Solasia

Sancuso®, the First Transdermal Patch for the Prevention of CINV Approved in China Opening up a New Chapter for Whole Process CINV Management

Tokyo, Japan, July 24th, 2018—Solasia Pharma K.K. (TSE:4597, Headquarters:Tokyo, Japan, President & CEO:Yoshihiro Arai, hereinafter "Solasia"), a specialty pharmaceutical company based in Asia, today officially announced that Sancuso® (Granisetron Transdermal System) has been approved for launch by the China National Drug Administration (CNDA). Sancuso® is the world's first and only transdermal patch of the 5-HT_3 receptor antagonist used for the prevention of nausea and vomiting in patients receiving moderately or highly emetogenic chemotherapy regimens. It provides chemotherapy patients with a persistently effective new noninvasive drug delivery system for the prevention of nausea and vomiting.

The chemotherapy-induced nausea and vomiting (CINV) is one of the most common and most painful adverse reactions during the chemotherapy process of cancer patients. According to statistics, without any anti-emetic measures, 70%-80% of chemotherapy patients would experience CINV[1]. CINV lowers patients' quality of life, causes metabolic disorders, malnutrition, weight reduction and fear for chemotherapy, and reduces their treatment compliance. In severe cases, patients will have to be treated with reduced dosage or even withdrawn from chemotherapy, with negative impacts on the treatment outcomes[2]. Therefore, authoritative guidelines including the NCCN guidelines have made clear that standard and whole process CINV management must be taken for patients receiving moderately and/or highly emetogenic chemotherapy[3].

The newly-approved 5-HT_3 receptor antagonist transdermal system features a skeletal structure and is originated by ProStrakan Inc., US. The patch can be attached by patients to the outer side of their arm. Depending on different chemotherapy courses, it can be used for up to 7 days and can meet the needs of patients with anticipatory nausea and vomiting or acute/delayed nausea and vomiting in different stages. Data from the clinical studies for registration purpose in some European countries and the United States as well as in China shows that Granisetron transdermal system has a more stable blood concentration[4] and similar safety profile with well tolerance compared to oral intake. Professor Qin Shukui, the deputy director of Hospital of People's Liberation Army of China /the vice chairman of CSCO (Chinese Society of Clinical Oncology) /the chairman of CRPC (The committee of Rehabilitation and Palliative Care) /the chairman of PLA Cancer Center & China Drug Clinical Trial Institution, said: "The whole process management of CINV before and after chemotherapy is the standard practice recommended by all major guidelines. The NCCN guidelines made clear that, after the last dose of chemotherapy, the emetic risk will last for at least 2-3 days for patients receiving highly emetogenic chemotherapy (HEC) and moderately emetogenic chemotherapy (MEC) respectively, so active protection is still needed[3]. But it is very difficult to follow the recommendation in China's clinical practice, especially for delayed CINV. In our country, 95% of the CINV drugs are injections, so it's very difficult to maintain CINV prevention once the patients leave hospital. Delayed nausea and vomiting of patients outside of hospital has become a blind zone. With the successful approval of Granisetron transdermal system, its 7-day stable efficacy makes the whole process CINV management possible, especially after discharging from hospital. This has greatly enhanced the treatment compliance and convenience. It can effectively help patients keep receiving chemotherapy and improve their quality of life."

As the only 5-HT_3 receptor antagonist transdermal system, Sancuso® was first approved for launch in the U.S. in 2008. Since 2011, the National Comprehensive Cancer Network (NCCN) [5] /American Society of Clinical Oncology (ASCO) [6] have recommended Sancuso® in their antiemetic guidelines. In 2014, the antiemetic guidelines of the Multinational Association of Supportive Care in Cancer (MASCC)/European Society for Medical Oncology (ESMO) [7] as well as China's antiemetic guidelines[2] also recommended the use of Sancuso®.

Yoshihiro Arai, President and Chief Executive Officer, Solasia, said: "Solasia company mission is [Better Medicine for a Brighter Tomorrow]. We have always focused on the patients, and striven to develop innovative products to treat cancer and support cancer treatment. We continue to bring 'quality medicines' to the market, to benefit more patients in China, Japan and other Asian countries. The approval of Sancuso® will help Solasia to deliver its unwavering commitment to Chinese patients. All of team members will continue to work hard to meet the needs of patients and healthcare professionals and embrace new challenges going forward."

About Sancuso®

Sancuso® is the Granisetron transdermal system used for the prevention of nausea and vomiting in patients receiving moderately or highly emetogenic chemotherapy regimens. Each 52cm^2 patch contains 34.3mg of

Granisetron and releases 3.1mg of Granisetron every 24 hours for up to 7 days. Granisetron transdermal system is a persistently effective noninvasive drug delivery system with a proven safety profile[8,9]. To date, Sancuso® has been launched in 22 countries and regions including the United States, UK, Germany, the Netherlands, and Denmark. In 2014, a clinic pharmacology study as well as a random and double-blind clinical study versus oral Granisetron was completed in China[10]. In July 2018, it was finally approved by the China National Drug Administration (CNDA).

About Solasia

Solasia is an Asia-based pharmaceutical company dedicated to developing and selling innovative cancer treatment supportive drugs for local markets. As to benefit patients in China, the company is focused on creating a cancer treatment system in Asia, by developing innovative cancer drugs, introducing and getting commercial development licenses for great products from leading pharmaceutical and biotech companies in Japan, Europe and U.S.A, and other Asian countries. Solasia actively responds to the needs of patients and healthcare professionals and works hard to improve patient's life and meet the key unmet needs in oncology. For more information about the company, please visit www.solasia.co.jp/en/

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