Lee's Pharmaceutical Announces its Anti-PD-L1 Antibody Socazolimab, Licensed From Sorrento Therapeutics, Receives Clearance to Start Phase 3 Trial as a First-line Treatment of Extensive-stage Small-Cell Lung Cancer

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- Socazolimab is an anti-PD-L1 antibody licensed from Sorrento for the Greater China Territory by Lee's Pharm.
- China's National Medical Products Administration ("NMPA") clears Lee's Pharm to conduct a Phase III, multicenter, randomized, double blinded, parallel-group clinical trial of Socazolimab (anti-PD-L1 monoclonal antibody, formerly known as ZKAB001) combined with chemotherapy in the first-line treatment of extensive-stage small-cell lung cancer.

SAN DIEGO, March 07, 2021 (GLOBE NEWSWIRE) -- China Oncology Focus Limited (COF), an affiliate of Lee's Pharmaceutical Holdings Limited (Lee's Pharm, HKEX: 950) announced that its anti-PD-L1 antibody, Socazolimab, licensed from Sorrento to COF for the greater China territory, has been cleared to begin a multicenter, randomized, double blinded, parallel-group clinical trial of Socazolimab (anti-PD-L1 monoclonal antibody, formerly known as ZKAB001) combined with chemotherapy in the first-line treatment of extensive-stage small-cell lung cancer. The clearance is based on the results from an earlier Phase Ib trial in which Socazolimab combined with carboplatin and etoposide showed a promising efficacy and safety profile in patients with extensive-stage small-cell lung cancer. The Principal Investigator for the clinical trial will be Professor Shun Lu from the Shanghai Chest Hospital and the site is expected to initiate patient recruitment in the second quarter of 2021.

Socazolimab is an in-licensed product from Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") for the People's Republic of China, Hong Kong, Macau and Taiwan. Three Phase I clinical trials of Socazolimab monotherapy have been completed: (1) recurrent or metastatic cervical cancer; (2) advanced urothelial carcinoma; and (3) high-grade osteosarcoma after adjuvant chemotherapy for maintenance purposes. For recurrent or metastatic cervical cancer, a pivotal study has been completed and breakthrough therapy designation was granted by the NMPA in February 2021. Lee's Pharm expects to file the New Drug Application for Socazolimab in recurrent or metastatic cervical cancer in the second quarter of 2021. Apart from monotherapies, several studies of Socazolimab combining with chemotherapy are being conducted in advanced urothelial carcinoma (Phase Ib), extensive-stage small-cell lung cancer (Phase III), and neoadjuvant treatment in esophageal carcinoma (Phase Ib+II).

Dr. Henry Ji, Chairman and CEO of Sorrento Therapeutics, stated, "We at Sorrento are pleased with the collaboration with our colleagues at Lee's Pharm and with the further advances of our first therapeutic antibody partnership in Socazolimab."

About Socazolimab

Socazolimab is a fully human anti-PD-L1 monoclonal antibody identified by Sorrento using its proprietary G-MAB™ library platform. COF received exclusive rights to develop and commercialize the antibody for Greater China, which includes Mainland China, Hong Kong, Macau, and Taiwan. Socazolimab has the following potential advantages over its competitors:

- Fully human antibody potentially allows it to have minimal immunogenicity; demonstrated by its negative antigen-derived antibody (ADA) generation in humans in studies to date.
- Potentially lower dose required to achieve efficacy compared to other anti-PD-L1 antibodies.
- Dual mechanism of action observed with both immune-checkpoint inhibition and antibody-dependent cellular cytotoxicity (ADCC) effect.

The antibody has been tested or is being tested in various cancer indications including recurrent or metastatic cervical cancer, maintenance therapy for high-grade osteosarcoma after adjuvant chemotherapy, locally advanced and metastatic urothelial carcinoma, extensive small cell lung cancer in combination with carboplatin and etoposide, and advanced urothelial carcinoma in combination with albumin-bound paclitaxel and esophageal carcinoma.

About Sorrento Therapeutics, Inc.

Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to treat cancers 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"), clinical stage immuno-cellular therapies ("CAR-T", "DAR-T™"), antibody-drug conjugates ("ADCs"), and clinical stage oncolytic virus ("Seprehvir™"). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including COVIGUARD™, COVI-AMG™, COVISHIELD™, Gene-MAb™, COVI-MSC™ and COVIDROPS™; and diagnostic test solutions, incl 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 IB 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.

About China Oncology Focus Limited

COF is a subsidiary of Lee's Pharm and a clinical development stage company focused on oncology. COF is currently developing several assets, including socazolimab (anti-PD-L1 antibody) in pivotal clinical trial stage; Zotiraciclib, an oral multi-kinase inhibitor in Phase I clinical trial for glioblastoma; Gimatecan, a topoisomerase I inhibitor in Phase I clinical trial for ovarian cancer and in Phase Ib/II clinical trial for small cell lung cancer in China; Pexa-vec (oncolytic virus) which is in global Phase Ib clinical trial for renal cell cancer. COF has built a pipeline of 10 assets through internal development and in-licensing. The diversity of its products creates a unique position for the company to use immune oncology as backbone therapy in combination with in-house products and develop potential paradigm-shifting treatment for cancer.

About Lee's Pharmaceutical Holdings Limited

Lee's Pharm is a research-driven and market-oriented biopharmaceutical company with more than 25 years of operation in the pharmaceutical industry in China. The Company is fully integrated with solid infrastructures in drug development, clinical development, regulatory, manufacturing, sales and marketing based in Mainland China with global perspectives. The Company has established extensive partnerships with over 20 international companies and currently markets 23 proprietary, generic and licensed-in pharmaceutical products in Mainland China, Hong Kong, Macau and Taiwan. The Company focuses on several key disease areas such as cardiovascular, woman health, paediatrics, rare diseases, oncology, dermatology, obstetrics and urology, and has more than 40 products under different development stages stemming from both internal research and development as well as from the licensing and development, commercialisation, and manufacturing rights from various United States, European and Japanese companies. Lee's Pharm has also involved in the business in ophthalmology through its investment in Zhaoke Ophthalmology Limited, an associated company of the Group.

For more information visit www.leespharm.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 the potential efficacy and safety profile of a Socazolimab product candidate; Lee's Pharm's plan to file a new drug application for Socazolimab in China; and the expected timing for filing a new drug application for Socazolimab in China. 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 any Socazolimab product candidate; 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.

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