DIEGO, Jan. 21, 2022 /PRNewswire/ -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") today announced the release of new data on the Omicron variant neutralizing antibody (nAb) STI-9167, COVISHIELD, an advanced stage antibody discovered and developed for clinical trials in an ongoing collaboration between immunologists and virologists at Sorrento and the Icahn School of Medicine at Mount Sinai ("Icahn Mount Sinai") in New York, NY.



Spike protein binding assays and neutralization assays using viruses representing all known SARS-CoV-2 variants of concern (VOCs) have been completed with STI-9167, and this nAb was observed to bind with high affinity and provide highly potent neutralizing activity (Omicron IC<sub>50</sub> = 25 ng/ml). Of noted significance, STI-9167 is unique when compared to tests of EUA-approved SARS-CoV-2 nAbs in that binding and neutralization properties are maintained against the emerging Omicron and Omicron (+R346K) variant, an increasingly prevalent Omicron lineage variant that encodes an additional R346K Spike protein mutation. Additionally, STI-9167 administered at a low dose (5mg/kg) by either the intranasal or intravenous routes provided strong protection against the clinical signs of infection by the Omicron variant in the K18-hAce2 transgenic mouse model of COVID-19, preventing weight loss and reducing virus titers in the lungs to undetectable levels.

"The generation and characterization of the STI-9167 nAb demonstrates the great collaboration between the scientists of Mount Sinai and Sorrento to address a global health crisis," said Domenico Tortorella, PhD, Professor of Microbiology at Icahn Mount Sinai.

"We selected antibody STI-9167 from large sets of diverse anti-SARS-CoV-2 spike neutralizing antibodies that we developed in our labs. It demonstrated the most effective cross-neutralization against all known SARS-CoV-2 isolates and variants of concerns, including the recent Omicron and Omicron (+R346K) variants," commented J. Andrew Duty, PhD, Assistant Professor of Microbiology and Director of the Center for Therapeutic Antibody Development at Icahn Mount Sinai.

"The currently EUA-approved nAbs have markedly reduced or absent binding and neutralization activities against omicron/omicron (+R346K) making

them inadequate to support current clinical needs," stated Mike A. Royal, MD, JD, MBA, Chief Medical Officer at Sorrento. "Alternative nAbs are sorely needed in the near term, particularly for the pediatric population which appears to be at higher risk for severe omicron infection and hospitalization. Our intranasal COVIDROPS formulation delivers our nAbs to the upper airways where Omicron is most likely to target and flourish, and as a non-invasive, easy to administer treatment, it is ideal for children. We have already begun to treat children with COVIDROPS (with STI-2099) in Mexico where the delta variant is still prevalent. Through Phase 2 studies in the US, United Kingdom and Mexico, we have seen a benign safety profile for intranasal delivery of our nAbs and expect a similar outcome with COVIDROP (with STI-9167)."

"We now have had experience with bringing multiple COVID-19 therapeutics into the clinic and advancing several into Phase 2 and/or pivotal development," says Mark Brunswick, PhD, SVP and Head of Regulatory Affairs and Quality at Sorrento. "We are well situated to rapidly bring forth COVISHIELD through the IND stage and into the clinic and expect to file this important IND in the next month."

Dr. Henry Ji, Chairman and CEO of Sorrento, commented, "The work by the teams at Sorrento and Mount Sinai has yielded a remarkable antibody with unique and valuable protective properties against Omicron and all other SARS-CoV-2 VOCs. Our COVISHIELD neutralizing antibody is the best-in-class and the most advanced candidate for combatting the prevalent Omicron and emerging Omicron (+R346K) VOCs. We are working diligently to position this antibody for use in COVID patients and are confident that our approach will provide an efficacious clinical solution not only in the near term but also as the pandemic continues to evolve."

A preprint manuscript was submitted on January 19, 2022 and will be published shortly online at [biorxiv.org](https://www.biorxiv.org).

The neutralizing antibody described was generated in the laboratories at Mount Sinai and exclusively licensed to Sorrento Therapeutics. Mount Sinai and Mount Sinai faculty members have a financial interest in Sorrento Therapeutics.

### **About STI-9167, COVISHIELD, Antibody**

Initially isolated as a SARS-CoV-2 (WA-1 strain) nAb candidate following vaccination of transgenic mice, the STI-9167 antibody was optimized to maximize protein stability and minimize interactions with host Fc gamma receptors. Using established master cell banks, GMP drug product has been generated at Sorrento in preparation for anticipated Phase 1 through pivotal Phase 2/3 human clinical trials. Tech transfer of methods and GMP processes in support of commercial-scale GMP manufacturing is currently underway.

### **About STI-9167 Clinical Development Plans**

Sorrento has demonstrated the protective effects of SARS-CoV-2 nAbs administered by either intravenous, IV, or intranasal, IN, routes in preclinical COVID-19 animal models and the safety of SARS-CoV-2 nAbs administered by IV and IN routes to human subjects. Current clinical study plans for STI-9167, pending feedback from regulatory agencies, call for evaluation of safety following antibody administration at single doses via the IV and IN routes in healthy normal adults or asymptomatic Omicron infected patients, followed by large Phase 2/3 clinical trials globally for newly infected COVID-19 patients.

### **About Sorrento Therapeutics, Inc.**

Sorrento is a clinical and commercial stage biopharmaceutical company developing new therapies to treat cancer, pain (non-opioid treatments), autoimmune disease 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"), immuno-cellular therapies ("DAR-T™"), antibody-drug conjugates ("ADCs"), and oncolytic virus ("Seprehvec™"). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including Abivertinib, COVI-AMG™, COVISHIELD™, COVI-MSC™ and COVIDROPS™; and diagnostic test solutions, including COVITRACK™ and COVISTIX™.

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 (PHN). RTX has cleared for Phase II trial for intractable pain associated with cancer and a Phase II trial in osteoarthritis patients. SEMDEXA announced highly statistically significant positive top-line results from its Phase III Pivotal Trial C.L.E.A.R Program for its novel, non-opioid product for the treatment of lumbosacral radicular pain (sciatica). ZTlido® was approved by the FDA on February 28, 2018.

For more information visit [www.sorrentotherapeutics.com](https://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 STI-9167, including the potential potency and neutralizing profile of STI-9167 with respect to SARS-CoV-2 and its variants of concern (VOCs); the preclinical and clinical testing of STI-1967; the potential safety and efficacy of STI-1967; the potential for STI-9167 to exhibit best-in-class neutralization against SARS-CoV-2 and all of its VOCs, including high potency against the Omicron and Omicron (+R346K) variants; the expected impact STI-9167 will have against current and future VOCs of SARS-CoV-2; the potential for STI-1967 to provide strong protection against infection by the Omicron variant; the expected dosing and/or route(s) of administration for STI-9167; Sorrento's internal drug product manufacturing capabilities in support of clinical development and its plans to engage global contract manufacturing organizations to provide or support commercial-scale manufacturing capacity; the expectations and timing for submitting Investigational New Drug (IND) applications for STI-1967 in the US, UK, Mexico and/or any other territories; the expected administration method(s) of STI-1967; the potential clinical trial design for STI-1967; the potential for preliminary data results to be replicated in preclinical and clinical studies; and Sorrento's potential position in the antiviral 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 seeking regulatory approval for STI-1967; risks related to conducting preclinical studies and seeking IND acceptance for STI-1967; 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 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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