



# Press Release

## **ProStrakan Announces 3 Abstracts for Sancuso® (Granisetron Transdermal System) Presented at the Multinational Association for Supportive Care in Cancer (MASCC) 2013 Annual Meeting**

Additional Analyses Further Evaluate Safety and Efficacy of Sancuso in Chemotherapy Induced Nausea and Vomiting (CINV)

July 9, 2013

BRIDGEWATER, NJ—ProStrakan, Inc. (“ProStrakan”) announces today (July 9, 2013) that 3 abstracts for Sancuso® (Granisetron Transdermal System) were presented at the Multinational Association for Supportive Care in Cancer (MASCC) 2013 Annual Meeting held June 27-29, in Berlin, Germany. The brand name for granisetron transdermal system (GTS) is SANCUSO (san KOO so). Sancuso is a serotonin subtype 3 (5-HT<sub>3</sub>) receptor antagonist indicated for the prevention of nausea and vomiting in patients receiving moderately and/or highly emetogenic chemotherapy for up to 5 consecutive days. A patch, Sancuso is applied 24-48 hours prior to chemotherapy, and stays on for up to 7 days, providing 5 full days of complete control of CINV.<sup>1</sup>

### **Comparison of the Transdermal Granisetron Patch to Oral Granisetron for Controlling Chemotherapy-Induced Nausea and Vomiting (CINV) in Multi-Day Chemotherapeutic Regimens for Breast Cancer Patients<sup>2</sup>**

Adam Brufsky, MD, University of Pittsburgh School of Medicine, analyzed data from a randomized, active control, double-blind, parallel-group, phase 3 study (NCT00273468) to compare the rates of complete control (CC; no vomiting, mild nausea, no rescue medication), complete response (CR; no vomiting, no rescue medication), and need for rescue medication in a post-hoc subset analysis of breast cancer patients using either GTS or oral granisetron. Patients undergoing treatment for breast cancer, receiving either moderately or highly emetogenic chemotherapy for 3-5 days were randomized to either GTS (7 day application) or Oral Granisetron (2 mg/day).

In a post-hoc analysis of data from a breast cancer patient subpopulation, the GTS patch was found to be as effective as oral granisetron therapy in measures of CC, CR, use of rescue medication, and patient satisfaction. GTS was well tolerated and adverse effects were mild. This retrospective analysis suggests that GTS may be an appropriate treatment option for the prevention of CINV in breast cancer patients receiving moderately or highly emetogenic multi-day chemotherapy. [MASCC-0788, June 27, 2013]. Dr Brufsky said, "In this retrospective analysis of breast cancer patients receiving highly and moderately emetogenic chemotherapy, a granisetron patch was non-inferior to oral granisteron, and may be an option for women with breast cancer receiving chemotherapy who have difficulty with oral anti-emetics."

### **Efficacy and Safety of the Granisetron Transdermal System for Chemotherapy-induced Nausea and Vomiting (CINV) in Elderly Patients<sup>3</sup>**

The objectives of this retrospective analysis were to examine the efficacy and safety of GTS for CINV in various age groups, including elderly patients ≥65 years of age. Performed on a previously reported phase 3 clinical study (NCT00273468) which compared the efficacy and safety of GTS with

oral granisetron for preventing CINV in patients receiving moderately emetogenic and highly emetogenic multi-day chemotherapy, A total of 582 patients were included in the preliminary sub-analysis (136 patients ≥65 years of age, 253 patients 50-64 years of age, and 193 patients <50 years of age).

This showed no significant difference in CC of CINV between the GTS and oral granisetron treatment groups in various age subgroups, including elderly patients ≥65 years of age. In addition, no significant differences were found in CR, use of rescue medication, or patient satisfaction between the two treatment groups in any age subgroup. Overall, the efficacy and safety of GTS were maintained in all age subgroups, suggesting that GTS is an appropriate antiemetic agent for a wide-range of ages including the elderly. [MASCC-0786, June 28, 2013].

