

Sorrento Therapeutics Logo

Sorrento and Celularity to Start Anti-CD38 CAR-T Phase 1 Clinical Trial in Patients With Relapsed or Refractory Multiple Myeloma (NCT03464916)

April 5, 2018

SAN DIEGO, April 05, 2018 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (NASDAQ:SRNE) and Celularity Inc announced today that the companies have started screening patients for its leading CD38 chimeric antigen receptor (CAR) T cell therapy drug development program, following FDA review allowing clinical trial initiation.

 Celularity logo

Phase 1, Open-Label, Dose-Escalation, Pharmacokinetic, and Pharmacodynamic Study of the Safety and Efficacy of CAR2 Anti-CD38 A2 CAR-T Cells in Patients with Relapsed or Refractory Multiple Myeloma (www.clinicaltrials.gov : NCT03464916). IND filing completed. Study cleared for patient enrollment.

The companies' CD38 CAR-T program is their most advanced program targeting this difficult-to-treat condition. This trial is currently the only active US-based clinical trial targeting CD38 using a CAR-T cell therapy.

The first investigational site at Roger Williams Medical Center, RI, is actively engaged in the clinical study execution, with additional sites to be included.

"Our CD38 CAR-T program has now officially entered clinical stage and will be treating patients as well as collecting valuable data in the upcoming months. This represents a major milestone for Sorrento and Celularity that clearly demonstrates our keen focus on advancing our therapeutics assets as well as our ability to deliver on the timelines we previously communicated," stated Dr. Henry Ji, Chairman and CEO of Sorrento before adding, "we expect to share initial clinical data from this study as soon as it becomes available."

"We are extremely pleased that we can begin this study in our ongoing efforts to improve treatment options for this and other serious diseases. Celularity, created through the contributions from Celgene Corporation, United Therapeutics, Human Longevity Inc., and founding strategic partner Sorrento, is uniquely positioned to combine its platform cellular technology with the vast tool set accessible from Sorrento," said Dr. Robert Hariri, Chairman and CEO of Celularity. "Celularity is building a deep pipeline of immunotherapeutic products from our proprietary placental cells including 'off-the-shelf' CAR-T and CAR-NK cell therapies," added Dr. Hariri.

Utilizing available cGMP manufacturing, Sorrento and Celularity estimate they can produce up to 300 patient treatments per year. These existing capacities easily cover the needs of the Phase 1 clinical study and would be sufficient to meet the requirements for subsequent advanced pivotal clinical studies.

Full details about the study available on www.clinicaltrials.gov

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"), intracellular targeting antibodies ("iTAb"), antibody-drug conjugates ("ADC"), and clinical stage oncolytic virus ("Sephrevir®").

Sorrento's commitment to life-enhancing therapies for cancer patients is also demonstrated by our effort to advance a first-in-class (TRPV1 agonist) non-opioid pain management small molecule in Resiniferatoxin ("RTX") and ZTlido™. Resiniferatoxin is completing a phase IB trial in terminal cancer patients. ZTlido was approved by the FDA on 02/28/18.

For more information visit www.sorrentotherapeutics.com

About Celularity, Inc.

Celularity, headquartered in Warren, New Jersey, is a private biotechnology company with proprietary, leading-edge technology and Intellectual Property to harness the power of the placenta. Their medicine asset portfolio consists of more than 200 issued or pending patents as well as pre-clinical and clinical assets including CAR constructs for allogeneic CAR-T/NK products, licenses of 100+ immunotherapy assets, and commercial stage bio-sourcing and functional regeneration businesses. For more information, please visit www.celularity.com. Follow Celularity on Social Media: @Celularity.

Forward-Looking Statements

This press release contains 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 developments of and prospects for Sorrento's and its subsidiaries' and affiliates' products and technologies, including their respective antibody and CAR-T products and technologies; Sorrento's ability to leverage the expertise of its employees, subsidiaries, affiliates and partners to assist the company in the execution of its strategies; outcome of the data from any clinical trial; Sorrento's M&A and licensing strategy; Sorrento's and its partners' abilities to accelerate the development of any lead programs in the clinic; the timing of expected clinical development programs and clinical trials and FDA submissions; Sorrento's and its subsidiaries' abilities to supply drug product; and expectations for Sorrento's and its subsidiaries', affiliates' and joint ventures' technologies and product candidates. 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, its subsidiaries', affiliates' and partners' technologies and prospects; 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 related to seeking regulatory approvals and conducting clinical trials; risks of supplying drug product; and other matters that are described in Sorrento's Annual Report on Form 10-K for the year ended December 31, 2017, 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

Sorrento Contact: Alexis Nahama, DVM (VP Corporate Development)
Telephone: 1.858.203.4120
Email: mediarelations@sorrentotherapeutics.com

Celularity Contact: Megan Thomas, Factory PR
Telephone: 1.212.941.9394
Email: celularity@factorypr.com

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