



Sorrento Announces Publication of Significant Positive Pivotal Trial Results of Abivertinib for the Treatment of Non-Small Cell Lung Cancer (NSCLC) in the Peer-Reviewed Journal Clinical Cancer Research

November 12, 2021

- Abivertinib is a novel third-generation epidermal growth factor receptor (EGFR) inhibitor that irreversibly targets mutant forms of EGFR and Bruton's tyrosine kinase (BTK) in advanced NSCLC patients resistant to first-line EGFR kinase inhibitor therapies.
- In this pivotal study conducted in China, 227 heavily pretreated NSCLC patients were enrolled and among 209 response evaluable patients, confirmed overall response rate (ORR) was 52.2%. Disease control rate (DCR) was 88.0%. The median duration of response (DoR) and progression-free survival (PFS) was 8.5 months and 7.5 months, respectively. The median overall survival (OS) was 24.9 months.
- Based on these significant treatment benefits that Abivertinib achieved in a heavily pretreated population, Sorrento is conducting an independent review process with more mature long-term data and will request a pre-NDA meeting with the FDA upon completion.

SAN DIEGO, Nov. 12, 2021 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") today announced the peer-reviewed publication of significant results from a pivotal study of abivertinib on 227 heavily pretreated NSCLC patients in the journal Clinical Cancer Research, authored by Dr. Yi-Long Wu, distinguished professor of Guangdong Lung Cancer Institute, awardee of the prestigious "International Association for the Study of Lung Cancer (IASLC) Scientific Award" in 2017, and the principal investigator of the study.

The full manuscript is available at: <https://clincancerres.aacrjournals.org/content/early/2021/11/04/1078-0432.CCR-21-2595>

Abivertinib is a pyrrolopyrimidine-based, third-generation EGFR/BTK inhibitor, which is structurally distinct from osimertinib. Abivertinib selectively inhibits EGFR-activating and resistant mutation with nearly 300-fold potency as compared with wild-type EGFR. The 300 mg BID abivertinib dose was based upon the pharmacokinetics, efficacy and safety profiles characterized in prior studies. In the pivotal study, 227 patients received this dose for a median treatment duration of 24.6 weeks (0.43-129). Among 209 response evaluable patients, confirmed ORR was 52.2% (109/209; 95% CI: 45.2%, 59.1%) and the DCR was 88.0% (184/209, 95% CI: 82.9%, 92.1%). The median DoR and PFS were 8.5 months (95% CI: 6.1, 9.2) and 7.5 months (95% CI: 6.0, 8.8), respectively. The median OS was 24.9 months (95% CI: 22.4, NR). All patients (N=227) reported at least 1 AE, with 96.9% (220/227) reporting treatment-related AEs. Treatment-related serious AEs were reported in 13.7% (31/227) of patients. Death was reported in 4.4% (10/227) of patients, and none was deemed related to abivertinib.

With the ORR of 52.2%, and OS of 24.9 months, comparable to approved 3rd generation EGFR inhibitors, abivertinib demonstrated significantly efficacious effects in overcoming resistant mutation in NSCLC. Based on these results, Sorrento is conducting an independent review process with long-term follow up data and intends to request a pre-NDA meeting with FDA. "We are very encouraged by the publication of these significant positive results of abivertinib on the treatment of advanced and heavily pretreated NSCLC lung cancer in Clinical Cancer Research and look forward to bringing abivertinib into the armamentarium of this multi-billion dollar indication," said Dr. Henry Ji, Chairman and CEO of Sorrento.

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 immunoncology 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, COVIGUARD™, COVI-AMG™, COVISHIELD™, COVI-MSC™ and COVIDROPS™; and diagnostic test solutions, including COVITRACK™, COVISTIX™ and COVITRACE™.

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. RTX has completed a Phase 1B trial for intractable pain associated with cancer and a Phase 1B trial in osteoarthritis patients. SEMDEXA is in a pivotal Phase 3 trial for the treatment of lumbosacral radicular pain, or sciatica. 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 safety and clinical benefits thereof; the efficacy of abivertinib in advanced and heavily pretreated patients with non-small cell lung cancer; the potential for data results to be replicated or continue to show improved clinical safety or efficacy; and Sorrento's plans to request a pre-NDA meeting for abivertinib. 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 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 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 therapeutic antibody product candidate 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.

Media and Investor Relations Contact

Dorman Followwill

Email: mediarelations@sorrentotherapeutics.com

Sorrento® and the Sorrento logo are registered trademarks of Sorrento Therapeutics, Inc.

G-MAB™, DAR-T™, SOFUSA™, COVIGUARD™, COVI-AMG™, COVISHIELD™, COVIDROPS™, COVI-MSC™, COVITRACK™, COVITI and COVISTIX™ are trademarks of Sorrento Therapeutics, Inc.

SEMDEXA™ is a trademark of Semnur Pharmaceuticals, Inc.

ZTlido® is a registered trademark owned by Scilex Pharmaceuticals Inc.

All other trademarks are the property of their respective owners.

©2021 Sorrento Therapeutics, Inc. All Rights Reserved.



Source: Sorrento Therapeutics, Inc.