



Lee's Pharmaceutical Announces Its Anti-PD-L1 Antibody Socazolimab, Licensed From Sorrento Therapeutics, Receives Breakthrough Therapy Designation in China for the Treatment of Recurrent or Metastatic Cervical Cancer

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- Socazolimab is an anti-PD-L1 antibody licensed from Sorrento for the Greater China Territory by Lee's Pharma.
- China National Medical Products Administration (NMPA) grants breakthrough Therapy Designation (BTD) to socazolimab for the cervical cancer indication.
- Lee's Pharma plans to file new drug application in China in Q2 2021.
- Sorrento congratulates Lee's Pharma on advancing clinical development of socazolimab.
- Lee's Pharma and Sorrento are entering expanded partnership discussions for the license of additional therapeutic antibodies from Sorrento's G-MAB library.

HONG KONG and SAN DIEGO, Feb. 09, 2021 (GLOBE NEWSWIRE) -- China Oncology Focus Limited (COF), an affiliate of Lee's Pharmaceutical Holdings Limited (Lee's Pharma, HKEX: 950), and Sorrento Therapeutics, Inc. (Sorrento, Nasdaq: [SRNE](#)), today announced that its anti-PD-L1 antibody, socazolimab, licensed from Sorrento to COF for the greater China territory, has been granted breakthrough therapy designation (BTD) by the China National Medical Products Administration (NMPA) to treat recurrent or metastatic cervical cancer.

The NMPA established its BTD program in July 2020 to facilitate the research and development of innovative drugs that treat severe life-threatening or quality-of-life impairing diseases with no existing therapy or with proven evidence to demonstrate clear clinical benefits as compared to existing therapies. Products with BTD from the NMPA may be considered for conditional approval and priority review when submitting a New Drug Application (NDA).

"China NMPA granted socazolimab breakthrough therapy designation in recognition of both significant unmet medical need and positive and promising clinical results of socazolimab treatment for patients with recurrent or metastatic cervical cancer," said Dr. Benjamin Li Xiaoyi, Chief Executive Officer of Lee's Pharma. "Cervical cancer is the fourth most lethal cancer in women worldwide and the third cause of cancer-related death in developing countries. There is currently no recommended standard of care treatment for this disease in China. Socazolimab has the potential to be the leading anti-PD-L1 antibody in the treatment of this indication. Socazolimab has demonstrated outstanding efficacy and safety profile in the clinical trials so far in treating cervical cancer patients."

Dr. Henry Ji, Chairman and CEO of Sorrento Therapeutics, stated, "We at Sorrento are happy with the collaboration with our colleagues at Lee's Pharma and are satisfied with the clinical advance of our first therapeutic antibody partnership in socazolimab. We currently plan to expand our partnership with Lee's Pharma and are in discussions regarding the co-development of additional therapeutic antibodies from Sorrento to treat hematologic and solid tumors."

Lee's Pharma plans to file a new drug application to China NMPA and request a fast-track conditional approval of socazolimab for the treatment of cervical cancer in Q2 2021.

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:

1. 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.
2. Potentially lower dose required to achieve efficacy compared to other anti-PD-L1 antibodies.
3. 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, advanced urothelial carcinoma in combination with albumin-bound paclitaxel and esophageal carcinoma.

About Lee's Pharmaceutical Holdings Limited

Lee's Pharma is a research-driven and market-oriented biopharmaceutical company with more than 25 years of operation in the pharmaceutical industry in Greater China. The Company is fully integrated with solid infrastructures in drug development, clinical development, regulatory, manufacturing, sales and marketing based in Greater China with global perspectives. The Company has established extensive partnerships with over 20 international companies and currently markets 23 proprietary 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, development, commercialization and manufacturing rights from various United States, European and

Japanese companies. Lee's Pharma is also involved in the area of ophthalmology through its investment in Zhaoke Ophthalmology Limited, an associated company of the Group.

For more information visit www.leespharm.com.

About China Oncology Focus Limited

China Oncology Focus Limited (COF) is a subsidiary of Lee's Pharma and a clinical development stage company focused in oncology with emphasis in immune 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; Gimitecan, 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 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 COVI-GUARD™, COVI-AMG™, COVI-SHIELD™, GeneMAB™, COVI-MSCTM and COVI-DROPS™; and diagnostic test solutions, including COVI-TRACK™, COVI-STIX™ and COVI-TRACE™.

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.

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 Lee's Pharma's plan to file a new drug application for socazolimab in China and to request fast-track conditional approval; the expected timing for a new drug application for socazolimab in China; the continued success of any current or future clinical trials for a socazolimab product candidate; discussions regarding potential expanded partnership opportunities between Sorrento and Lee's Pharma; potential license agreements between Sorrento and Lee's Pharma for additional therapeutic antibodies from Sorrento's G-MAB library, including licenses for therapeutic antibodies to treat hematologic and solid tumors; socazolimab's potential status as the leading anti-PD-L1 antibody in the treatment of recurrent or metastatic cervical cancer; the safety and potential efficacy of a socazolimab product candidate; and the potential for socazolimab's data results to be replicated or continue to show clinical safety or efficacy in current or future clinical trials. 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, 2019, 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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