Sorrento Announces FDA Authorization to Proceed With Phase 2 Study of Abivertinib (Fujovee™) to Treat Metastatic Castrate Resistant Prostate Cancer (MAVERICK Trial)

May 17, 2022

- FDA granted IND clearance for Abivertinib (Fujovee™) for the Phase 2 MAVERICK study to be conducted in participants with metastatic castrate resistant prostate cancer (mCRPC) at multiple centers in the United States.
- Abivertinib is a novel small molecule tyrosine kinase inhibitor (TKI) that selectively targets both mutant forms of the epidermal growth factor receptor (EGFR) as well as Bruton's tyrosine kinase (BTK) and has been shown to inhibit extragonadal androgen production in preclinical models due to the interplay between BTK inhibition and 3βHSD.
- The study will enroll patients with progressive mCRPC harboring the adrenal-permissive HSD3β1(1245C) allele (germline heterozygous or homozygous) and will include two cohorts: abiraterone-naïve and abiraterone-progressing. Presence of the HSD3B1 allele is associated with earlier castration resistance and shorter overall survival.
- The global market for CRPC for 2021 was $2.7 billion, with the U.S. accounting for 67% ($1.83 billion), and a CAGR of 4.15%, projected to reach $4.56 billion with the U.S. projected to account for 68% ($3.08 billion) by 2031(1).

SAN DIEGO, May 17, 2022 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") today announced that it has received clearance from the FDA for its investigational new drug application (IND) for Abivertinib (Fujovee™) for the Phase 2 MAVERICK study to be conducted in participants with metastatic castrate resistant prostate cancer (mCRPC) at multiple centers in the United States. The MAVERICK study will be conducted in a partnership with the Prostate Cancer Clinical Trials Consortium and will enroll participants with both abiraterone-naïve and abiraterone-progressing mCRPC. The MAVERICK trial will be conducted as an open-label study of Abivertinib with abiraterone in up to 100 participants harboring the adrenal-permissive HSD3β1 allele (heterozygous or homozygous). The primary objective of the study is to evaluate the efficacy of Abivertinib with abiraterone via an assessment of 6-month radiographic progression-free survival (rPFS) and the primary endpoint is the 6-month rPFS defined as a percent of subjects alive and without progression by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 for measurable disease and Prostate Cancer Working Group 3 (PCWG3) criteria for bone metastases. Participants will remain on treatment until radiographic progression, unacceptable toxicity, intercurrent illness or other reasons (such as subject withdrawal).

Extragonadal androgen production requires the activity of 3β-hydroxysteroid dehydrogenase isoenzyme-1 (3β-HSD1) encoded by the HSD3β1 allele and an identified single nucleotide polymorphism (SNP) can create an adrenal-permissive phenotype that allows for more rapid development of mCRPC resulting in earlier castration resistance and shortened overall survival. Increased BTK expression has been observed in various solid tumors, including prostate cancer, and it is believed that the interplay between BTK inhibition and 3βHSD is responsible. BTK inhibition has been shown to inhibit androgen production, particularly from extragonadal precursor steroids, in preclinical models. In addition to selectively targeting both mutant forms of EGFR (T790M and exon 19 and 21 mutations), Abivertinib irreversibly binds to the BTK receptor, preventing phosphorylation of the receptor. Abivertinib is an oral capsule taken twice daily and has been well tolerated across multiple cancer types in doses up to 300 mg twice daily.

The global market for CRPC for 2021 was $2.7 billion, with the U.S. accounting for 67% ($1.83 billion), and a CAGR of 4.15%, projected to reach $4.56 billion, with the U.S. projected to account for 68% ($3.08 billion) by 2031(1).

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, COVISHIELD™ and COVI-MSC™; 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 (Fujovee™); the therapeutic and clinical potential of Abivertinib; the potential safety and efficacy of Abivertinib, including Abivertinib’s

potential efficacy against castrate resistant prostate cancer (CRPC); the global market for CRPC in 2021 and the amount accounted for in the U.S., the projected CAGR for the CRPC global market and the amount of the CRPC global market that the U.S. will account for by 2031; the expected number of participants in the Phase 2 MAVERICK study and the expected time that trial participants will remain on study. 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 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 Report 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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References

(1) Datamonitor and Sorrento Internal Research.

Source: Sorrento Therapeutics, Inc.