Sorrento Announces Significant Positive Pivotal Trial Results as Assessed by an Independent Review Committee (IRC) With Matured Long-Term (Over Three Years) Follow-Up Data of Abivertinib for the Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC)

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- Abivertinib is a novel third-generation epidermal growth factor receptor (EGFR) inhibitor that irreversibly targets mutant forms of EGFR in advanced NSCLC patients who are resistant to first-line EGFR kinase inhibitor therapies.
- In this pivotal study conducted in China, matured data of 209 response evaluable NSCLC patients were assessed by an IRC. The overall response rate (ORR) as confirmed by the IRC was 56.5% (118/209) and among them, 11 patients had complete responses (CR) with a CR rate of 5.3% (11/209) and median overall survival (OS) of 28.2 months.
- Based on these significant positive results from the IRC assessment, Sorrento is closing the study and preparing the materials for a pre-New Drug Application (NDA) meeting with the FDA and potentially submitting for approvals to regulatory agencies of other countries.

SAN DIEGO, Aug. 23, 2022 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") today announced positive results from a pivotal study of Abivertinib on 209 response evaluable, heavily pretreated NSCLC patients by an IRC assessment with matured long-term follow up data.

Abivertinib is a pyrrolopyrimidine-based, third-generation EGFR inhibitor, which is structurally distinct from osimertinib. Abivertinib selectively inhibits EGFR-activating and resistant mutation with nearly 300-fold greater potency as compared with wild-type EGFR. Previously, a positive interim result assessed by investigators was published in the peer-reviewed Clinical Cancer Research journal with interim data (https://clincancerres.aacrjournals.org/content/early/2021/11/04/1078-0432.CCR-21-2595). In these IRC-assessed preliminary topline results with more matured long-term follow up data (previously 16.8 months, now 38.8 months), Abivertinib showed significant treatment benefits in 209 response evaluable, heavily treated NSCLC patients with ORR of 56.5%, and notably a significant CR rate was seen with Abivertinib (5.3%) in comparison with that of osimertinib (Tagrisso) (0.5%)*, while the ORR rate is comparable between the two drugs. This combined data, the ORR of 56.5%, the CR rate of 5.3%, and median OS of 28.2 months (versus Tagrisso's median OS of 26.8 months) **, is potentially superior to that of the approved third generation EGFR inhibitor (osimertinib). Abivertinib demonstrated significantly efficacious effects in overcoming the resistant mutation in NSCLC. Based on these results, Sorrento is closing the study and preparing the pre-NDA materials and NDA package. Sorrento will request a pre-NDA meeting with the FDA and other regulatory agencies around the world with potential NDA filings pending agreements with the regulatory agencies in different countries.

"We are very encouraged by the significant positive results of Abivertinib assessed by the IRC with long-term follow up data and look forward to meeting with the FDA and other regulatory authorities for the possibility of bringing Abivertinib to the U.S. and global markets," said Dr. Henry Ji, Chairman and CEO of Sorrento. Abivertinib is one of the multiple clinical and pre-clinical stage assets obtained by Sorrento in the previously completed acquisition of ACEA Therapeutics, Inc. in June of 2021.

*https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/208065Orig1s000MedR.pdf

** https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208065s025lbl.pdf

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 next-generation tyrosine kinase inhibitors (TKIs), 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 STI-1558, COVISHIELD™ and COVIDROPS™; and diagnostic test solutions, including COVIMARK™.

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 postherpetic neuralgia (PHN). RTX has been cleared for a Phase II trial for intractable pain associated with cancer and a Phase II trial in osteoarthritis patients. Positive final results from the Phase III Pivotal Trial C.L.E.A.R. Program for SEMDEXA™, its novel, non-opioid product for the treatment of lumbosacral radicular pain (sciatica), were announced in March 2022. 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 Abivertinib, including the potential efficacy of Abivertinib and any potential superiority to osimertinib (Tagrisso); Sorrento's plans to close the study and prepare materials for pre-NDA meetings with the FDA and other regulatory agencies and Sorrento's plans of bringing Abivertinib to the U.S. and global markets. 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, including, but not limited to risks related to safety and efficacy of Abivertinib and seeking regulatory approval for Abivertinib; 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 continuing or 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, 2021 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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