Cumberland Pharmaceuticals Acquires Sancuso® From Kyowa Kirin North America

January 4, 2022

Nashville-based pharmaceutical company will acquire U.S. rights from Japan-based Kyowa Kirin

SANCUSO® is an established, FDA-Approved Oncology Supportive Care Medicine

NASHVILLE, Tenn. and BEDMINSTER, N.J., Jan. 4, 2022 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ: CPIX), a specialty pharmaceutical company, announced today that it has entered into and closed on a definitive agreement to acquire the FDA-approved oncology-supportive care medicine SANCUSO® (*granisetron transdermal patch*), from **Kyowa Kirin, Inc**. the U.S. affiliate of Japan-based Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE: 4151), a global specialty pharmaceutical company focused on discovering and delivering novel medicines.

SANCUSO is the first and only FDA-approved prescription patch for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment. The active drug in SANCUSO, granisetron, slowly dissolves in the thin layer of adhesive that sticks to the patient's skin and is released into their bloodstream over several days, working continuously to prevent chemotherapy-induced nausea and vomiting (CINV). It is applied 24 to 48 hours before receiving chemotherapy and can prevent CINV for up to five consecutive days. Alternative oral treatments must be taken several times (day and night) to deliver the same therapeutic doses.

"In 2020 there were nearly two million new cases of cancer in the U.S. and each year over half a million Americans undergo chemotherapy, with many suffering from the side effects of their treatment. With SANCUSO, patients are given a simple, easy-to-apply preventative solution that doesn't require swallowing any pills – which can be difficult for patients experiencing nausea," said A.J. Kazimi, chief executive officer at Cumberland Pharmaceuticals. "We are honored to take responsibility for the brand and introduce it through our commercial organization, ensuring that it is delivered to the patients who need it."

Under the terms of the agreement, Cumberland will acquire U.S. rights to SANCUSO and will assume full commercial responsibility for the product – including its marketing, promotion, distribution, manufacturing and medical support activities. Net sales of the brand in the U.S. were over $14 million in 2020. The financial terms of the acquisition include a $13.5 million payment to Kyowa Kirin upon closing, up to $3.5 million in milestones and tiered royalties of up to 10% on U.S. net product sales. Kyowa Kirin will retain international rights, continuing to deliver the product to address oncology patients' needs throughout the rest of the world.

"Since its launch in 2008, we have established SANCUSO as an important supportive therapeutic solution for oncology patients across the country," said Gary Zieziula, president of Kyowa Kirin North America. "We believe that Cumberland is well positioned to optimize the value of the brand and ensure that this unique product continues to deliver important therapeutic benefits to oncology patients."

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the delivery of high-quality, prescription brands designed to improve patient care. The Company develops, acquires, and commercializes products for the hospital acute care, gastroenterology and rheumatology market segments. The Company's portfolio now includes eight FDA-approved brands.

The Company also has a series of Phase II clinical programs underway evaluating its ifetroban product candidate in patients with

cardiomyopathy associated with Duchenne Muscular Dystrophy ("DMD"), Systemic Sclerosis ("SSc"), and Aspirin-Exacerbated Respiratory Disease ("AERD").

More information can be found on the Company's website at www.cumberlandpharma.com.

About Kyowa Kirin

Kyowa Kirin strives to create and deliver novel medicines with life-changing value. As a Japan-based global specialty pharmaceutical company with a more than 70-year heritage, the company applies cutting-edge science, including expertise in antibody research and engineering, to address the needs of patients across multiple therapeutic areas such as nephrology, oncology, immunology/allergy and neurology. Across its four regions – Japan, Asia Pacific, North America and EMEA/International – Kyowa Kirin focuses on its purpose, to make people smile, and is united by its shared values of commitment to life, teamwork, innovation and integrity.

Learn more about the Company at www.kyowakirin.com.

About SANCUSO®

SANCUSO is the only skin patch approved by the U.S. Food and Drug Administration for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients receiving moderately and/or highly emetogenic chemotherapy. When applied 24 to 48 hours before receiving chemotherapy, the SANCUSO patch slowly and continuously releases the medicine contained in the adhesive through clean and intact skin areas into the patient's bloodstream. It can be worn for up to seven days in a row for chemotherapy regimens of up to five consecutive days.