## **Effects of Body Mass Index on the Efficacy and Pharmacokinetics of**

### **Granisetron Transdermal System<sup>4</sup>**

James Gilmore, PharmD and Sally Haislip, RPh of Georgia Cancer Specialists in Atlanta, GA, along with Deborah Braccia, PhD, MPA, of ProStrakan, Inc., presented a data analysis from a single-center, open-label, phase 1 study (NCT00868764) and a double-blind, placebo-controlled phase 3 study (NCT00273468) on the effects of body mass index (BMI) on GTS pharmacokinetics and efficacy. BMI is a measure for human body shape based on an individual's weight and height. In the phase 1 study, 30 healthy volunteers were divided by BMI. BMI did not affect the pharmacokinetic profile of granisetron administered via the GTS in a phase 1 study in healthy volunteers.

The post-hoc analysis of a phase 3 study of chemotherapy patients showed no significant difference in CC of chemotherapy-induced nausea and vomiting between the GTS and oral granisetron treatment groups regardless of BMI. In addition, no significant differences were found in CR, use of rescue medication, or patient satisfaction between the two treatment groups. Overall, the efficacy of GTS was maintained regardless of BMI, and GTS was well tolerated by all BMI subgroups studied. [MASCC-0787, June 28, 2013]. "We are excited to be able to demonstrate that BMI does not affect the pharmacokinetics or efficacy of the granisetron transdermal system. This should allay any concerns about the utilization of this product in patients that have above or below normal BMI," said Dr. James Gilmore.

To find out more about Sancuso, please visit [www.sancuso.com](http://www.sancuso.com). For reimbursement and co-pay information please visit [www.patientrxsolutions.com](http://www.patientrxsolutions.com). For any other questions, including Medical inquiries, please call 1-800-SANCUSO.

### **About CINV**

Nearly 14 million Americans are estimated to be living with cancer – a number that is expected to increase to almost 18 million by 2020.<sup>5</sup> Additionally, more than 1.6 million new cancer cases were expected to have been diagnosed in the United States in 2012.<sup>6</sup> Most people diagnosed with cancer are treated with chemotherapy, a type of treatment that has extended the lives of many patients, but which can sometimes cause unpleasant side effects that negatively affect patients' quality of life.

One of the more debilitating side effects of chemotherapy is chemotherapy-induced nausea and vomiting (CINV), a term that describes the symptoms of nausea and vomiting that occur in reaction to chemotherapeutic agents.<sup>8</sup> For cancer patients receiving chemotherapy or radiation therapy, CINV can make it very difficult to adhere to the treatment regimen, and sometimes results in an interruption or delay of treatment.<sup>8</sup> Moreover, CINV can lead to metabolic imbalances, worsening of patients' self-care and functional ability, deterioration of patients' performance status and mental status, nutrient depletion, anorexia, surgical wound dehiscence (bursting open or splitting), esophageal tears, and patients' refusal to receive potentially useful or curative therapy.<sup>9, 10</sup>

## **About SANCUSO® (Granisetron Transdermal System)**

SANCUSO® (Granisetron Transdermal System) is the first and only 5-HT<sub>3</sub> receptor antagonist available as a transdermal patch for the prevention of CINV. SANCUSO is indicated for the prevention of nausea and vomiting in patients receiving moderately and/or highly emetogenic chemotherapy for up to five consecutive days' duration.<sup>1</sup>

SANCUSO is contraindicated in patients with known hypersensitivity to granisetron or to any of the components of the patch. Granisetron may mask a progressive ileus and/or gastric distention caused by the underlying condition. Mild application site reactions have occurred; remove the patch if severe reaction or a generalized skin reaction occurs. Patients should avoid direct exposure of application site to natural or artificial sunlight by covering with clothing while wearing the patch and for 10 days after removing it. The most common adverse reaction in patients receiving SANCUSO is constipation (5.4%). SANCUSO contains granisetron. Healthcare professionals should avoid prescribing any additional products that contain granisetron. No clinically relevant drug interactions have been reported in clinical studies with SANCUSO.<sup>1</sup>

## **About ProStrakan Inc.**

ProStrakan, Inc., located in Bridgewater, NJ, is dedicated to commercializing specialty oncology pharmaceuticals that address the unmet needs of patients with cancer and the healthcare professionals who care for them in the United States. ProStrakan Inc. is a subsidiary of Kyowa Hakko Kirin, a global specialty pharmaceutical company focused on developing new drugs and antibody technologies to enhance human life.

To learn more about us please visit: <http://www.prostrakan-usa.com>

*DISCLOSURE NOTICE: The information contained in this release is as of July 1, 2013. ProStrakan assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

*This release contains forward-looking information that involves substantial risks and uncertainties about granisetron transdermal system, including its potential benefits and risks as well as clinical trial data relating to granisetron transdermal system and the potential implications of such data. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data, and the need for additional clinical studies to confirm certain results discussed in this release; whether and when regulatory authorities in jurisdictions in which applications for granisetron transdermal system pending or will be submitted will approve such applications as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.*

Contact:

For Corporate Questions

Callum Spreng, Communications  
[callum.spreng@prostrakan.com](mailto:callum.spreng@prostrakan.com)

Tel: +44 (0)1896 664000  
Mob: +44 (0)7803 970103

For Questions on Sancuso

Sue Smith, Sr. Dir. Marketing  
[sue.smith@prostrakan.com](mailto:sue.smith@prostrakan.com)

Mobile 908-432-6797

---

[1] SANCUSO® (Granisetron Transdermal System) prescribing information. Bridgewater, NJ: ProStrakan Inc.;2012.

<sup>2</sup> Brufsky, A. Comparison of the Transdermal Granisetron Patch to Oral Granisetron for Controlling Chemotherapy-Induced Nausea and Vomiting (CINV) in Multi-Day Chemotherapeutic Regimens for Breast Cancer Patients. MASCC, MASCC-0788, June 27, 2013, Berlin, Germany.<sup>3</sup>Braccia D<sup>1</sup>, Howell, J. Efficacy and Safety of the Granisetron Transdermal System for Chemotherapy-induced Nausea and Vomiting (CINV) in Elderly Patients, MASCC. [MASCC-0786, June 28, 2013], Berlin, Germany.

Siegel R, DeSantis C, Virgo K, et al. Cancer treatment and survivorship statistics, 2012. *CA Cancer J Clin.* 2012; Epub before print June 14, 2012. doi: 10.3322/caac.21149.

<sup>4</sup> Gilmore, J., Haislip, S., Braccia, D. Effects of Body Mass Index on the Efficacy and Pharmacokinetics of Granisetron Transdermal System, MASCC, MASCC-0787, June 28, 2013, Berlin, Germany.

<sup>5</sup> Siegel R, DeSantis C, Virgo K, et al. Cancer treatment and survivorship statistics, 2012. *CA Cancer J Clin.* 2012; Epub before print June 14, 2012. doi: 10.3322/caac.21149.

<sup>6</sup> Siegel R, Naishadham D, Jemal A. Cancer statistics, 2012. *CA Cancer J Clin.* 2012;62:10-29.

<sup>7</sup>Chemotherapy-induced nausea and vomiting. *Mosby's Medical Dictionary*, 8<sup>th</sup> edition. Elsevier, Inc.; 2009. Available at: <http://medical-dictionary.thefreedictionary.com/chemotherapy-induced+nausea+and+vomiting>. Accessed June 18, 2013.

<sup>8</sup> National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Antiemesis, v.1.2013. Available at <http://www.NCCN.org>. Retrieved June 18, 2013.

<sup>9</sup> Laszlo J. Emesis as limiting toxicity in cancer chemotherapy. In: Laszlo J, ed. *Antiemetics and Cancer Chemotherapy*. Baltimore, MD: Williams & Wilkins;1983:1-5.

<sup>10</sup> Richardson JL, Marks G, Levine A. The influence of symptoms of disease and side effects of treatment on compliance with cancer therapy. *J Clin Oncol.* 1988;6:1746-52.

Copyright © 2013 ProStrakan Inc. All rights reserved. This information is intended only for residents of the United States. The product information provided in this site is intended only for residents of the United States. The products discussed herein may have different product labeling in different countries.

SAN-032 July 2013