Learn more at www.sancuso.com.

Forward-Looking Statements

This press release contains forward-looking statements, which are subject to certain risks and reflect the companies' current views on future events based on what it believes are reasonable assumptions. No assurance can be given that these events will occur. As with any business, all phases of the companies' operations are subject to factors outside of its control, and any one or combination of these factors could materially affect results of operations. There can be no assurance that anticipated results associated with the brand will be realized or that they will have the expected effects. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date hereof. The companies do not undertake any obligation to publicly revise these statements to reflect events after the date hereof. Investors should refer to filings with the government securities agencies for more information, including the risk factors associated an investment in each company.

Please see SANCUSO Indication and Important Safety Information below

Indication

SANCUSO® (granisetron transdermal system) is indicated for the prevention of nausea and vomiting in adults receiving moderately and/or highly emetogenic chemotherapy regimens of up to five5 consecutive days.

Important Safety Information

Contraindications:

SANCUSO is contraindicated in patients with known hypersensitivity to granisetron or to any of the components of the transdermal system.

Warnings and Precautions:

Progressive Ileus and Gastric Distention: SANCUSO may mask a progressive ileus and/or gastric distention. This should be particularly considered before use of SANCUSO in patients who have had recent abdominal surgery. Monitor for decreased bowel activity, particularly in patients with risk factors for gastrointestinal obstruction.

Serotonin Syndrome: The development of serotonin syndrome has been reported with 5-HT3 receptor antagonists. Patients should be monitored for the emergence of serotonin syndrome, especially with concomitant use of SANCUSO and other serotonergic drugs. If symptoms of serotonin syndrome occur, discontinue SANCUSO and initiate supportive treatment. Patients should be informed of the increased risk of serotonin syndrome, especially if SANCUSO is used concomitantly with other serotonergic drugs.

Skin Reactions: In clinical trials with SANCUSO, application site reactions were reported that were generally mild in intensity and did not lead to discontinuation of use. The incidence of reactions was comparable with placebo. If severe reactions, or a generalized skin reaction occur (e.g., allergic rash, including erythematous, macular, papular rash or pruritus), remove the SANCUSO transdermal system.

Increased Drug Exposure with Use of External Heat Sources: Prolonged exposure to heat results in increasing plasma concentrations of granisetron during the period of heat exposure. Do not apply a heat pad or heat lamp over or in the vicinity of the SANCUSO transdermal system and avoid extended exposure to heat.

Phototoxicity with Ultraviolet Light Exposure: Granisetron may be affected by direct natural or artificial sunlight, including sunlamps. An in vitro study using Chinese hamster ovary cells suggests that granisetron has the potential for photogenotoxicity. To avoid a potential skin reaction, advise patients to cover the application site of the transdermal system with clothing if there is a risk of exposure to direct natural or artificial sunlight throughout the period of wear and for 10 days following its removal.

Adverse Reactions:
The most common adverse reaction (≥ 3%) is constipation.
You are encouraged to report suspected adverse reactions to Kyowa Kirin, Inc. at 1-800-Sancuso or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
Please click here for full U.S. prescribing information.

SOURCE: Cumberland Pharmaceuticals Inc. and Kyowa Kirin Inc.

View original content to download multimedia:https://www.prnewswire.com/news-releases/cumberland-pharmaceuticals-acquires-sancuso-from-kyowa-kirin-north-america-301453182.html

SOURCE Cumberland Pharmaceuticals Inc.; Kyowa Kirin Inc.

Cumberland Contact: Shayla Simpson, Cumberland Pharmaceuticals, (615) 255-0068; Kyowa Kirin Contact: Lauren Walrath, Kyowa Kirin North America, (646) 526-4454, lauren.walrath.g4@kyowakirin.com; Media Contact: Molly Aggas, Dalton Agency, (704) 641-6641, maggas@daltonagency.com